ISSUE NO.20

JUL 22 - SEP 22



# PHARMACY AND POISONS BOARD NEWSLETTER

Better pharmacy services as PPB/PSK go for joint self-regulation framework

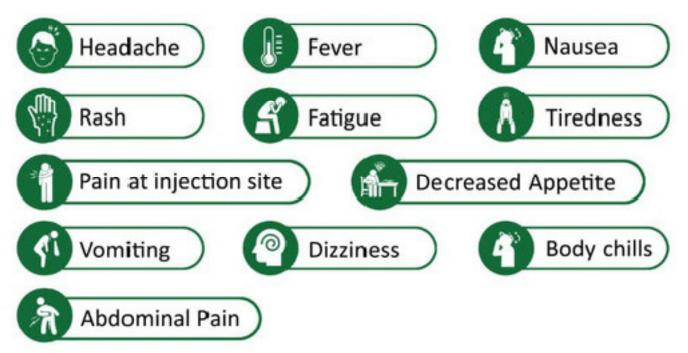
COVID-19 SARS-CoV-2

Vaccine

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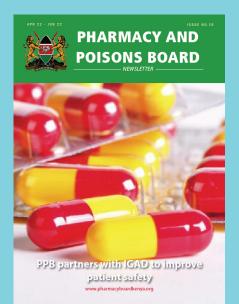


# COMMONLY REPORTED SIDE EFFECTS OF COVID-19 VACCINES



You are encouraged to report ANY side effect you may experience after vaccination to Pharmacy and Poisons Board through any of the channels below:

PUBLIC/PATIENTS		HEALTH WORKERS	
Website	pv.pharmacyboardkenya.org/padrs/add	Website	pv.pharmacyboardkenya.org/
Phone	+254 795 743 049	Email	pv@pharmacyboardkenya.org
	or report to the nearest health facility	Phone	+254 795 743 049



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#### **About The Newsletter**

The PPB Newsletter is a publication of the Public Relations Department. It is designed to act as a tool of communication, documenting and disseminating important news and information to staff and stakeholders of the Board

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# **Editor's Note**

### Looking to the future

#### Dear readers,

I am delighted to bring you this quarter's newsletter. I am also encouraged by the feedback received from readers. This edition recounts the various activities and projects in which the Pharmacy and Poisons Board staff were involved in during the first quarter (July - September) of the financial year 2022/23.

We will be striving towards making PPB Newsletter more relevant and practical. Besides news on the latest happenings at PPB and from the industry, there will be more perspectives from practitioners and handy tips on applying regulatory practices.

If you have any suggestions or ideas on what you would like to see in PPB Newsletter or you would like to contribute a story, get in touch with us at pr@pharmacyboardkenya. org

Look out for the refreshed PPB Newsletter in December!

Fudy

#### **ONGOING EVENTS**

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



### PHARMACY AND POISONS BOARD

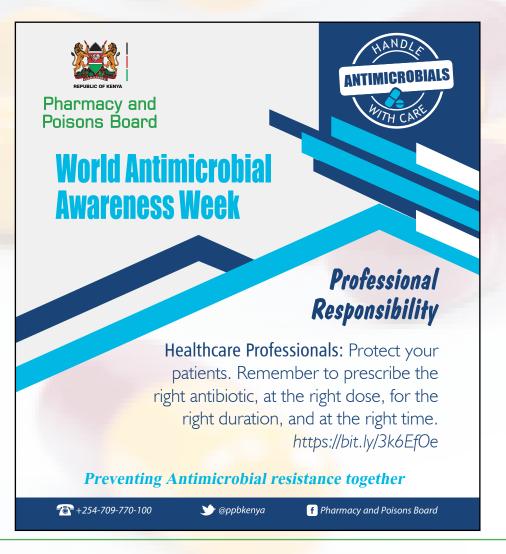
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Pharmacy and Poisons Board



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# Pharmacy profession is an integral part of the healthcare delivery system

#### By Dr. F. M. Siyoi, Chief Executive Officer, Pharmacy and Poisons Board



Pharmacy and Poisons Board Chief Executive Officer, Dr. F. M. Siyoi

World Pharmacists' Day is a time when we pause to celebrate the critical role played by pharmacists in healthcare delivery to the population.

This year's World Pharmacists' Day theme "Pharmacy united in action for a healthier world," emphasizes the pharmacist's goal of exemplifying leadership, community, ownership, and solidarity within the health care industry.

Most of us understand that pharmacists are in charge of supply chain of health products. However, the role of pharmacists is much more significant in the healthcare delivery system than we probably realize.

Over the past four decades, the role of the pharmacist has evolved from an individual who was primarily responsible for safely and

accurately dispensing medicines to a patient, to an individual who works side-by-side with physicians, nurses, and other healthcare professionals in sophisticated, highly specialized healthcare practice settinas assure to appropriate medication therapy management.

The focus of the profession of pharmacy has shifted from technical, product-oriented, functions to patient-centered care, desired patient outcomes, medicines information and medication use review. This shift is generally referred to as Pharmaceutical Care.

In addition to dispensing medications and ensuring patient safety, today's pharmacists are taking a larger role as an integral part of the health care team across the entire continuum of patient care and treatment.

Pharmacists are the most accessible and trusted healthcare professionals. This accessibility allows them to perform a wide array of patient care activities, including counseling, medication management, and preventive care. Beyond the care provided to individual patients, pharmacists have expanded their reach to desian and implementation of interventions that promote and protect the public health of communities.

Indeed, significant advancements have been made in Kenya in delivering efficient and modern pharmacy services and in expanding the range of services offered by pharmacists in the care and treatment of patients. The commitment of the pharmacy profession to patient care, and the hard work and determination to sustain the supply of health commodities and key pharmaceutical care services throughout the COVID-19 pandemic, have been a source of immense pride.

Some interventions by pharmacists include: Health education & awareness creation; access to health products & technologies; pharmaceutical care; health programs management; safety monitoring and quality assurance of medicines.

Pharmacists also play a key role in prevention and management of both communicable and non-communicable diseases such as cardiovascular diseases, cancer, diabetes, chronic respiratory disease, mental health HIV, Malaria, tuberculosis and neglected tropical diseases.

Historically, the Pharmacy and Poisons Board as a regulator pharmacy practice has of supported the pharmacists and pharmaceutical technologists' role in public health. To achieve its mission to protect and promote the health of the public, the Board has increased access to pharmacy services at primary healthcare level by enhancing participation of pharmaceutical personnel at the primary healthcare facilities.

Today, there are more than 3684 registered pharmacists employed in different sectors of the pharmaceutical industry in Kenya. In addition, the Pharmacy and Poisons Board has accredited seven (7) universities have been approved

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to offer Bachelor of Pharmacy and twenty-two (22) colleges to offer diploma in pharmaceutical technology. This is critical in training and capacity building of human resource needed to support pharmaceutical services in Kenya.

As we look at the emerging forces shaping the future of health care, it is clear that accelerated innovation and utilization of information and technology (IT) in the pharmaceutical industry are the game-changers in shaping growth and sustainability in the industry.

### Nairobi hosts Antimicrobial resistance Forum



Health CAS Dr. Rashid Aman makes his remarks at the AMR Forum

In view of the ongoing Covid-19 pandemic, several studies globally have indicated a high rate of antimicrobial prescribing and self-medication for those with symptoms of Covid-19, much of which is unnecessarily promoting Antimicrobial resistance (AMR).

Speaking during the National AMR Forum in Nairobi on July 22, 2022, Chief Administrative Secretary for Health, Dr. Rashid Aman observed that optimal utilization on microbiology laboratories is critical in ensuring that the continuous engagement of patients, the clinical & laboratory teams supporting the judicious use of antimicrobial agents continues as guided by our National Antimicrobial Stewardship Guidelines.

"Inaction, will have dire consequences for human, animal, plant and environmental health, hence the call to accelerated action in curbing the growing threat of antimicrobial resistance in the next version of the National Action Plan," said the CAS.

The CAS advised that the next action plan should target elimination or reduction of OTC sales of antimicrobial drugs that are important for medical or veterinary purposes, reducing the overall need for antimicrobial drugs by improving infection prevention & control, hygiene, biosecurity & vaccination program in humans, agriculture and aquaculture.

"In addition, we need to end the use of antimicrobial drugs that are of critical importance to human medicine in promoting growth in animals, limiting the amount of antimicrobial drugs administered to prevent infection in healthy animals and plants and ensuring that their use is performed with regulatory oversight," he said.

He also highlighted the need for ensuring access to quality and affordable antimicrobials for animal and human health and promoting innovation of evidence based and sustainable alternatives to antimicrobials in food systems.

To achieve this, the CAS said there is need to present a strong economic case for investing in containment of antimicrobial resistance with robust estimates of the costs and benefits of implementing national action plans on antimicrobial resistance to galvanize investment.

Studies have predicted a continued rise in antimicrobial resistance globally leading to 10 million people dying every year and a 3% reduction in Gross Domestic Product (GDP) by the year 2050. The GRAM report 2022 estimated that, at least 1.27 million deaths per year are directly attributable to AMR.



AMR Forum participants group photo

In 2019, the highest rates of AMR burden were in sub-Saharan Africa where six pathogens accounted for 73.4% of deaths, 1 in 5 deaths caused by AMR occurred in children under the age of five – often from

previously treatable infections.

"This new evidence shows that AMR is a leading cause of death globally, higher than HIV/AIDs or Malaria, a warning signal that AMR is already putting extra pressure on frontline healthcare workers by making common infections harder to treat and preventing them from saving millions of lives," he observed.

# Pharmaceutical technologists are among the most accessible healthcare providers

Pharmaceutical technologist plays a significant role in provision of pharmaceutical care services.

Speaking on July 21, 2022, during the 18th annual scientific conference for the Kenya Pharmaceutical Association, the Pharmacy and Poisons Board (PPB) Head of Central Region, Dr. Tom Kauki highlighted that pharmaceutical technologists are among the most accessible healthcare providers and are among the best trained personnel to help patients use their medicines.

Dr. Kauki who was representing the PPB CEO, Dr. F. M. Siyoi noted that medicines have become a very important and powerful tool more than ever in improving the health status of populations and in the long-term reducing healthcare costs.

He urged the participants to use their grassroot reach to educate members of the public on dangers of self-medication which has become rampant.

He further disclosed that the Board has established systems that has increased efficiency in business processes to facilitate pharmaceutical technologists



KPA delegates sign a visitors book at PPB booth



Dr. Tom Kauki addresses KPA members in Mombasa

in their work to ensure access to medicines and their appropriate use, improve adherence and coordinate care transitions among others.

He informed the practitioners that the PPB has a new Board of Directors and has also gazetted new Pharmacy and Poisons Rules 2022, to improve service

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delivery. The Board has also continued to decentralize its services in order to reach all stakeholders with new offices opened in Kisii, Kitale, Kiambu and Murang'a, he added. This year's conference theme was "Emerging trends in healthcare".



KPA conference participants follow proceedings



#### Health CS inaugurates PPB Board of Directors

Health CS Mutahi Kagwe with PPB Board of Directors

The new Board of Directors of the Pharmacy and Poisons Board, was inaugurated by the Cabinet Secretary for Health Senator Mutahi Kagwe on July 01, 2022.

Speaking in Malindi where he inaugurated two other boards, the National Hospital Insurance Fund (NHIF) and the Kenya Healthcare Professionals Oversight Authority (KHPOA), the CS said the government is committed to expanding health service coverage with a focus on quality and reduction of healthcare costs.

The CS said the ministry is ready to offer support to ensure the three boards actualise their respective mandates as the country prepares for assessment by the World Health Organisation towards certification to maturity



Board Chairman



Board Member

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**Board Member** 



**Board Member** 



Board Member

level 3.

He noted that recent publication of six statutory instruments has set the Pharmacy and Poisons Board, closer to fulfilling the key requirements for the certification.

The Board will be chaired by Dr. Rodgers Atebe with Dr. Fred Siyoi as CEO. Muleli Mutuku, Dr. Paul Magutu Njaria, Dorcas Wanjiru Ngechu, Dr. John Munguti Kisengi, Miriam



**Board Member** 

Wairimu Ndirangu, Stephens Ogutu Oyaya and Dr. Diana Marion are members.



Group photo of PPB Board Members

# Better pharmacy services as PPB/PSK go for joint self-regulation framework

The Pharmacy and Poisons Board (PPB) is collaborating with the Pharmaceutical Society of Kenya (PSK) to develop a self-regulation framework to promote Good Pharmacy Practices in the country.

A Memorandum of Understanding (MoU) between the PPB and PSK is underway to deepenthe cooperation targeted at ensuring pharmacists take full responsibility of upholding ethics and professionalism in the practice of pharmacy.

Speaking in his office on August 25, 2022 during a courtesy call



PPB CEO, Dr. F. M. Siyoi during a meeting with PSK CEO, Dr. Lucas Nyabero and Dr. Thuo Kamau

by PSK, the PPB Chief Executive the PSK for reaching out to Officer Dr. Fred Siyoi commended the government in its quest to

have self- regulation as a way to minimize malpractice and protect the public.

The MoU is intended to provide a framework to assist the joint working of the two organizations in order to support each other role and functions.

"The collaboration will not only benefit the profession but also the health sector and the people of Kenya at large by ensuring the highest quality of pharmacy care and the appropriate use of medicines and health products," said Dr. Siyoi when he met PSK Chief Executive Officer, Dr. Lucas Nyabero and Board member Dr. Thuo Kamau.

Dr. Nyabero said self-regulation of the profession of pharmacists is necessary to maintain ethical standards of practice and regulation of their activities to ensure they contribute to the appropriate use of medicines.

"There is need to support each other to ensure the patients are using medicines appropriately. The Pharmacy and Poisons Board is giving us a lot support on this to ensure professionalism is highly observed in the pharmaceutical sector," Dr. Nyabero said.

He observed that self-regulation framework and the Green Cross are some of the strategies the PSK has advanced in order to ensure that patients are provided with high quality pharmaceutical care country-wide.

Dr. Thuo Kamau also disclosed that the PSK is working on a pharmacy benefits management scheme which will enable pharmacies with a Green Cross to dispatch medicines to patients and be reimbursed by the NHIF.

It is widely accepted that our population's health needs will continue to change and place greater demand on existing health services. Dr. Siyoi said that the PPB works for public interest to protect and promote the health, safety and well-being of patients and the public, by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies.

"We need a healthy population to contribute to our economic growth and in particular the county's Vision 2030," said Dr. Siyoi.

# African Medical Devices Regulators Forum lobby for recognition at the IMDRF meeting

On September 27, 2022, Dr. Paulyne Wairimu, Chair of the African Medical Devices forum represented Africa at the International Medical Device Regulators Forum (IMDRF) in Sydney meeting.

"The IMDRF is a voluntary group of medical device regulators from around the world who have come together to accelerate international medical device regulatory harmonization and convergence," said Dr. Wairimu.

The IMDRF was established in October2011, when representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and the United States, as well as the World Health Organization (WHO) met in Ottawa to address the establishment and operation of this new Forum.



International Medical Device Regulators Forum participants

The African Medical Devices Regulators Forum (AMDF) was invited by the IMDRF Secretariat, through the Chair who is currently the Therapeutic goods administration of Australia, to present at the 22nd Management Committee which was held on 12 to 14th September 2022 in Sydney, Australia. Dr Paulyne Wairimu, Head of Medical Devices at the Pharmacy and Poisons Board, represented the African continent as the Chair of the AMDF. In addition, during the IMDRF meeting, an open stakeholders' forum was held which included MedTec industry players such as the Global Medical Technologies alliance (GMTA)



Dr. Paulyne Wairimu pose for a photo with IMDRF Forum participants

and Global Diagnostic Imaging, healthcare IT& Radiation therapy trade association (DITTA).

During the Open stakeholder meeting, AMDF presented on

the current achievements in advocating for the acceleration of regulatory practices by African Regulators as well as key highlights that the group has achieved such as organizing workshops for capacity building initiatives and dissemination of guidelines developed by the AMDF Technical Experts and Endorsed by the AMRH Steering Committee.

Dr. Wairimu said at the Closed door, Management Meeting of the IMDRF Members, AMDF presented specific request including consideration as a member of the IMDRF or considerations for approved observer status to the IMDRF.

Further, AMDF members asked to be considered and incorporated to the working groups of the IMDRF such as principles of IVD medical devices, medical device clinical Evaluation and Good regulatory practices; in addition, AMDF requested the support of IMDRF members for twinning programs that will help in accelerating regulatory practices in Africa.

# PPB, ARSO sign agreement to support HPTs regulation

The African Organization for Standardisation (ARSO) is supporting the African countries to develop harmonised African standards in promoting the pharmaceutical industry growth.

The Pharmacy and Poisons Board (PPB) is among the institutions that have signed an agreement with ARSO to support regulation of Health Products and Technologies (HPTs) through the standards developed by ARSO.

On September 1, 2022, PPB Head of Medical Devices, Dr. Paulyne Wairimu paid a courtesy call on the African Organisation for Standardisation (ARSO) Secretary General, Dr. Hermogene Nsengimana and discussed the areas of agreement in relation to capacity building, harmonisation of standards, and implementation. Dr. Hermogene said ARSO is



committed and will engage all standards are fully implemented by regulatory bodies to ensure the member states in the continent.

### **USP top official visits PPB**



PPB Chief Executive Officer, Dr. F. M. Siyoi during a meeting with USP officials

The Senior Vice President, Global Health & Manufacturing Services at the United States Pharmacopoeia (USP) Dr. Emily M. Kaine paid a courtesy call on the Pharmacy and Poisons Board (PPB) Chief Executive Officer, Dr. F. M. Siyoi, on 26 July, 2022.

Dr. Emily who was accompanied by the USP/PQM+ Director, Eastern and Southern Africa Dr. Evans Sagwa among other representatives reiterated USP's commitment to support Global health in particular strengthening regulatory systems and local manufacturing including regional harmonization initiatives.

The meeting also discussed areas of continued improvement especially on medical devices regulation, post marketing surveillance activities and promotion of local manufacturing of vaccines.

In his remarks, PPB CEO Dr. Siyoi

expressed his gratitude to the United States Pharmacopoeia (USP/PQM+) for their continued support which, has helped the PPB strengthen its regulatory systems.



A group photo of the meeting participants

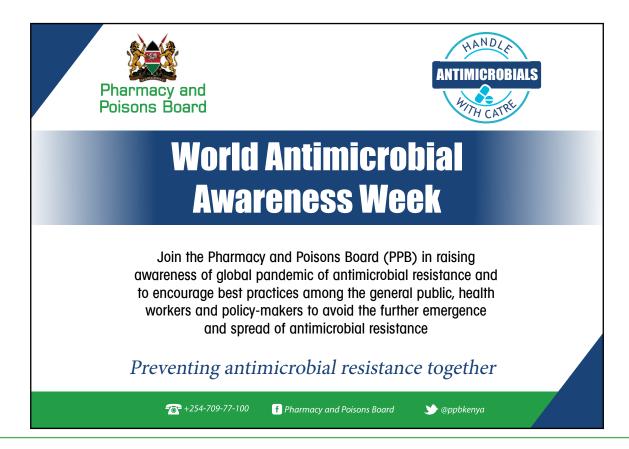
### **PPB CEO meet with AUDA-NEPAD**



A group photo after a meeting with a delegation from AUDA-NEPAD

The Pharmacy and Poisons Board, Chief Executive Officer Dr. F. M. Siyoi on September 29, 2022 held talks with a delegation from the African Union Development Agency

& New Partnership for Africa's Development (AUDA-NEPAD) to discuss the implementation of activities under the African Union Smart Safety Surveillance (AU-3S). The team was led by Prof. Aggrey Ambali, the AUDA Supervisor and Advisor to AU -3S.



## **PUBLIC NOTICE**

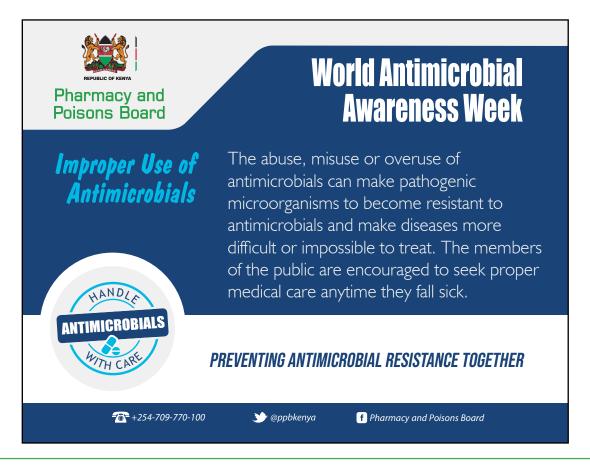
### PUBLIC NOTICE ON ILLEGAL TRADE OF MEDICAL PRODUCTS ON E-COMMERCE PLATFORMS

The Pharmacy and Poisons Board's mandate is to protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies.

It has come to the attention of the Board that some e-commerce platforms, are trading in medical products, including prescription only medicines, in total disregard to the provisions of the Pharmacy and Poisons Act (CAP 244, Laws of Kenya. The Board is working with the Communications Authority of Kenya to pull down the concerned domains and is carrying out investigations on all online platforms involved in the said illegality so as to take necessary regulatory actions on persons and parties involved.

In this regard therefore, we appeal to the members of the public to buy medical products only from authorized premises whose license status can easily be verified using a health safety code visibly placed in medicine outlets by sending an **SMS** to **21031**.

The Board would also like to thank the members of the public for the continued engagement in matters that involve safe use of medical products and welcome any feedback by calling us on 0709770100 or sending an email at admin@ pharmacyboardkenya.org and pv@pharmacyboardkenya.org.





PHARMACY AND POISONS BOARD

### **PUBLIC ALERT**

#### **USE OF DICLOFENAC FOR PAIN MANAGEMENT**

The Pharmacy and Poisons Board (the Board) is mandated under the Pharmacy and Poisons Act (Cap 244) to disseminate information on medical products to health professionals and to the public in order to promote their rational use. The Board therefore wishes to draw the attention of the public to the use of •Non-Steroidal Anti-inflammatory Drugs' (NSAIDs), specifically Diclofenac for pain management.

NSAIDs as a class, if used at high dose and for long periods, are associated with an increased risk of blood clots in the arteries especially in patients with underlying heart or circulatory conditions or with certain cardiovascular risk factors, which in some cases has led to heart attack or stroke.

Diclofenac is a widely used medicine for relieving pain and inflammation, particularly in painful conditions such as arthritis. Overall, the benefits of diclofenac are greater than its risks. Therefore, to mitigate the risks associated with use of diclofenac, the public is notified of the following:

- There is a small risk of heart attack or stroke in patients taking systemic diclofenac regularly, especially at high doses (150 mg daily) and for long periods;
- Use of diclofenac is no longer recommended for patients with history of a heart attack or stroke, heart failure, blockages to blood vessels to the heart or brain or have had an operation to clear or bypass such blockages, or circulatory problems that restrict blood flow to your limbs;
- If you smoke or have other risk factors such as high blood pressure, high blood cholesterol, diabetes, your doctor will need to assess if you should use diclofenac and the best way to take it;
- If you are on long-term diclofenac treatment you will need to have your treatment reviewed to ensure that it is still right for you. You are advised to speak to your prescriber at your next scheduled appointment;
- You should not stop taking your treatment without talking to your health professional;
- If you have any questions, speak with your health professional:

The Borad advises the public against self-medication with pain killers, especially declofenac. Declofenac should only be dispensed or used upon prescription by a duly qualified health professional.

The Board would like to thank the public for the continued efforts to ensure safe use of medicines and encourage them to provide feedback by contacting the Board through 0795 743 040 or sending an email to pv@pharmacyboardkenya.org or report any suspected adverse events or quality defects on medical products and health technologies at http://pv.pharmacyboardkenya.org

#### CHIEF EXECUTIVE OFFICER



## **DANGERS OF SELF-MEDICATION**

Self-medication has potential risks such as;

- Hiding of severe disease hence delay in seeking medical advice
- 2 Wrong identification of diseases leading to wrong choice of medicines
- 3 Can lead to side effects (mild, moderate to severe)
- 4 Exposure to harmful medicines interactions
- 5 Other risks include wrong dosages, wrong route of administration, risk of medicines abuse and addiction

For more information visit: www.pharmacyboardkenya.org



PPB Newsletter

Guaranteeing Quality and Safety of Medicines