Issue No. 12 | January - April 2019

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

MAGAZINE

PPB installs National Drug Control System

In this issue...

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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Ensuring quality, safety and efficacy of medical products and health technologies

PUBLIC NOTICE

TO ALL AUTHORIZED DEALERS IN MEDICINES

Sale of Prescription Only Medicines

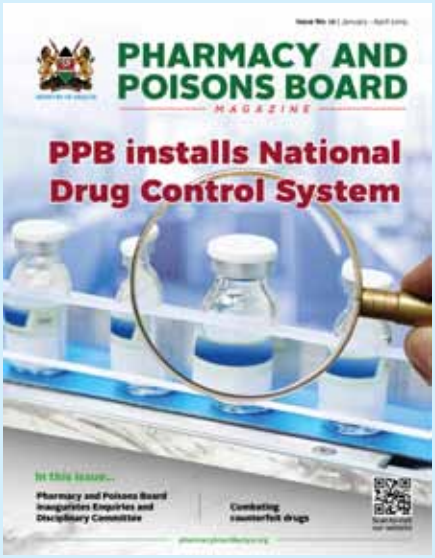
The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244, Laws of Kenya. The PPB is mandated to regulate the practice of pharmacy and the trade in medical products and health technologies.

In an effort to continually protect the health of the public and improve patient safety, ALL authorised dealers in medicines (wholesalers and retailers) are reminded to STRICTLY adhere to the Law governing sale of Prescription Only Medicines(POMs), more specifically:

1. Dispense **POMs ONLY** to persons in possession of a valid prescription in line with Section 29 of the Pharmacy and Poisons Act CAP 244;
2. Maintain the applicable records in line with section 30 and 31(2) of the Pharmacy and Poisons Act and provide, on demand, returns on the utilization of the above stated category of products;

Be advised that failure to comply with the Law will attract strict legal and administrative action.

Pharmacy and Poisons Board @ppbkenya info@pharmacyboardkenya.org



Editorial Board

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 the staff and stakeholders of the Board.

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Editor's Note

Thank you to everybody who took time to share their praise for the redesigned Pharmacy and Poisons Board Magazine. We are delighted to hear that the new format was well-received by the members, and hope that the presentation of the magazine matches the quality of the content produced by our contributors.

The Magazine highlights the showcase events of the year and dives into some of the most recent developments on pharmacy practice, combating counterfeit drugs, pharmaceutical reforms, registration of medical devices and drug control system among others.

A huge thank you to all who contributed by writing the wonderful and inspiring articles, without which there wouldn't have been this Magazine issue.

I am looking forward to expanding the scope of the PPB magazine to include book reviews, and op-eds. If you are interested in contributing, please let us know.

Happy reading!

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

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Pharmacy and Poisons Board inaugurates Enquiries and Disciplinary Committee

On 31st January 2019, the Pharmacy and Poisons Board (PPB) Enquiries and Disciplinary Committee (EDC)was inaugurated by a member of the Board Dr. Rogers Atebe on behalf of the PPB Chairman, Dr. Jackson Kioko. The EDC is a quasi-judicial committee with the power to hold hearings, conduct investigations relating to errant pharmacists and pharmaceutical technologists in order to maintain ethical and professional pharmacy practice.

Members of the Enquiries and Disciplinary Committtee pose for a photo, at PPB

1. What is the purpose of the committee?

The sole objective of the Enquiries and Disciplinary Committee ("the EDC") is to ensure compliance with the laws and regulations pertaining to the profession and practice of pharmacy. This is in particular through enforcement of the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya, Code of Ethics and Conduct for pharmacists and pharmaceutical technologists and taking disciplinary action for any breach of the code;

2. What's the composition of the committee?

The EDC draws its membership from the Board Members of the PPB, the president of The Pharmaceutical Society of Kenya (PSK) and Chairman of Kenya Pharmaceutical Association (KPA).

3. What are its functions?

The functions of the EDC are:

i. To receive and assess complaints filed by the parties through the Registrar;
ii. To conduct enquiries over professional misconduct
iii. Determine issues against persons or institutions brought before the Board in line with the Conduct of enquiries Rules and other regulations
iv. Hear and determine the complaints received by the institution;
v. Maintain proper records of its sittings and deliberations which shall include but not limited to summons, proceedings, affidavit, exhibits, ruling, judgement etc

vi. Develop and implement its own operating procedures in line with the Conduct of enquiries Rules and the laws of Kenya
vii. To develop and implement the Code of Ethics and Conduct for pharmacists and pharmaceutical technologists and take disciplinary actions for any breach of the code;
viii. To periodically review and assess the adequacy of the TORs and recommend any proposed changes to the Board for approval;
ix. To perform such other duties and responsibilities as are consistent with the purpose of the Committee and as the Board or the Committee shall deem appropriate

4. In the light of concerns regarding the importation of fake or substandard medicines into the country, will the committee be mandated to take disciplinary action against offenders?

The EDC is mandated to ensure that pharmacists and pharmaceutical technologists maintain ethical and professional pharmacy practice. In the event that a professional engages or deals in importation of fake or substandard medicines in the country, this is a criminal activity and also borders on professional misconduct and unprofessional conduct. This person would therefore fall squarely within the purview of the EDCs mandate thus calling for the institution of administrative action. These include but are not limited to:

a. Suspension of the professional's practice license
b. Deregistration from the register of pharmacists and striking out from the roll of pharmaceutical technologists

Dr Rogers Atebe chairs the inaugural Enquiries and Disciplinary Committtee meeting at PPB

7. Will the committee be looking into cases where the wrong drugs were prescribed for patients? What are some of the disciplinary measures it will take against the offenders?

Upon receipt of prescription a pharmacist or pharmaceutical technologist is supposed to dispense as per prescription. However, in cases where a professional negligently gives patient wrong medication contrary to the prescription and if the same is reported it is within the mandate of EDC to take the necessary measures like:

a. Suspension of the professional's practice license
b. Deregistration from the register of pharmacists and striking out from the roll of pharmaceutical technologists

8. Are there pharmacists using their leases wrongly, e.g. to dispense controlled substances to individuals without prescription from recognized medics? What are some of the measures the committee will put in place to eradicate this practice?

Professionals are expected to adhere to the Code of Ethics and Conduct for pharmacists and pharmaceutical technologists. In case of breach of the same, the committee is empowered to take the necessary measures as outlined above upon hearing the complaint.

9. Are there any pharmacists on your radar for misconduct currently? Kindly provide a list if possible.

There are pending cases before the committee. PPB will give the outcome upon conclusion of the cases.

Combating counterfeit drugs

A group photo of presenters at the Combating Counterfeit Drugs workshop

A three-day workshop to combat counterfeit drugs was held on 6th February 2019, in Nairobi. The workshop which was organized by CWAG Africa Alliance in collaboration with the Pharmacy and Poisons Board aimed to combat transnational criminal activities.

Addressing the participants drawn from government agencies the Pharmacy and Poisons Board (PPB) Chief Executive Officer (CEO), Dr. F. M. Siyoi said the Board is keen on enhancing capacity for inspection, surveillance and enforcement since access to quality and affordable medical supplies is crucial to attainment of Universal Health Coverage.

"We have identified key areas that require capacity building to enhance institutional and personal skills towards strengthening our regulatory mandate. These include cybercrime/ internet trade in medicines; Illicit trade and use of controlled prescription medicines; Drug Counterfeiting; Cross Border collaborations and Pharma-Crime identification techniques," he said.

The CEO said the Board has put in place appropriate regulatory measures, to ensure the protection of the consumer. These initiatives includes;

- GPS mapping of registered premises
- Product Evaluation and Registration
- Online licensing system
- Inspection of manufacturing sites to ensure they comply with Good Manufacturing Practices
- Issuance of import permits for Pharmaceutical Products including donations
- deployment of drug inspectors to all ports of entry
- Online reporting system www.pv.pharmacyboardkenya.org where one can report any suspicious product for the PPB to take action
- Active and Proactive Post-market surveillance of registered pharmaceuticals
- Collaboration with International and Bilateral organizations such as Interpol and WHO in the fight against Substandard/Spurious/Falsely labelled/Falsified, counterfeits (SSFFCs) medical products.
- Sharing of the Post Market Surveillance results to ensure continued collaboration.
- Use of mini labs and spectrometers in post marketing surveillance and
- Introduction of a Health safety code for members of the public to verify registered premises

Several government agencies namely Anti- Counterfeit Authority, Ministry of Health, Interpol, Directorate of Criminal Investigation, Anti-Doping Agency, Immigration, Pfizer Global Security team and the Kenya Bureau of Standards attended the workshop, which ended on February 8, 2019.

Ministry to launch Medical Equipment Management Policy

Ministry of Health Chief Administrative Secretary Dr. Rashid Aman speaks at the Medical Devices Management Policy Forum

The Ministry of Health is finalizing a policy on management of medical devices that will provide direction and guidance on medical equipment management and assist in building capacity for counties and other health service providers to ensure success of quality healthcare.

The revelations were made by the Ministry of Health, Chief Administrative Secretary (CAS), Dr. Rashid Aman, during the external stakeholders' forum aimed at deliberating the draft Medical Devices Management policy for Kenya, on February 27, 2019.

He emphasized that just like commodities, medical devices and equipment are critical components of healthcare system and will play a critical role to ensure delivery of quality health services in line with the Government's Universal Health Coverage (UHC) goal.

"UHC goal is anchored on provision of quality, effective and efficient health services whether prevention, treatment, diagnostic or rehabilitative services. Therefore, it is important that medical devices and equipment are rationally acquired, utilized properly, perform as expected and are safe to users, patients and the general public," he said.

He noted that although Kenya has made progress in increasing access to medical devices/equipment, acquisitions of these devices including those donated have not been rational.

He said the management of these devices have remained sub-optimal resulting to under-utilization of huge-investment medical devices, wastage of resources as a result of investing in medical devices that do not meet priority health needs of a given section of the populace, investment in medical devices which are incompatible with existing infrastructure, sometimes low quality, or do not function properly.

"It is in view of these challenges and quality concerns that the Ministry of Health initiated the process of developing a policy on management of medical devices in March 2016," he revealed.

The policy is expected to provide direction and guidance on medical devices/equipment management and also assist in building the capacity of counties, considering they are procuring entities as well and other service providers in the health sector with proper tools and knowledge regarding medical devices.

Full implementation of the guidelines on submission of documentation for registration of medical devices and roll out of the online portal

By Felistas Chepwogen & Gedion Murimi

Background:

The Pharmacy and Poisons Board in 2012, instituted the listing of all medical Devices in accordance to the stepwise regulatory framework approach recommended by the *WHO global model regulatory framework for Medical Devices including In vitro diagnostics (IVDs).* This was to enable the gathering of important information about the manufacturers, importers, distributors, suppliers and the Medical Devices in the Kenyan Market as a situational analysis leading to the development of a national registry.

Head ICT at the Pharmacy and Poisons Board Gedion Murimi, trains participants on the online Medical Devices registration portal

Major achievements since 2014;

i. The manual reviewing of documentations for all applications in 2015 and control of import and export of all incoming medical devices and IVD's.
ii. Development of the online platform for receipt and evaluation of all submitted applications enabling the development of a national database capturing information on industry players and market portfolio of all Medical Devices including In-Vitro Diagnostics in Kenya.
iii. The constitution of two technical committee Medical Devices and In-Vitro Diagnostics
iv. The holding of three stakeholders consultation meetings
v. Deployment of five fulltime staff at the Medical Devices Department
vi. Development and implementing of Guidelines on Submission of Documentation for Registration of Medical Devices including Invitro-Diagnostics
vii. The launching of the online portal registration of medical devices and IVDs effective January 2019

Roll out of the new portal on Registration/Listing of Medical Devices including In-Vitro Diagnostics

The new portal has four sections;

i. Individual registration; for the purposes of registration of class C and D, the Board recommends that the applicant, should have an officer with a training background in medical fields
ii. Premise licensing; all the premises involved in the storage and distribution of medical devices should comply with minimum requirements

iii. Medical devices listing for class A and B, and Registration of class C and D – all the applications should be classified, grouped, all the necessary documentations attached and payment made per product application accordingly.
iv. GMP documentations and audits – manufacturing site details, quality management systems certifications, inspection and report writing.

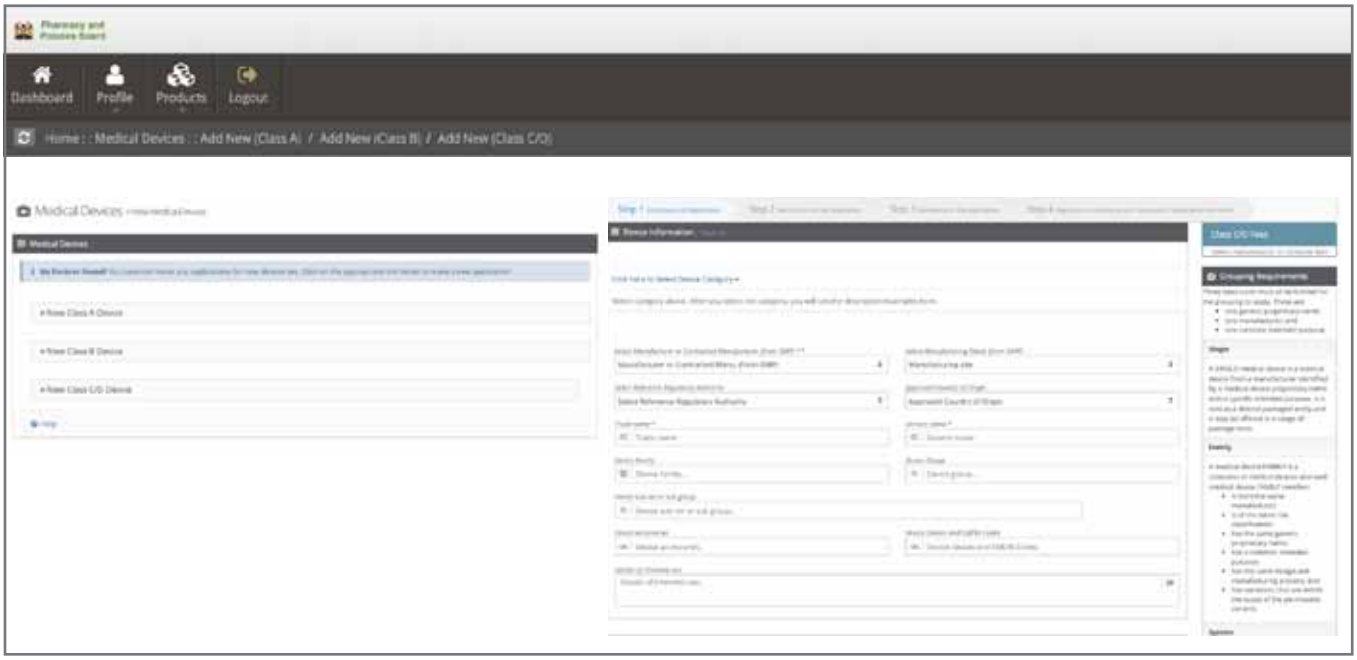
Information to applications

i. Applicants to submit online applications for product registration applications for marketing authorization of Class C and D using the Common Submission Dossier Template (CSDT) for medical devices and IVDs and listing is requirement for Class A and B.
ii. Applicants to access the Pharmacy and Poisons Board online portal: portal.pharmacyboardkenya.org and log in using password provided. One registration/access is required for all sections and all the fields to be completed.
iii. Applicants to get more information on the Pharmacy and Poisons Board website; www.pharmacyboardkenya.org or contact us via Email: medicaldevices@pharmacyboardkenya.org

Friday, 8th February, 2019

Participants during stakeholder consultation meeting held on 7th and 8th February 2019, KICC, Nairobi, Kenya

New Medical Devices System



Licensing updates

By Dr Wilfred Ochieng, Director Pharmacy Practice and Regulation of Training, Pharmacy and Poisons Board

The Pharmacy and Poisons Board Technical Committee Members pose for a photo

The pharmacy practice environment in Kenya is fast changing presenting a number of opportunities that PPB can seize and challenges that have to be mitigated for effective regulation. Good pharmacy practice will be very important if the country is to achieve Universal Health Coverage (UHC)

The ratio of pharmacists and pharmaceutical technologists to population has been on the rise and there is hope that Kenya is poised to move closer to the global average in the coming years. This has been bolstered by the growth in number of universities training pharmacists within Kenya as well as the renewed interest by Kenyans who are practicing pharmacy in diaspora to return and join the local practice scene.

Despite all this, the problem of pharmacies operating unlawfully has persisted and there is a growing need for pharmacists and pharmaceutical technologists to engage more in self-regulation. The Board has been continually urging the Pharmaceutical Society of Kenya (PSK) and the Kenya Pharmaceutical Association (KPA) to provide a better framework for self-regulation by enforcing the code of ethics. The problem of absentee superintendents, "hawking or leasing of licenses", falsification of documents or misrepresenting facts relating to business ownership for purposes of securing pharmacy registration for non-pharmacy professionals are some of the most glaring. Furthermore, the rate at which new pharmacy premises are being opened has been alarming. Similarly, very many pharmacy licenses are not being renewed every year thus leading to a vicious circle of opening and closure or abandonment (leaving with unqualified persons). The density of pharmacies in certain locations doesn't even make economic sense.

In view of the foregoing, the Board seeks to have more up to date pharmacy practice data, engage the licensees more closely and meaningfully and involve all stakeholders in creating a practice environment that, though dynamic, will remain fair and responsive to the patient needs and allow achievement of individual professional career goals. Recent changes/requirements demanded by the Board were specifically geared towards better implementation of legal requirements and the guidelines approved by the Board.

Section 23 (3) of the Pharmacy and Poisons Act provides that "The registration of any premises under this section shall become void upon the expiration of thirty days from the date of any change in the ownership of the business carried on therein". Many Pharmacy owners have either been ignoring this provision in the law or just needed to be reminded of the same. At the beginning of the 2019 license renewal period, a Know Your Customer (KYC) requirement was incorporated in the licensing portal to ensure that both personnel and business data are updated to what is current. There is a commitment/ declaration as to the correctness of the data provided to deter misinformation.

Section 21 of the Pharmacy and Poisons Act comprise provisions on how a body corporate may carry on the business of a pharmacist. After successful inception of online licensing, the Board saw a need to incorporate these provisions in the system as part of mistake proofing.

The system for verification of license validity status allows any interested party to search from the

Board's website and get real time status. The public have also been empowered to check premise license status by sending the Health Safety Code free of charge to 21031.

In addition, the Board inaugurated the Enquiries and Disciplinary Committee (EDC) with a view to dealing with cases of professional misconduct. This will provide an avenue of hearing and determining professional misconduct cases out of court. The Pharmacy and Poisons Act, cap 244 Laws of Kenya provides for various types of punishment which may include deregistration.

Continuing Professional Development (CPD)

Fitness to practice is a necessity in every profession. Every pharmacist and pharmaceutical technologist has been empowered to take charge of their own CPD activities with minimal intervention from the Board. The recently launched CPD module is part of regulatory human resource information systems (RHRIS), the online system for management of licensing. It enables each practitioner to choose from a list of approved programmes/ activities, subscribe, undertake the CPD and get points allocated automatically upon verification of participation or completion of the activity/program. Furthermore, each practitioner can plan for the whole year and monitor their progress and compliance as time goes to ensure compliance by the time they are applying for license renewal. To support this initiative, the Board is calling on eligible CPD providers to develop adequate programmes/activities which upon accreditation shall ensure members have a rich basket of activities to pick from. We commend the Pharmaceutical Society of Kenya (PSK), Kenya Pharmaceutical Association (KPA) and Hospital Pharmacists Association of Kenya (HOPAK) for taking the lead in this area.

Technical Expert Committees

The Board, in executing its mandate, usually engages experts from various fields to undertake specific assignments in their areas of expertise. In 2018, a call was made for eligible experts who are interested in serving in specific technical committees to apply. We are happy to report that the following three committees whose terms of reference revolve around Pharmacy Practice were appointed and inaugurated in December 2018.

1. Training and Assessment Technical Committee (TATC)
2. Continuing Professional Development (CPD) Committee
3. Committee on Pharmacy Specialties

We take this opportunity to congratulate the members and wish them fruitful deliberations as we strive towards excellence in pharmacy practice in Kenya.

Technical Committee inaugration session

PPB installs National drug control system to aid issuance of special permits

National Drug Control system pre-production team

Dr. F. M. Siyoi chairs a meeting on the National Drug Control system

Kenya is a signatory to three International Conventions on Narcotics Substance of 1961, 1971 Psychotropics Convention and 1988 Precursor Substance Convention. The Conventions undertake a major role in limiting the production, manufacture, export, import, distribution and stocking of or trade in, use and possession of the controlled drugs in a bid to ensure that they are exclusively used for medical and scientific purposes.

The 1971 Psychotropics Convention was adopted to limit the diversion and abuse of certain psychotropic substances and the Precursor Substance Convention of 1988 initiated measures to prevent the diversion of precursor and essential chemicals into the illicit manufacture of illicit drugs.

Licit Control Unit within PPB is mandated to implement the three Conventions in line with the International Narcotics Control Board (INCB) requirements to

(i) limit the use of Narcotics, psychotropic and Precursor substances to medical and scientific purposes and
(ii) ensure availability for intended purposes only and prevent diversion of these products for illicit purposes.

The Licit Control Unit is currently undertaking pre-production of the National Drug Control system which will be used in issuance of special permits, calculation of accurate estimates, monitoring of the available quota of the controlled products allocated in real time and ensuring that they are available for medical and scientific purposes only. This can only be achieved through the use of the available recommended and adopted systems agreed upon by member countries through the guidance of INCB.

The NDS system was developed by United Nations Office on Drugs and Crime (UNODC) a non-profit making organization to solve challenges faced by member countries in controlling the products under the three Conventions.

User group members adopted this as a standardized communication, reporting and monitoring tool which communicates both to the trading country and the INCB on real time basis.

Countries which have implemented the NDS system have reported improvement in control, assessment of the need, reporting and annual estimation of their countries annual requirements.

NDS being a Platform for issuance, uploading, exchanging of import and export authorizations between trading countries, is a desktop and web-based application designed to expediate the process of permit issuance.

This will be a major link between the regulator, stakeholders and the international community in controlling Narcotics, Psychotropic and Precursor substances within the country and trading countries.

Attaining full integration between the PPB, INCB and stakeholders will help close gaps and loopholes which are currently a hinderance to service delivery and will improve accuracy, accountability and transparency in operations and eventually improved confidence globally with an ultimate achievement as per Pharmacy and Poisons Board vision and mission.

Nyanza region crackdown on illegal pharmacies

Head of Good Distribution Practice and Ports of Entry, Dr. Dominic Kariuki briefs the Media on crackdown of illegal premises in Kisumu County

Over seventy pharmacies in Nyanza region have been closed down in an operation by the Pharmacy and Poisons Board (PPB) covering Kisumu, Migori, Siaya, Homabay, Kisii and Nyamira on February 22, 2019.

Addressing the media in Kisumu County, the Head of Good Distribution Practice and Ports of Entry Dr. Dominic Kariuki said the proprietors of the premises have been arrested and charged.

He said the crackdowns will continue in order for PPB to streamline operations in the sector. He noted that although the number of illegal pharmacies in the region has gone down, cases of absentee superintendents where licensed outlets are left in the hands of unqualified persons are on the rise.

> “...the operation also seized government drugs with Kenya Medical Supplies Agency (KEMSA) labels...

“We have summoned those professionals found engaging in these malpractices for disciplinary action,” he noted.

The operation also seized government drugs with Kenya Medical Supplies Agency (KEMSA) labels.

Dr. Kariuki advised all pharmacies with expired drugs to quarantine them and get in touch with regional PPB inspectors for safe disposal.

He also disclosed PPB has set up mini laboratories at regional offices for random sampling and testing of medicines in the market to ensure they are of good quality and safe.

The Board has also trained health workers on identification of poor quality medicines and put in place reporting tools to safeguard members of the public against harmful drugs.

PPB drug inspectors load medicines impounded from illegal outlets in Kisumu County

Routine Monitoring of Quality of Selected Medical Products in Central Region

PPB drug analysts screen samples of medicines collected in Nyeri County

A collaboration of three directorates at the Pharmacy and Poisons Board represents a promising strategy towards the Sustainable Development Goal of ensuring access to quality, safe and efficacious medical products.

The three Directorates namely Inspectorate, Surveillance and Enforcement; Medicines Information and Pharmacovigilance and Quality Control have been routinely monitoring the quality of medical products by screening using the handheld Raman Spectrometers and the Minilab kits on Analgesics, Antidiuretics, Antihypertensives, Lifestyle drugs, Antibiotics and Antifungals.

In the spirit of togetherness, the directorates visited counties in Central region notably Kiambu, Kirinyaga, Murang'a, Nyandarua and Nyeri to assess the quality of selected health products circulating in the region.

The exercise involved screening of samples using the handheld Raman Spectrometers; collection of samples for minilab screening; establishment of storage conditions (Temperatures

Raman Spectrometer screening

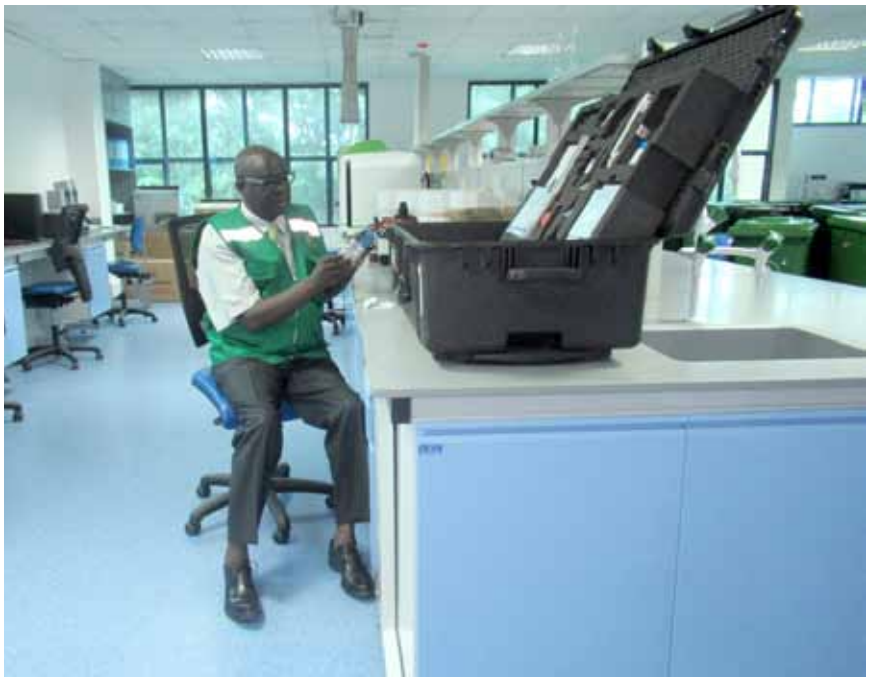
and Relative Humidity); performance of basic tests using the minilab kits; check list of the registration status of the facilities and assessment of products that have different packaging from registration.

The activity targeted 18 medical products namely; Amoxicillin Clavulanate, Cefixime, Cefuroxime, Ciprofloxacin, Clarithromycin, Co-trimoxazole, Diclofenac, Furesomide, Glibenclamide, Griseofulvin, Herbal Preparations, Levofloxacin, Levonorgestrel, Metformin, Metronidazole, Paracetamol, Salbutamol and Sidenafil. These formulations were characterized by Raman Spectrometry and Thin Layer Chromatography.

The medical products were sampled from fourteen preselected facilities including distributors/ wholesalers in the private sector and public health facilities.

Quality of health products and technologies is an important factor in disease prevention and treatment.

Health products are an essential component of healthcare service delivery. Essential medicines policies are crucial to promoting health and achieving sustainable development. Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage (UHC) and Sustainable Development Goal emphasizes the need to develop medicines to address persistent treatment gaps. Access to good quality health products increases public confidence in healthcare systems.



Quality Control Director Dr. Naikuni inspects the minilab kit at PPB lab

> "...The medical products were sampled from fourteen preselected facilities including distributors/wholesalers in the private sector and public health facilities...

Launch of a Government project to improve drug safety

PROFORMA project launch participants group photo

The Government on October 22, 2018 launched a new project to improve drug safety in the country. The Regional Medicine Regulatory Harmonization (PROFORMA) project was launched by the Chief Administrative Secretary for the Ministry of Health, Dr. Rashid Aman who was represented by the Pharmacy and Poisons Board Member, Dr. Rugendo Birichi.

The PROFORMA grant is a joint venture between experts from academia, National Medicines Regulatory Authorities (NMRAs) and WHO-collaborating centers in pharmacovigilance and Regional Centers of Excellence (RCOREs).

The project aims to strengthen the national Pharmacovigilance (PV) infrastructure and post-marketing surveillance systems by forging partnerships between local academic institutions and National Medicine Regulatory Authorities leveraging on existing structures. Emphasis were put on the implementation of pharmacovigilance in clinical trials and post-marketing surveillance in public health programs involving mass drug administration and immunization.

Dr Christabel Khaemba , Head Pharmacovigilance addresses participants at the Regional Medicine Regulatory Harmonization (PROFORMA) project launch in Nairobi

Speaking at the event Dr. Rugendo said the government is committed to provide Kenyans with safe, quality and efficacious medical products and health technologies to safeguard their health. He further noted that there is an urgent need to develop and strengthen the pharmacovigilance system for patient safety.

In attendance was the Pharmacy and Poisons Board Chief Executive Officer, Dr. F.M. Siyoi who applauded stakeholders for their financial and technical support in improving medicines safety in the country.

"The PROFORMA Project has come at the right time when Kenya is geared towards attainment of Universal Health Coverage," he acknowledged.

Coast Region sensitization workshop

Opinion leaders at the public outreach sensitization workshop in Coastal region

The Pharmacy and Poisons Board held a stakeholder sensitization workshop with County Commissioners, District Officers, Local Chiefs, Security Officers and Community Health Workers from Kilifi and Mombasa Counties to enhance pharmaceutical regulation in the region.

The workshop objective was to raise awareness of the mandate of the PPB and to enhance regulatory support.

Speaking at the event PPB regional head, Dr. Paddy Agoro emphasized the need for building collaboration and partnerships with grassroots government agencies to safeguard public health.

The workshops which were held in Mombasa and Kilifi discussed topical issues related to counterfeit medicines, prescriptions use, pharmacy practice and over-the counter medicine sales.

"Use of falsified medicine adds to the burden of untreated diseases in the country and side effects from the use of such drugs can lead to aggravation of illnesses. As law enforcers you hold powers to influence policy and shape public opinion and must help us to weed out unregistered pharmacies in this region," he said.

He also urged the pharmacists in the region to help the Board in combating misuse of prescription drugs. "Professionals should stop selling over the counter any drug classified as prescription only medicine,' he advised.

Agoro called on the policy enforcers to sensitize the public on the need to deposit unused and expired medicines at their nearest local pharmacies for proper disposal and advised the public to use the health safety code to verify legal pharmacies.

Dr Paddy Agoro PPB Head Mombasa region engages the stakeholders at an outreach workshop

"Although medicines treat many conditions and diseases, unused medicine should be disposed, to reduce the danger from accidental exposure or intentional misuse," he said.

As a Board we shall continue to collaborate with the county governments to ensure that only efficacious medicines are available in the Kenyan market, he added.

Over100 people attended the two-day workshop and resolved to work together with the Board to share intelligence information on suspected falsified medicine, unregistered practitioners and premises through whatsup platform.

They pledged to support the Board activities in the two counties by sharing information with the public through public 'barazas' or any other social gatherings.

Government launches joint action on Anti-Microbial Resistance

Delegates group photo durng the opening of the Anti-Microbial Resistance (AMR) Symposium

Anti-Microbial Resistance (AMR) has been identified as one of the most complex public health threats affecting multiple sectors ranging from health, food safety, agriculture, environment and trade.

According to the Chief Administrative Secretary (CAS) in the Ministry of Health, Dr. Rashid Aman, no single government department or independent organization can tackle AMR alone.

"Containing, controlling and preventing emergence of AMR demands for well-coordinated actions across multiple levels, sectors, disciplines and with a broad range of stakeholders," said Dr. Aman during the opening of the National Antimicrobial Resistance Symposium themed "Tackling Antimicrobial Resistance Together," in Nairobi 14th, November 2018.

The CAS acknowledged that AMR presents the global, regional and national communities with extensive challenges considering its depth and breadth and called for strengthened and formal governance and coordination mechanisms to synchronize the response to AMR, to ensure optimization of resources and effective monitoring and evaluation of actions.

He revealed the two Ministries of Health and Agriculture have embarked on a process to consolidate efforts to implement sustainable measures to mitigate any further emergence and spread of AMR.

"Having in mind a one-health approach to the management of AMR, the two Ministries have jointly developed a Policy and a National Action Plan to implement," he said.

He noted that the inauguration of the National Antimicrobial Stewardship Inter Agency Technical Committee and the AMR Secretariat reinforces the commitment of the government to implement the AMR policy.

Training of Assessors on Dossier Assessment using the EAC Evaluation Template

By Dr. Felistas Chepwogen, Head Medical Devices & Focal person EAC-MRH Program

The East African Community Medicines Regulatory Harmonization (EAC-MRH) Programme was launched in 2012 with a charitable purpose of improving access to safe, efficacious and good quality essential medicines in the EAC Partner States. One of the specific objectives of the EAC-MRH Programme is the establishment of a framework for joint assessment and approval of medicinal product applications for registration and inspections of medicine manufacturing sites, and to ensure that these assessments are integrated into national regulatory decision-making.

Following the approval of harmonized medicines registration guidelines, requirements and procedures by the 29th meeting of the EAC Council of Ministers in September, 2014 and subsequent commencement on the use and domestication by Pharmacy and Poisons Board from 1st January, 2015, a number of training have been conducted both at the regional and national levels on the domestication of EAC harmonized guidelines and procedures.

Dr. Lawrence Nzumbu issues a Certificate of Participation to Dr. Felistas Chepwogen, before the CEO, Pharmacy and Poisons Board, Dr. F. M. Siyoi.

In March 2018, the Pharmacy and Poisons Board organized a stakeholder sensitization on the EAC harmonized guidelines and followed by a one-week training of assessors on dossier assessment using the EAC Screening Template and Dossier Assessment Template in January 2019.

The assessment session was attended by 30 medicines assessors drawn from the different departments of the Board; and was facilitated by Dr. Lawrence Nzumbu - an Expert under WHO prequalification and Dr. Peter Mbwiiri- A Senior assessor from Pharmacy and Poisons Board.

The main objective of the training was to develop a cohort of assessors who will specialize in the assessment of different parts of a dossier and improve quality of assessment at the Board. The training entailed power point presentations, discussions and practical sessions on actual dossier assessment and report writing.

In his remarks the Chief Executive Officer, Dr. Fred M. Siyoi, informed the trainees on the need to have a paradigm shift in the conduct of dossier assessment and ensure quality assessment in an effort to ensure quality and efficacy of generic products marketed in Kenya.

He also emphasized the need to screen all the applications for market authorization with the aim of ensuring complete applications and reducing workload on the assessors.

Turkey Embassy Commercial Counselor visits PPB

The Commercial Counselor at the Turkey Embassy in Kenya, Mr. Murat Can Kiling on February 18, 2019 paid a courtesy call on the Pharmacy and Poisons Board CEO, Dr. F. M. Siyoi. Mr. Murat was accompanied by Turkish health care delegation to familiarize with the Kenyan principalities of medical products and health technologies registration and timelines.

Burundi Ambassador to Kenya visits PPB

The Pharmacy and Poisons Board, Chief Executive Officer, Dr. F. M. Siyoi on October 15, 2018 hosted delegates from two Standing Committees of the National Assembly of Burundi accompanied by the Burundi Ambassador to Kenya H.E. Rémy Barampama. The team was in the Country for a benchmarking tour to analyze Bills related to the regulation of drugs, pharmacy practice, optician profession and the art of traditional healers. During the deliberations, Dr. Siyoi assured the delegation that the Ministry of Health, through Pharmacy and Poisons Board will support the Republic of Burundi in the establishment of the Burundi National Medicines and Food Regulatory Authority (ABREMA).

Visit by Argentina country Commercial Attache`

The Commercial Attache` at the Argentina Embassy in Kenya, Mr. Nicolas Ramos on November 16, 2018 paid a courtesy call on the PPB Chief Executive Officer, Dr. F. M. Siyoi. Accompanying him was the Assistant Commercial and Multilateral Affairs Ms. Mary Njunge. The meeting centered on the pharma regulatory system, trade procedures and pharma investment opportunities in Kenya.

Malawi Delegates visit PPB

The Malawi Ministry of Health Project Implementation Unit (PIU) for Global Fund procured products, the National Drug Quality Control Laboratory and the Pharmacovigilance Centre visited PPB on October 11, 2018 to benchmark on the Kenya's Pharmacovigilance system and share experiences on quality and safety surveillance of medicinal products in both countries. The team was received by Pharmacy and Poisons Board CEO, Dr. F.M. Siyoi.

Botswana Medicines Regulatory Authority benchmarking

The Director of Inspection and Licensing at The Botswana Medicines Regulatory Authority, Dr. Seima Dijeng and the Corporate & Legal Counsel Latelang Chakalisa visited Pharmacy and Poisons Board (PPB) on December 20, 2018. Their interest was on the pharmacy regulatory processes especially on Enforcement, Investigation and Legal. The duo were received by the PPB CEO, Dr. F. M. Siyoi.

Stakeholders engagement

Director Inspectorate, Surveillance and Enforcement, Dr. Jacinta Wasike chairs a meeting of CEOs of Kenya Pharmaceutical Manufacturing Companies

The Pharmacy and Poisons Board held a stakeholder engagement meeting with CEO's of Kenya Pharmaceutical Manufacturing Companies on November 6, 2018 to deliberate on issues affecting the pharma sector and their respective role in the big four agenda specifically on manufacturing.

The meeting chaired by the Director Inspectorate, Surveillance and Enforcement, Dr. Jacinta Wasike centered on regulation of pharmaceutical manufacturing and the Kenya Good Manufacturing Practice (GMP) roadmap implementation.

The stakeholders applauded PPB's efforts to ensure compliance and pledged to manufacture quality, safe and efficacious pharmaceuticals by adhering to the set GMP standards.

A similar meeting with the Federation of Kenya Pharmaceutical Manufacturers and PPB CEO, Dr. F. M. Siyoi was held on January 30, 2019, to discuss matters affecting the local pharmaceutical industry and address challenges facing the sector.

Federation of Kenya Pharmaceutical Manufacturers meet the PPB CEO, Dr. F. M. Siyoi

On December 15, 2018 the Board conducted a sensitization workshop on effective enforcement of the Pharmacy and Poisons Act, CAP 244 of the Laws of Kenya targeting Prosecution Counsels in the Office of the Director of Public Prosecutions from Kiambu County.

Dr. Tom Kauki engages the prosecution Counsels in Kiambu County

PPB officers group photo with prosecution Counsels in Kiambu County

The East Africa Secretariat in collaboration with partner states - National Medicines Regulatory Authorities (NMRAs) convened a National Stakeholders Consultative meeting on 4th and 5th February 2019 in Nairobi. The two-day meeting brought together key stakeholders in Pharmacovigilance implementation in Kenya to amend, validate and make recommendation for the draft Africa Community Harmonized Guidelines on Pharmacovigilance system strengthening.

Participants at the Good Distribution Practice, Transportation and Waste disposal Guidelines workshop

Director Inspectorate Surveillance and Enforcement Dr Jacinta Wasike addresses stakeholders at the Good Distribution Practice, Transportation and Waste disposal Guidelines workshop

A stakeholders meeting to discuss Good Distribution Practice, Transportation and Waste disposal Guidelines was held on February 12, 2019 at the Kenya School of Monetary Studies. The meeting drew stakeholders from the Ministry of Health, the Kenya Association of Pharmaceutical Industries, Pharmaceutical Society of Kenya, Kenya Pharmaceutical Association and Kenya Medical Supplies Authority.

Representatives of the Federation of Kenya Pharmaceutical Manufacturers, county pharmacists, Mission for Essential Drugs and Supplies, International Committee of the Red Cross, Group 4 Securicor, EvironSafe and Bio hazard also attended the meeting chaired by the Director Inspectorate Surveillance and Enforcement Dr. Jacinta Wasike. Stakeholders present ratified the guidelines for adoption.

The Pharmacy and Poisons Board Nairobi Region, Drug Inspector in Charge, Mr. Julius Kaluai attended the Kenya Pharmaceutical Association (KPA) meeting held in Westland Nairobi on February 9, 2019.

The KPA bi-monthly meeting centered on emerging issues relating to inspectorate and pharmacy practice in general namely sell of prescription only medicines, absentee superintends and control of records in relation to controlled drugs.

PPB drug inspector in charge of Nairobi region Mr. Julius Kaluai addresses participants at the Kenya Pharmaceutical Association meeting

Nairobi International Trade fair

The PPB showcased at the Nairobi International Trade Fair themed "Promoting Innovation and Technology in Agriculture and Trade." The event which was held between 1st to 7th October 2018 provided a platform for the Board to interact with members of the public face to face.

PPB staff engage with visitors during the Nairobi International Trade Fair

The generics debate: a panacea towards affordable medicines?

By Kibet Kisorio

The latest push by insurers in Kenya for rules that will require hospitals to prioritize generic drugs over brand medicines has once again reignited the controversial generic medicines debate. On one hand, the insurers claim that the same is a strategy to tame the rising cost of medical insurance. On the other hand, Kenya Medical Association (KMA) have accused the insurers for what it termed as an attempt to curtain doctors autonomy charging that no entity has the right to limit them to the type of drugs they prescribe for patients.

What then are generic medicines?

The World Health Organization (WHO) defines a generic product as "a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights".

On the other hand, the European Medicines Agency (EMA) defines a generic medicinal product as a "product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.[1]

The American Food and Drugs Authority (FDA) define generic drug as a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.[2]

A distinction however must be drawn between generic drugs from counterfeits. The latter are often manufactured products without the authority of the owner of the intellectual property right subsisting within a certain jurisdiction where the goods are protected. Generic drugs on the other hand are manufactured under the same strict conditions as their branded counterparts thus they have what is termed as bioequivalence as far as efficacy is concerned. Notably, counterfeiting can apply to both branded and generic products.

The link between patents and generics

The fact that pharmaceutical patents play a key role in generic debates is not in doubt. But what then is a patent? The World Intellectual Property Organization (WIPO) defines a patent as an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. Ordinarily, Patent rights excludes third parties from accessing the patented invention without the consent of the right-holder. It is therefore upon the expiry of a patent when generic products enter the market and usually force prices down through competition.

[1]Reg. 726/2004, Art 10, 2b EMA
[2]https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm167991.htm

The justification for reduced prices of generic medicines is attributed to the fact that since no royalties are paid for a patent or trademark due to its expiry. Generic medicines are therefore generally cheaper because the manufacturers do not have to go through the expensive research and development phase that innovators go through. It must be emphasized however that generic products just like innovator products contains substances with direct effect in the diagnosis, cure mitigation, treatment or prevention of diseases otherwise known as active ingredients. WHO maintain that the generic versions must have equivalent properties and action similar to the innovator's brand and are interchangeable.[3] Generics therefore work in the same way and have the same benefits as branded medication.

The generic products are generally embraced by developed and developing countries because of their perceived cost advantages in relation to branded products. Sihanya argues that a healthy generic sector stimulates competition, reduces prices, and makes access to medicines a reality. He adds that generics provides opportunity in developing countries for the creation of a domestic industry observing that making copies is an industrial reality for developing countries compared to research and development (R&D) in new drugs and therapies.[4]

The use of generics in realization of UHC

The disease burden in most of the developing countries in which Kenya is included has turned out to adversely impact the development prospects of many a developing economy. Sadly, many of these diseases are treatable but, access to affordable medicines remains a huge challenge not only in Kenya but the entire African region. The president in his second term strategy outlined priority areas of critical focus touted as the Big Four Agenda in which amongst others, affordable healthcare is given prominence.

Against the foregoing background, the reduction of out-of-pocket expenditure on medicines is certainly central to realization of affordable healthcare in Kenya. The use of cheaper generic formats is critical to ensuring affordable access to quality safe and efficacious prescription generic medicines. Patients who would not ordinarily afford the cost of branded medicines have the option of purchasing affordable equivalent generic version. Increased availability of generic drugs therefore translates into reduced cost of treatment.

[3]See http://apps.who.int/medicinedocs/en/m/abstract/Js21608en/

[4]See Sihanya (2016) *Intellectual Property and Innovation Law in Kenya and Africa Transferring Technology for Sustainable development, Sihanya Mentoring & Innovative Lawyering Publishers, Nairobi, PP 561-562*

The South African approach on generic drugs in combating HIV/AIDS disaster is instructive for Kenya. In 1997, under the then President Nelson Mandela, the South African government in significant part to protect the health of the public by making essential medicines more affordable enacted the Medicines Substances Control Amendment Act No. 90. Among other things, the Act permitted the manufacture of generic HIV/AIDS drugs and encouraged the promotion of generic alternatives by requiring pharmacists to "inform all members of the public about the benefits of the substitution for a branded medicine of an interchangeable multi- source medicine." *(Section 22F(1)(a) of the Medicines and Related Substances Control Amendment Act 90 of 1997.)* Currently, generic medicine has not only saved South Africa healthcare billions, but has increased access to affordable medicine for millions of patients

Conclusion

Medicines are major contributors to the health and wellbeing of a people. The story of Kenya's affordable healthcare therefore, cannot be written down without affordable medicines at the core. Generics come in handy. Additionally, health being a devolved function, county governments should embrace generics which would be a solution to the financial constraints afflicting counties.

The Pharmacy and Poisons Board being Kenya's regulatory agency remains fully committed in her mission towards ensuring quality, safety and efficacy of medical products and health technologies including generic medicines. It is a fact that Kenyans as of right, continue demanding for affordable healthcare thanks to the express provisions of the constitution.

Beneath the generics debate, there is need for sustained public awareness to debunk the myth that generics are inferior. The public should be made aware that by choosing generic they will reap the same treatment outcomes as they would from an innovator product. A balance should however be drawn on the fact that doctors enjoy professional autonomy when administering treatment to patients. An encouragement for them to embrace generic drugs as a way of reducing the cost of treatment to Kenyans would in no way fly in the face of the sacred doctor -patient confidentiality.

Mr Kisorio is the Board's Legal Counsel. He is passionate about Intellectual Property Law.

The economic strength of Universal Health Coverage

By Judy Sheri

President Uhuru Kenyatta signs off the UHC Service Charter with the Governors of Machakos, Nyeri, Isiolo and Kisumu counties as Health CS Sicily Kariuki looks on.

The goals of UHC are shaping the global health agenda emphasizing that all people, irrespective of socioeconomic status, should have access to health services they need, without incurring financial hardship.

These ideas, echoing the 1948 Universal Declaration of Human Rights, were reinforced as a central strategy for global health in the World Health Organization (WHO) 2010 World Health Report and a 2012 United Nations General Assembly Resolution.

More and more countries have begun to roll out programmes that have greatly improved access to healthcare. In Thailand, the amount of people without any health coverage has fallen from 30% to 4% in the last decade thanks to its Universal Coverage Scheme. In Mexico, Seguro a popular public insurance scheme provides comprehensive health services with financial protection for more than 50 million people who previously had no coverage. In Turkey, 95% of the population is now covered by formal health insurance. Japan has been leading efforts to promote Universal Health Coverage (UHC) worldwide. The goal behind these efforts is to improve health outcomes by making access to high-quality health services more affordable and equitably distributed.

Twenty-two other countries, including Brazil, South Africa and Ghana have implemented plans that seek to achieve UHC. The World Bank estimates that in the last decade the cumulative effect of these programmes has meant that 2 billion more people are now covered by some form of affordable health plan who were not previously.

Back home on December 13, 2018, the President of the Republic of Kenya, H.E President Uhuru Kenyatta launched the UHC pilot

programme in four pilot counties of Machakos, Nyeri, Kisumu and Isiolo - aimed at improving the living standards and most importantly the health of all Kenyans.

UHC is being called the third global health transition; it has emerged as the single most powerful concept that public health has to offer. It is inclusive and sole tool to establish continuum of care by linking strategies to equities. It has the potential to unify services and delivers them in a comprehensive way as seen in Thailand or Japan that ranks 10. Lessons can also be learnt from UK's NHS for it has been lauded in its quality of care, efficiency and low cost at the point of service.

These economies have proved that universal coverage is the hallmark of a government's commitment to improve the wellbeing of all its citizens. The whole ideas is to learn lessons from countries with successful health systems and best practices to shape one's own journeys to UHC, making adjustments and adaptations as they build experience.

As highlighted in the work on wealth and income inequality by the French economist Thomas Piketty in his 2014 book, *Capital in the Twenty – First century.*

UHC is important as a means to fight poverty in the age of deepening income inequality worldwide.

In simple terms UHC is a triple win: It improves people's health, reduces poverty, and fuels economic growth. This type of healthcare will help to improve the health of the general population, since every member of society has equal access to medical care.

Like education, UHC is an important investment in human capital, which is necessary for economic growth and development; UHC lays the framework of opportunity for what Aristotle called "human flourishing," an idea that has been elaborated by Nobel Prize winning economics Amartya Sen.

> "...UHC is important as a means to fight poverty in the age of deepening income inequality worldwide...

Hence, it will lead to a reduction in the amount of illness suffered by the general population, create healthier people, and increase productivity. Citizens can get free treatment for basic conditions without fear of not being able to afford them. This can help reduce the spread of infectious diseases and other common health problems that people may ignore if they can't afford healthcare.

Without a doubt, people work more when they live healthier lives, which allow them to contribute as much as they can to the nation's economy. Beyond improving health, expanding UHC could potentially promote economic well-being, reduce economic inequalities, and bolster social and political stability.

Improving population health could accelerate economic growth by improving labor productivity, school attendance, educational attainment, cognitive function, capital accumulation, and fertility control. Healthy populations translate into productive and stable nations.

Health CS Sicily Kariuki interacts with patients at Athi RIver Health Centre

In focus: Senior staff media training

A media training workshop for Pharmacy and Poisons Board senior management was held on 14th and 15th February 2019. The aim of the training was to strengthen the Board's engagement with the media.

Corporate Social Responsibilty

The Public Relations Department conducted a Corporate Social Responsibility (CSR) on the 21st December, 2018 at the Ongata Special Home and Training Centre in Ongata Rongai, Kajiado County.

The home which has 24 children with special needs is run by a couple who relies on well-wishers for support. The visit presented an opportunity to interact with the less fortunate in the society and appreciate sacrifice of the couple to help the less fortunate.

Pharmaceutical reforms to improve access to medicines

Cabinet Secretary for Health Sicily Kariuki addresses media during the Horn of Africa Pharmaceutical Conference and Expo

The Ministry of Health is revamping the pharmaceutical sector to improve access to quality, safe and efficacious medicines and medical products.

Health Cabinet Secretary for Health, Sicily Kariuki said the reforms which include standardizing of procedures and practices in the pricing and distribution of pharmaceutical and non-pharmaceutical supplies will enable Kenyans to access affordable medical products in the country without financial hardship.

She made the remarks on October 3, 2018 during the opening of the Horn of Africa pharmaceutical conference at a Nairobi hotel.

The CS said the ministry will review and update all the current essential commodity lists, operationalize Medicines and Therapeutics Committees in all County Health facilities and monitor pricing of drugs through updated Market Price Index data.

Among other reforms expected is the roll out of electronic commodity management information system (CMIS) to link stores to all user units in the health sector and costing of essential health products as per the guidelines of the Universal Health Coverage advisory panel.

The CS commended the Pharmacy and Poisons (PPB) for organizing the second Horn of Africa Pharmaceutical Conference and expo whose theme was "Access to Medical Products in Attainment of Universal Health Coverage (UHC)," with an ultimate aim to improve access to safe, efficacious and good quality health products in the Horn of Africa through knowledge sharing and collaboration.

"PPB has actively participated in the implementation of the wider Government of Kenya development policies that embrace the implementation of the Vision 2030 development blueprint by setting up systems to enhance efficiency and effectiveness in control and management of medical products in the country," she noted.

The PPB, Chief Executive Officer, Dr. F.M. Siyoi thanked the delegates for attending the conference to strengthen partnership in regulation of medical products. "PPB believes that a structured, collaborative effort to achieve universal health coverage can meet the shared goals of global health stakeholders of expanding patient access to quality medicines through innovative solutions and long-term sustainability of the health sector," he said.

Participants group photo during the Horn of Africa Pharmaceutical Conference

Ensuring safe, quality and efficacious medical products in Kenya

Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage (UHC), and Sustainable Development Goal 3.b emphasizes the need to develop medicines to address persistent treatment gaps.

The goal of Universal health coverage (UHC) is to ensure that all people obtain the health services they need without suffering financial hardship when paying for them. This goal is based on the idea of an affordable continuum of care from preventive to curative and rehabilitative services for which essential health system resources are required.

The Pharmacy and Poisons Board has actively participated in the implementation of the wider Government of Kenya development policies that embrace the implementation of the Vision 2030 development blueprint by setting up systems to enhance efficiency and effectiveness in control and management of medical products in the country.

Access to quality and affordable medical supplies is an indicator of a functioning health care system and it is crucial for UHC. To achieve the highest standards of safety, efficacy and quality for medical products and technologies, the Pharmacy and Poisons, has put in place appropriate regulatory measures, to ensure the protection of the consumer as envisaged by the laws regulating drugs in force in Kenya.

What are medical products?

Medical product refers to any product used specifically for health care purposes, i.e. to prevent, diagnose, treat, monitor, or alleviate disease or injury, or for related purposes. This includes medicines for humans and animals, medical devices, and biological products. Other terms like therapeutic products, medicinal substances or health technologies may also be used.

What are health technologies?

Health technology refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. Healthcare has evolved into a highly complex technological field, with new products constantly being introduced or old ones modified to deliver multiple solutions.

Just like in ICT, technology is advancing and converging in healthcare. A medicine may be integrated into a medical device to be administered in a controlled manner (e.g. pre-loaded insulin syringe or a contraceptive implant; or a medical equipment may have integrated functions for diagnosis, administering medication, monitoring vital signs and recording data. This trend requires regulators to constantly adapt their competencies and systems in order to effectively assess the safety, quality and efficacy of emerging health technologies.

What measures are in place to assure that medical products in Kenya are safe?

Access to safe medical products is a cornerstone of public health around the world. The PPB has established a comprehensive and functional regulatory system to ensure that only safe, good quality and efficacious medical products are available in Kenya.

Some of the measures in place include:

1. Human Resource: A key asset for the PPB is the expertise of its technical staff. The PPB invests heavily in formal training of key staff through sponsorship to post-graduate courses in regulatory science, and also skills upgrading in collaboration with WHO and other partners.

2. International Standards: The PPB applies and adapts international standards generated through standard-setting mechanisms like the WHO Prequalification Programme, the Global Vaccine Safety Forum and the International Medical Device Regulators Forum. To engender confidence in the standards, PPB experts actively participate as a partner to these initiatives - as assessors, inspectors or in consultative forums.

3. Regulatory Harmonization: To minimize the risk of substandard or falsified medicines moving across borders, to strengthen national and regional systems for regulation and law enforcement. The PPB collaborates with International, Regional and Bilateral organizations like the Interpol and WHO in the fight against falsified medicines.

- The PPB fully supports the ongoing East African Community Medicines Regulation Harmonization Project (EAC MRH) and IGAD to improve access to safe, efficacious and good quality essential medical products within the EAC and IGAD region.
- The PPB works closely with other government agencies and regulators (e.g. Kenya Revenue Authority, Anti-Counterfeit Agency, Kenya Bureau of Standards and Kenya Trade Network Agency) in ongoing initiatives to streamline cross-border trade.

4. Product Registration: Any medical product offered for use in Kenya should be registered by the PPB. The product undergoes a stringent procedure which requires the submission of a broad range of data and evidence of quality, safety and effectiveness. PPB assessors review these data to determine the risk-benefit profile of the product, and before issuance of marketing authorization. The registration status is updated annually to enable the PPB to take into account any risk concerns that may arise during use.

- Laboratory Testing: Regulatory decision-making requires laboratory testing of products to assess quality standards. The PPB ensures that all products before being registered are tested in WHO-prequalified laboratories. In Kenya, the two pre-qualified laboratories are the National Quality Control Laboratory (NQCL) and the MEDS laboratory.

The Board has also acquired Modern equipment such as the Raman Spectroscopy and minilab technology to screen medical products as they come at ports of entry and during post market surveillance.

5. Inspection of Manufacturing Sites: PPB Inspectors routinely audit facilities used for manufacturing of medical products to ensure they comply with set standards of Good Manufacturing Practices (GMP). Where possible, some audits are conducted jointly with World Health Organization (WHO) or other regulators.

6. Control of Imports and Exports: The PPB has an elaborate cross- border control system that ensures only approved medical products enter our country.

- Any medical product imported into or exported out of Kenya (including donations) are authorized by the PPB.
- Medical products imported into the country are only allowed when they enter through designated Points of Entry (POE) manned by PPB officials deployed to inspect and authorize imports and exports along with other border control agencies.
- PPB has gazzetted eleven (11) Ports of Entry namely: Kilindini Port, Lunga Lunga, Namanga, Jomo Kenyatta International Airport, ICD Embakasi, ICD Pepe Athi River, EMS City Square, Isebania, Busia, Malaba and Eldoret International Airport. Plans are underway to designate nine (9) more POEs namely: Taveta, Moyale, Mandera, Kisumu Airport, Lokichogio, Liboi, Nadapal, Wilson Airport, Moi International Airport Mombasa and General Post Office Mombasa

7. Post market surveillance: The PPB monitors the quality, efficacy and safety of a medicine after release to the market, as part of pharmacovigilance. This is achieved through various activities, e.g.

- The PPB Pharmacovigilance Centre enables healthcare providers or the public to report suspected poor quality and adverse reactions. The Centre is linked electronically to the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden. The system is online and enables real time exchange of data on products across the world. Any person can report suspicious medical product at www.pv.pharmacyboardkenya.org. Such information assists PPB to determine whether a product should be retained in the market, or to impose restrictions on its marketing and use.
- The PPB works with NQCL to ensure products are sampled and tested.

8. Control of Clinical Trials: The PPB controls the conduct of any studies in Kenya involving the use of a medical product on human participants. Some of the recent clinical trials include those for malaria and Ebola vaccines. PPB has developed an electronic application platform for registration of clinical trial that assists in the approval and monitoring clinical trial in the country.

9. Control of Pharmacy Profession: The PPB also regulates the training and licensing of pharmacists and pharmaceutical technologists. Licensing of pharmacy wholesale and retail outlets is also done by the PPB. Licensing ensures that medical products are distributed and dispensed according to required standards and from a recognized premise.

- ***Accreditation of Training:*** PPB approves all courses for pharmacy degree or diploma training, and accredits training institutions offering the courses. Only trainees from accredited institutions are eligible for registration or enrolment by the PPB. Currently, 23 training institutions are accredited to train pharmaceutical technologists, and 5 Universities to train pharmacists. Accredited institutions are regularly inspected to ensure conformance with standards. The list of approved training institutions is published on the PPB website www.pharmacyboardkenya.org
- ***Licensure of Practitioners:*** Only Pharmacists and Pharmaceutical Technologists can be licensed to practice pharmacy. The license-holder is required to be physically present in the premises whenever it is open to the public. Annual Practice Licenses are issued with a photo of the responsible professional for each premise; whole details can be verified electronically through Quick Response (QR) code and the health safety code 21031. The PPB regularly inspects pharmacy premises – either alone or jointly with other health regulatory bodies; through applying Global Positioning Systems (GPS) mapping to enhance efficiency.

10. Enforcement: The PPB is empowered by law to investigate and prosecute pharmaceutical crimes. This may entail arresting offenders, confiscating products or closing down premises. In 2013/2014 the percentage of inspections to court cases was 65.74% and in 2014/2015 the percentage was 59.12%.

11. Centre of Excellence: The PPB is designated as a Regional Centre for Regulatory Excellence (RCORE) in Pharmacovigilance in 2014 by the New Partnership for Africa Development (NEPAD). This makes the PPB a model Pharmacovigilance Centre for training and expertise for other African Countries. Similarly, the WHO-Prequalified National Quality Control Laboratory offers other countries for quality control and training services.

The Board is confident that new endeavors to create an independent accountability system, will ensure that crucial actions are taken to protect investments made in essential medicines, and that these investments translate into health and development for all.

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Ensuring quality, safety and efficacy of medical products and health technologies

PUBLIC NOTICE

Report suspected adverse events and poor quality medicine

The Pharmacy and Poisons Board (PPB) is the National Medicines Regulatory Authority for Medical Products in Kenya. The mandate of the PPB is to promote and protect public health by ensuring that medicines, medical devices and other health technologies are safe, efficacious and of accepted quality.

To continuously monitor the quality and safety of medicines circulating in the Kenyan market, PPB has established a strong national Pharmacovigilance system that helps to track, monitor and evaluate quality, and safety of medicines.

You can report: suspected side effects from medicines, adverse events from vaccines, incidents with medical devices and suspected poor quality medicines online at **www.pv.pharmacyboardkenya.org; email pv@pharmacyboardkenya.org or call (+254) 0795743049.** You can also contact any health care provider near you to report.

This information will be treated with confidence and will go a long way in enhancing the monitoring of medicines and medical devices so as to ensure their safety, quality and efficacy

Pharmacy and Poisons Board @ppbkenya info@pharmacyboardkenya.org

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Ensuring quality, safety and efficacy of medical products and health technologies

- When you visit your local pharmacy to buy medicines, look out for the **Health Safety Code.**
- Type the **code** and SMS it to **21031** to verify the registration status of the pharmaceutical outlet. You'll receive a message confirming the registration status of the outlet. SMS is free.
- For your own safety, always buy your medicines from a registered pharmaceutical outlet.

For more information visit: www.pharmacyboardkenya.org

info@ pharmacyboardkenya.org Pharmacy and Poisons Board

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