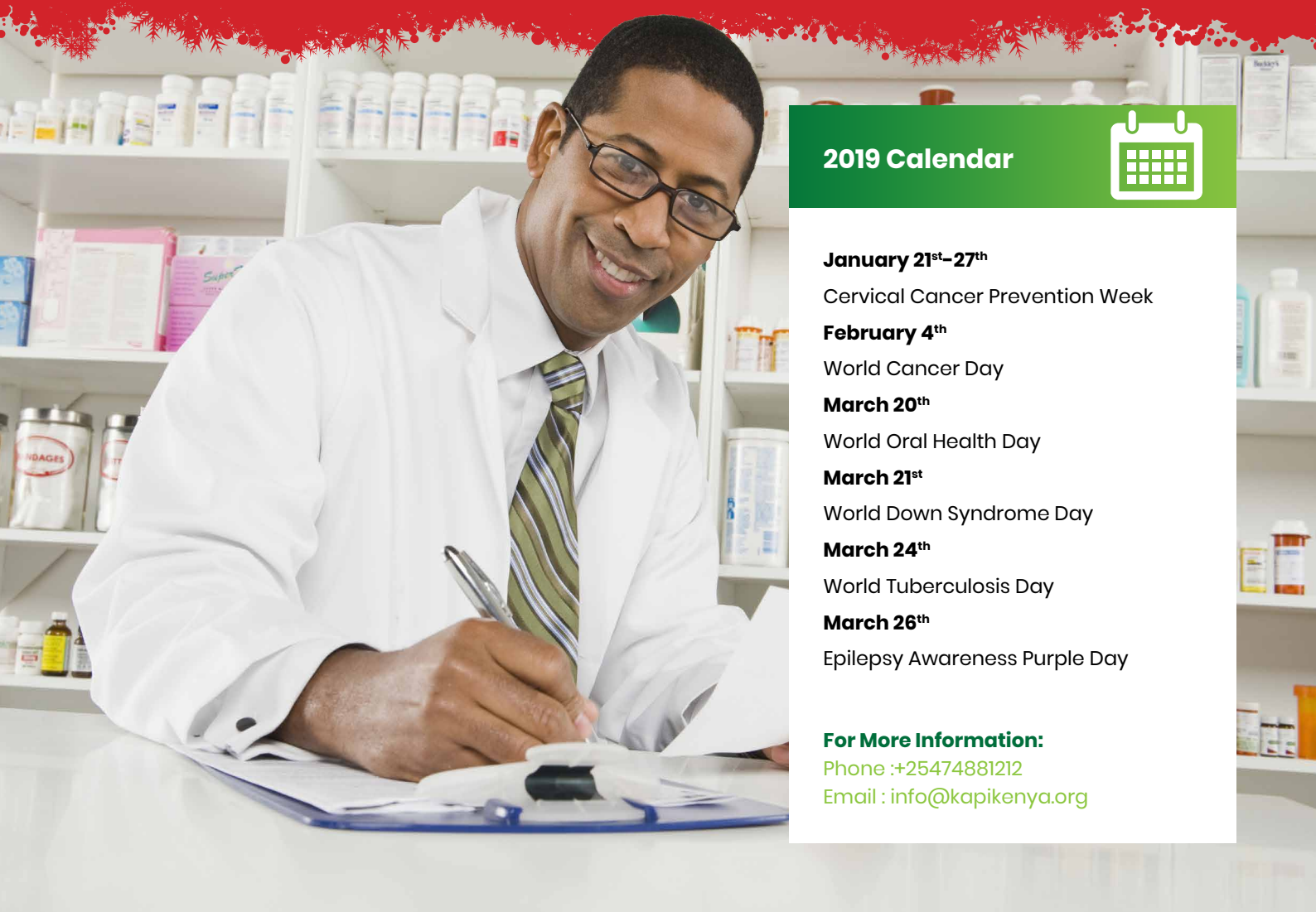


# PHARMA NEWS

A Kenya Association of Pharmaceutical Industry Newsletter



## 2019 Calendar



### January 21<sup>st</sup> - 27<sup>th</sup>

Cervical Cancer Prevention Week

### February 4<sup>th</sup>

World Cancer Day

### March 20<sup>th</sup>

World Oral Health Day

### March 21<sup>st</sup>

World Down Syndrome Day

### March 24<sup>th</sup>

World Tuberculosis Day

### March 26<sup>th</sup>

Epilepsy Awareness Purple Day

### For More Information:

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## In this issue



Horn of Africa Conference 2018



Members of compliance committee during the IFPMA Meeting



KAPI Chair Speaking during the 2018 Pharma Expo

## KAPI joins AMRH Partner Platform

Kenya's pharmaceutical umbrella body has joined the African Medicines Regulatory Harmonization partnership platform (AMRH-PP) with NEPAD & WHO as Joint Secretariat..

The move by the Kenya Association of Pharmaceuticals Industry (KAPI) sets the stage for the creation and implementation of regulations geared towards harmonization and alignment of pharma products to the WHO priorities.

Speaking when announcing this new partnership, KAPI's Chairperson Dr. Anastasia Nyalita described it as timely as the pharmaceutical industry has been dealing with cases of unregulated pharmaceuticals and the proliferation of the same.

"We are pleased to finally be members of the AMRH-PP. This partnership henceforth is one that will ensure that we deliver the much needed quality healthcare, through proper alignment and strengthening of our regulatory systems," said Dr Nyalita.

The African Medicines Regulatory Harmonization partnership platform (AMRH-PP) is the African Chapter of the WHO Coalition of Interested Parties (WHO-CIP) whose mandate is to serve African interests and priorities in the medicine regulatory space, which will in the long run improve the public health sector in Africa.

"KAPI's mission is to promote ethical, innovative and responsible healthcare industry, and through this partnership we become part of a team that is all working towards the same goal, for the consumer's benefit. Better regulations in the long run translate to not only quality products and services but also affordability of the same," Dr Nyalita added.

With Kenya's large market for pharmaceutical products, the risk of unregulated pharmaceuticals is one that could have dire effects on the consumers, both within the country and in the region at large.

It is for this reason that KAPI and other pharmaceutical industry players have been pushing the agenda of regulation, through the dispensation of quality health products and services.

This partnership of a wider scale also serves in the interest of the achievement of the government agenda for quality Universal Healthcare, which is likely to be achieved through this and many more similar collaborations by players in the same industry.

AMRH-PP hosted its second annual meeting as well as launch the AMRH Week in Kigali, Rwanda on 12th December 2018 attended by KAPI, WBG AND IFPMA among other members.

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## Horn of Africa Conference

The Horn of Africa conference in was held at the Movenpick hotel between 3rd and 5th October 2019, and hosted various professionals namely; policy makers, regulators, academics, investors, scientists and patient representatives among others.

KAPI committee representatives were Dr. James Mukoro, Dr. Darshi Shah who presented on the regulatory challenges offering clear solutions to the delays in registration and variation reviews. Dr. Mercy Njuguna, highlighted on the evolution of medical devices regulation and addressed the need for more active stakeholder engagement to ensure that the policies developed are practical and in tandem with the global standards.

In attendance was the CS who highlighted the need to streamline the pharmacy practice and enforce strict Laws that will eradicate the menace of counterfeits/substandard medicine. Additionally, with the roll out of universal health coverage she was keen on getting a solution from the industry players and Pharmacy and Poisons Board on the pharmaceutical prices which are considered highly priced for average citizens thereby limiting access to essential medicines in Kenya.

It was themed “Access to medical products in Attainment of Universal Health Coverage”, an issue that is very key to the government as it is listed among their development agenda goals they intend to meet.

The Pharma Horn of Africa’s aim is to bring together key stakeholders in an effort to enhance their co-operation on issues related to the development of the pharmaceutical sector.

Some of the key topics discussed during the three-day session were; regulatory requirements for pharmaceutical products, distribution practices and parallel importation just to name a few.

### Parallel importation highlights:

At the KCB leadership center, the pharmacy and poisons board organized a final review of the parallel imports trade rules.

Representing KAPI, Dr. Winnie Nganga - KAPI Executive Secretary, highlighted on the adverse effects of illegal imports on the consumers in the region.

“Consumers across the region are faced with the danger of consuming substandard pharmaceutical products due to the high proliferation of unregulated products in the East African region. KAPI and several other stakeholders present today including the government have been working hard to ensure that there are proper regulations in place pertaining to the parallel importation of drugs, with the goal providing affordable pharmaceutical products to all consumers”, said Dr. Ng’ang’a.



### Alexandra Spang

Alexandra Spang is the General Manager/Managing Director GlaxoSmithKline Pharmaceutical Kenya Limited.

Alexandra has gained broad experience at GSK working in Kenya, Nigeria, Mauritius, Cote D'Ivoire, Germany and the United Kingdom (at GSK House). Alexandra has held various commercial and strategic roles with increased responsibilities and has worked on both medicines and vaccines across varied markets.

Alexandra holds an MBA in Marketing and Corporate Taxation from the European Business School and an MSc in Health Economics, Policy and Management from the London School of Economics, with a special interest in value-based pricing. She is also a certified pharmaceutical representative from the German Chamber of Commerce.

Kenya being a key market for GSK in Africa, Alexandra is driving both commercial innovation as well as representing GSK with its breadth of community partnerships and Global Health programmes.



### Andrew Waititu

Andrew Waititu, CEO, GE Healthcare in East Africa, is a seasoned business leader whose vision is to identify and nurture individuals and corporates looking to deliver transformative change in emerging markets. Born and raised in Kenya, Andrew developed a keen interest in Information Technology while attending a part time course during his gap year and went on to carve out a 24-year career, spanning several geographies.

As the General Manager, Healthcare, he is responsible for the P&L of the business in greater East Africa region, ensuring the growth of the portfolio of GE offerings in a sustainable and responsible manner delivering transformative healthcare projects. Andrew also acts as the ambassador for the digital industrial strategy within the company transforming the face of healthcare delivery in the countries we operate in.

His dual passion for Africa and ICT has seen him hold several leadership roles across the continent, starting at IBM, before proceeding to Microsoft and SAP. Andrew's focus on the use of technology to drive industry and change in Africa have seen him sit on various advisory boards; A sitting board member of the American Chamber of Commerce, former Vice Chair of

the ICT sector committee of the Kenya Private Sector Alliance (KEPSA), the apex private sector body in Kenya. Andrew is further involved in growing the next crop of successful local companies as a board member of Odyssey Capital, Goodinfo Consulting, Virtual City and is the Chair of Manifest Destiny, a Kenyan private equity fund.

Andrew believes that technology based intellectual property will form a major pillar in drawing Africa into the 21st Century, breaking away from the shackles of low-value exports and extractives on the continent.

Andrew holds a Masters in Computer Science and an MBA both from the University of Liverpool.





### **Marseille Onyango**

Mr. Marseille Onyango is the Country Manager for Janssen Kenya, a Johnson and Johnson company from 1st June 01 2018.

He is responsible for the strategic direction of Johnson and Johnson in Kenya.

Prior to joining Johnson & Johnson, Marseille has held sales and marketing positions of increasing significance from 2006 within the Kenyan market in Sandoz, Astrazeneca, Glenmark and Indoco Remedies. His last role before joining Janssen was Country Group Head, East Africa at Sandoz and Head of Marketing and Promotion, East and Southern Africa for Novartis Social business. He earlier served as a regional sales manager at Astrazeneca with a record of excellence in sales and people management.

Marseille graduated in Bsc.(Hon) Major Biochemistry and Chemistry at the Egerton University and holds an MBA, Strategic Management degree from The Catholic University of Eastern Africa. His dissertation was on Effects of generic substitution of firms' pharmaceutical medicines as a competitive strategy at chemist outlets in Western Kenya in 2012.

He is a coach and mentor to many leaders in the pharmaceutical industry in Africa and a life and soft skills coach.



### **Luis Dionisio**

Luis was appointed as Managing Director of Imperial Managed Solutions, previously known as Imperial Health Science (IHS), to provide strategic direction, develop staff to perform as effective teams and develop future leaders, incorporate new service offerings and provide current and new service offerings within new industry verticals.

Luis is a commercially successful professional with more than 25 years of international experience in logistics and supply chain. He has been pivotal in the growth and acquisition of new clients as well as managing relationships with multinational clients in various sectors: Pharmaceutical, Public Health, Petrochemical, Consumer Electronics, Automotive Retail and Aftermarket, FMCG.

The ability to balance vision and strategy with operational excellence, coupled with business acumen has equipped him well in achieving peak performance in managing and growing businesses and divisions, projects, teams and individuals.

With a keen eye on information and insight derived from business trend analytics he's able to monitor and drive business performance efficiently and effectively.

Luis holds a Master of Business Administration (MBA) with Milpark Business School in South Africa and is a Fellow of the Chartered Institute of Logistics and Transport (FCILT) in the United Kingdom.

Over the past 25 years he's been involved in several international projects, leading teams of individuals from diverse sectors, designing and redesigning processes, infrastructural development, managing project timelines as well as cost and resource allocations.

Luis has a personal interest in the training and development of teams managed, developing their technical and management ability to perform at an optimal level, to ensure sustainable platforms and succession planning for future growth.



## Pharma Industry Bodies Lobby the Government to Defer Imprecise Bill

The pharmaceutical industry players can now enjoy a period of relief following the deferment of the 2018 Health Laws Amendment Bill that had been tabled in parliament by the house leader of majority, Hon Aden Duale.

This followed active engagement by key industry players such as the Pharmaceutical society of Kenya and the Kenya Association of Pharmaceutical Industry with the lawmakers, asking for the withdrawal of Chapter 244 of the bill.

Cap 244 of the Health Bill proposes presidential appointments of individuals with non-pharmacy background to lead the Pharmacy and Poisons Board, as well as group both pharmacists and pharmaceutical technicians as “pharmacy practitioners” and have them under one board.

According to the Pharma watchdogs, this move would adversely affect professionalism in the sector, and would water down the qualifications for degree and diploma holders who according to this bill would be grouped.

Another issue that arose from the bill is the need to ensure conformity to standards for the pharmaceutical products purchased by companies outside KEMSA.

The bill was also protested by pharmacy students who took to the streets to petition the house speaker to stop this bill from sailing through citing the same concerns that their qualifications would be irrelevant.

Upon the deferment of the bill, the pharma industry players await the decision following a review of petitions forwarded to the office of the house majority leader.



### KAPI Participates in the 4<sup>th</sup> Kenya Pharma Expo

The Kenya Association of Pharmaceutical Industry chairperson, Dr. Anastasia Nyalita was one of the participants in the 4th edition of the Kenya Pharma Expo 2018.

This is an international exhibition on complete pharma manufacturing focusing East African pharma markets.

The expo was successfully held at the KICC, Nairobi October 17-19, 2018 at KICC Nairobi, Kenya.





# 2019 Pharma Trends Forecast

**Top Trends 2019 include:**



**Radical Re-Organization:**

Internal change is happening fast in 2019. It's driven by a basic economic need to flex the cost structure. But more importantly, it's fueled by a new commitment to mix talent, encourage collaboration and always innovate from the perspective of the patient.



**Accelerating Evidence:**

Regulators around the world are creating policies and collaborations to test novel science and technology faster to understand the real-world impact of treatment and seamlessly learn across geographies.



**Relearning Launch:**

The need for bold launches is greater than ever; yet we enter 2019 constrained by resources and drive. As the science and economics grow more complex, teams need to prepare markets more comprehensively, redefining both metrics and regional relevance.



**Search for the Right Patients:**

Data is taking on science. Next year, the most important insight won't be how a drug works, but who it works for. Systems, media and disrupters are getting much more sophisticated in how they find, engage and support those patients with the best choices and experience just for them.



**Demand for Decision-Driving Insights:**

Pharmaceutical leaders are passionate about the opportunity to create change – and seeking the momentum to act on it. Look for new calls to more quickly create business cases, advance institutional data fluency and infuse behavioral science in everything we do.

**Rewired HCP:**

The profession of provider has radically changed as we enter 2019. Physicians find themselves working with less control, higher financial stakes and increasing mental health challenges – all in a climate with more information at their fingertips and less time than ever.



**Relieving Burden:**

The weight of the work is piling up on our most critical stakeholders. Old and new players are stepping in with strategies and services that reduce friction, complexity and inconvenience across the clinical and commercial landscape.



**Value Puzzle:**

Debates about value may be old, but innovation, politics and data have re-energized them for 2019. People, payer and advocates want to know: Is it worth it? And who should pay?



**System of One:**

Care increasingly happens where health happens: at the clinic, at home, at local pharmacies and even on the phone. In 2019, the patient experience – from everyday health to clinical trial inclusion – will be more transient, opportunistic and data-centered.



**The New Top Talent:**

Massive shifts in the expectations of customers and the reality of healthcare are driving demand for talent ready to excel in this new era. Companies are retooling, rethinking and recruiting for 2019.



**Data alone won't be enough to solve today's and tomorrow's complex problems. Data will need to be synthesized to deliver decision-driving insights and targeted solutions that deliver on the possibilities of science.**



**Alistair Macdonald** - Chief Executive Officer of Syneos Health

## Committee Highlights

- **Compliance Committee**

This year, members of the compliance committee participated in the IFPMA Africa meeting that took place in Accra Ghana in September. The meeting attracted over 100 participants from Africa and beyond.

The members; Kendi, Cheryl and William of (Sanofi, Jansen & GSK respectively) participated as trainers.

The members displayed an outstanding dedication to maintaining high industry standards and were lauded for accepting to share their broad experience with the rest of the continent.

- **Trade, Policy, Research and Regulations Committee**

Below are the highlights of the activities done in the last three months;

1. Position papers were developed on the below;
  - PPB notice on COAs from NQCL only will be accepted for drug registration.
  - TFDA notice on having registration numbers on commercial packs
  - Parallel importation trade rules
2. Presentations at the Horn of Africa conference.
3. Interventional meetings with PPB on drug registration/medical devices topics.





# *Celebrating*

## **The Late Dr William Mwatu- Immediate Former KAPI Chairman**

Dr. Mwatu boasted over 30 years' experience working the pharmaceutical and healthcare industry having started his career in the late 1980's with the Ministry of Health in Kenya as District Pharmacist, before moving on to the private sector, where he started off as a Company Pharmacist and Quality assurance manager, a position he held for 4 years before moving to Regulatory Affairs and New products development role for two years following which he moved on to the areas of Regulatory Affairs, Clinical Research and Medical affairs an area where he spent over 10 years and has extensive experience in within the East and Southern African Regions. He is the immediate former Chairperson of KAPI.



He has been an instrumental part of KAPI as he was part of the team that helped resuscitate KAPI which had been moribund for several years after its initial inception in 1978. He was part of the small think-tank offering selfless service to re-look at how to reinvent KAPI and make it relevant to the 21st Century. By the mid 2000's, KAPI was already making waves and William's input was highly evident in the successes enjoyed then. William helped to fight counterfeits and substandard medicines in a manner only an impassioned selfless leader would, and there were great successes to show for it. The borders then, were open and porous, and William worked with many government sector colleagues to seal these loopholes and bring some order and sanity to the industry.

He was also one of the actors involved in the setup and enactment of the Anti-Counterfeit Act that signified a great victory against this malignant cancer that involved sophisticated criminal networks that had Kenya and Africa as a prime target. We can only speculate on how many lives were saved because of his valiant efforts but no doubt he will get his reward in the afterlife.

William wore so many hats with a dedicated fervour and indeed served with a passion unmatched by any, opening the frontiers for drug research and pharmacovigilance or drug safety surveillance in the continent, and was part of the group that launched the Association of clinical research professionals (ACRP), launched many a career in this nascent area and made Kenya the go-to place for clinical trial research especially in tropical diseases such as Malaria.

He was also involved in reviewing and offering an industry opinion on many Regulatory guidelines and laws, helping to shape the regulatory environment in so many ways that cannot be enumerated here, lest it would fill several pages. One thing that stood out was his passion for building bridges, being a key stakeholder that led to the first ever continental Regulatory Harmonisation effort in the East Africa Community Medicine Regulatory Harmonisation bringing together 6 EAC Countries to come up with guidelines for easing the registration of drugs and common ways of working. His efforts were also felt in the continent, also effectively serving as an industry advisor and mouthpiece in the Africa Medicines Harmonisation efforts. And if you think he stopped there, then you'd be wrong.

He established key links with the global players in the industry, helping KAPI to become an IFPMA –(International federation for Pharmaceutical Manufacturers Associations) Council member and one of the key industry stakeholders in all of Africa and through him, KAPI established important contacts and working relationships with Access Accelerated, World Bank and International Finance Corporation that will no doubt yield many fruits for the benefit of patients in Kenya.

Dr. Mwatu will be remembered as the father of the industry, an advisor, a mentor to many including myself, an advocate for doing the right thing, his investment in ethical practices above all else and his commitment to making patients get medicines with the best possible quality, safety and efficacy.

*By Dr. Francis Karanja*



# The year that was



KAPI Chair launches Pharma Expo



Bayer's Global Head of Agricultural Affairs and Scientific Affairs Jesus Madrazo (second right) addresses media during a briefing to shed more light on Bayer's acquisition of Monsanto





RB's Marketing Manager, Damira Golubic demonstrated handwashing to children during this year's Global Handwashing Day



Some members of compliance committee during the IPMA Meeting

## Current Members



MacNaughton Ltd

## Local and International Affiliations / Partners

