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KAPI Newsletter

PHARMANEWS

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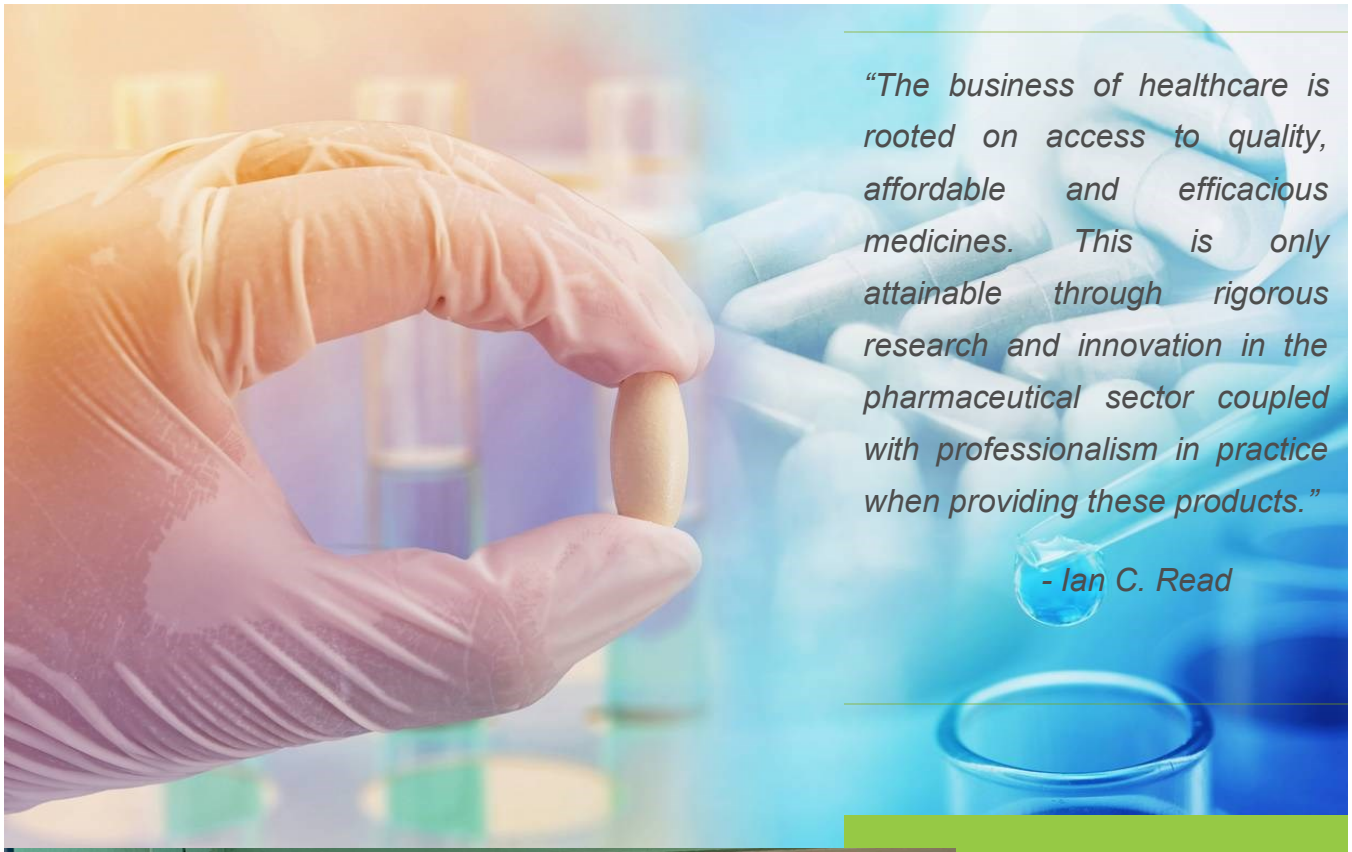

"The business of healthcare is rooted on access to quality, affordable and efficacious medicines. This is only attainable through rigorous research and innovation in the pharmaceutical sector coupled with professionalism in practice when providing these products."

- Ian C. Read

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Message from the Chair

It's been an amazing 2019 for KAPI, with roll-out of the revised KAPI Code, that is aligned with the new IFPMA Code of Pharmaceutical Practices, stakeholders' engagements, including engagements outside of the mainstream health sector players, Advocacy, Members' and CEO's Forums, enhanced collaboration with IFPMA and initiation of the formation of the East Africa Association of Pharmaceutical Industry, EAAPI, among other initiatives.

Of course, this was not without challenges especially in Regulations and Policy arena, and we continue to watch closely, the evolution and impact of the PVOC, MOH-led Pricing Policy Formulation as well the implementation of the recently gazetted Parallel Trade Rules.

Looking into 2020, we will continue our close collaboration with Pharmacy & Poisons Board, PPB, enhance as well as further broaden our stakeholder engagement and collaboration, and roll out innovative initiatives to create more value for our members and stakeholders. Critical during Q1,2020, is the finalization and implementation of our 2020-2024 Strategic plan.

It's a joy to be coming to the end of this year and a win for the much we've been able to achieve together despite the challenges.

I am grateful for the support you have accorded the KAPI Leadership Team from the Executive Committee to Sub-Committees. Without your active contribution and participation, we would not have achieved what we have and for that, I am very grateful.

As we usher the festive season, I wish you all good health, joy and peace of mind. Let's meet in 2020 for another year of great works.

Yours-In-Service,

Dr. Anastasia Nyalita.

Kenya Association of Pharmaceutical Industry (KAPI) Commitment to Patient Safety through Pharmacovigilance

The Patient remains the core focus of any pharmaceutical company and Patient Safety its prime commitment. This is because medicines are 'double-edged swords' - they are meant to do good for the patient but may also cause unnecessary harm. This commitment, in its simplest understanding, is called Pharmacovigilance (PV).

The aims of Pharmacovigilance within the industry are essentially the same as those of regulatory agencies - that is to protect patients from unnecessary harm by identifying previously unrecognized medicine concerns, elucidating predisposing factors, interpreting and identifying false safety signals from true signals and quantifying risk in relation to benefit.

At KAPI, we have a growing participation of industry-led Pharmacovigilance Champions who come together on a regular basis to discuss key local and regional PV regulations, how they enable us improve further with utmost efficiency and to discuss other relevant emerging issues in the betterment of our commitment to Patient Safety.

Some KAPI Pharmacovigilance Committee Members after a meeting

"The Patient remains the core focus of any pharmaceutical company and Patient Safety is its prime commitment.

Dr. Jayesh Pandit,
Pharmacovigilance Committee Chair

Participants pose for a picture outside the Sir Thomas More Building at Strathmore University at the end of Day 1 of the Biologics and Biosimilars Workshop

KAPI Partnered with IFPMA, Novartis Foundation & Strathmore University for an African Biotherapeutics Workshop

The Kenya Association of Pharmaceutical Industry (KAPI) in partnership with International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), Novartis Foundation and Strathmore University Centre for Research in Therapeutic Sciences (CREATES) hosted a two-day workshop on biologics and biosimilars on 28th and 29th November 2019 at The Strathmore University, Nairobi Kenya.

The workshop drew participants from regulators, industry experts, pharmacists, researchers and academicians who all converged to learn and share their experiences. The focus was on the regulatory landscape of biotherapeutics in Africa with over 20 regulators in attendance from Kenya, Ethiopia, Tanzania, Uganda, Rwanda, Ghana, Nigeria, Ivory Coast, Senegal, Zimbabwe, Namibia and Botswana.

The workshop focused on building capacity on use of biologics & biosimilars as therapeutic agents, understanding the underlying science behind their development and the regulatory concerns that influence their access and use. During the two days it was evident that participants have witnessed the huge potential biotherapeutic agents have presented in managing clinical conditions especially with the shift in epidemiological profiles. With a shift from infectious conditions, NCDs are becoming a mainstay and biotherapeutics have proven to be a suitable redress to this menace.

> *"What's needed moving forward is to find a way to optimize their use through proper research in development, monitoring during use, reporting of outcomes both positive & negative on use and collaboratively using these forums to ensure we advance together.*

This was the main call at the end of the two-day conference with a common consensus on the need to proactively look into regulations and the infrastructural capacities required to promote access to quality, safe and efficacious biotherapeutic agents for use by patients who need them.

KAPI at the 4th Scientific Conference on Medical Products Regulation in Africa

KAPI took part in the 4th Scientific Conference on Medical Products Regulation in Africa by the African Union, NEPAD Agency. WHO and UN NEPAD have made instrumental strides towards the harmonization of medicines regulation under the African Medicines Regulatory Harmonization (AMRH) program. KAPI intends to take a center stage in the next steps to augment local & international advocacy for an enabling pharmaceutical industry. AMRH presents great opportunities especially at the backdrop of *African Continental Free Trade Area (AfCFTA).*

KAPI Leaders Meeting with MEDS Managing Director Dr. Jane Masiga and her leadership team on 13th Nov. 2019

KAPI Leaders Pay MEDS Managing Director a Courtesy Call to Deliberate on Kenyan Pharma Sector

The Kenya Association of Pharmaceutical Industry (KAPI) in efforts to deliver on it's mandate to create a conducive business environment in the pharmaceutical sector paid a courtesy call to The Mission for Essential Drugs Managing Director, Dr. Jane Masiga,

This came at a time when the pharmaceutical sector is undergoing changes driven by different policy directives by the government. Of concern being the Kenya Food and Drug Authority (KFDA), Preferential Pricing for Local Manufacturers, Enriched Certificate of Conformity (COC) dubbed PVOC, and the government directive to have Kenya Medical Supply Authority (KEMSA) as the sole supplier to public facilities.

These concerns put a strain on sector players who are key for the realization of the Presidents' Big Four Agenda of Universal Health Coverage (UHC) which relies on an efficient pharma supply chain with quality, safe and efficacious medicines being made available to patients who need them. This courtesy meeting made it clear to both parties that the changes that are underway however well intentioned should be put to discussion with all stakeholders in the sector to help refine as well as develop a clear & feasible implementation plan. KAPI and MEDS resolved to collaboratively engage for the overall good of the sector and the Kenyan people we serve.

This is among several other stakeholder engagement activities KAPI through its leaderships intend to foster to build consensus for a responsive and conducive pharmaceutical industry that serves the interests of the public.

KAPI at 8th East Africa Healthcare Federation (EAHF) Conference 2019

KAPI collaborated with the Kenya Healthcare Federation (KHF) towards the 8th EAHF Conference which was held in Kenya on 5th and 6th September 2019. This is an annual conference where private health sector players convene to deliberate on ways to improve healthcare in the region. They share insights on good practices, highlight challenges and shortfalls in the sector and put forth remedies for the same.

KAPI took part in the conference as thought leaders where we had our members participate in the panel discussions i.e. Willy Soriney, a member of the Executive Committee moderated a panel on "*Innovative Models for improving Access and Affordability"* of healthcare services & products. His insights were critical as it underscored the value of R&D

companies in ensuring innovative products, services and systems are made available for the delivery of health care to patients who need these. He urged stakeholders to embrace these innovations and their producers to create synergy in the sector.

KAPI Perspective on Enriched Certificate of Conformity (COC): PVOC Guidelines

KAPI Meeting with KEBS Managing Director, Lt. Col. Rtd. Bernard Njiraini on PVOC.

The Kenya Bureau of Standards (KEBS) under the directive of the President, expanded its jurisdiction to ascertain quality in pharmaceutical products in the country through the adoption of new inspection guidelines for imports. This have been followed with back and forth deliberations by different stakeholders to establish better mechanisms of approaching the whole new provision. This is in light of the potential consequences of the directive which include delays in importation, shortage of essential medicines, increased medicine prices to the public among others.

The Kenya Association of Pharmaceutical Industry (KAPI) through the leadership took part in a consultative meeting with the KEBS Managing Director Lt. Col. (Rtd.) Bernard L. Njiraini on the 24th October 2019 at KEBS offices. This was later followed with consultative discussions among the member companies through the CEO's Championed by George Onyango (CEO, GlaxoSmithKline) to develop a position paper as an industry to this effect.

The main concerns with the PVOC rollout was the limited time available for importers, suppliers and manufacturing sites to comply, the lead times and delays by inspection agencies, additional costs and resultant stock outs. Importation of medicines also have some unique requirements that the blanket rollout of the regulations ignored.

The key items proposed by the team include;

1. Raman spectroscopy which was included in the panel of tests to be expunged as it is difficult to carry out due to the intricacies and high costs involved in testing every product in every batch.

2. Agency to adopt a waiver process to allow for exceptional importation of products with short shelf life where the importer provides a letter of undertaking and consumption data in the market. To be considered also include compassionate or emergency care and epidemic outbreak products.

3. Agency to enforce a 2-4 days inspection timelines with the inspection agencies. Close tracking and monitoring also required.

4. Agency to consider further reduction of the inspection charges being levied as it translates to final products costs.

5. Waiver mechanism for cold chain and special case products such as patient specific importation packs.

As an industry association, we are committed to ensuring availability of safe, quality and affordable medicines and medical devices through compliant, ethical and legal supply chain. We therefore support all efforts to ensure PPB guidelines are respected by all importers.

KAPI Compliance Training Day: 21st November 2019

Discussion sessions during the KAPI Compliance Training

The KAPI Compliance Committee held a Compliance Training workshop which drew over 60 participants from member companies. This workshop was organized to ingrain the values that KAPI holds pertaining ethical practice in the pharmaceutical space.

The workshop was designed to create awareness on the KAPI Code of Practice to members, contextualize the provisions of the code to real life experiences and to evoke participants to abide by the provisions. The day started with a brief overview delivered by the Chairperson of the committee, *Dr. Jack Kileba* to CEO's of member companies who were at a CEO's Breakfast Meeting to review progress made and chart a way forward on engagement with KAPI as well as the national pharmaceutical business environment.

The CEO's were enthusiastic about the code and committed to take responsibility for their teams to ensure we walk the talk. They proposed various approaches that the association can adopt to reinforce adoption of the code. The CEO's nominated, *Newton Siele, CEO Phillips Pharmaceuticals* to champion their involvement working with the committee to ensure Compliance is not just a term we put across but an integral component of our practice. It's what makes us different and unique, it's our value system.

KAPI and IFPMA Officials Pay PPB a Courtesy Visit

Kenya Association of Pharmaceutical Industry (KAPI) leadership earlier this year hosted the IFPMA Director of Biotherapeutics and Scientific Affairs, *Ms. Janis Bernat* for a courtesy meeting with the Pharmacy and Poisons Board (PPB).

This meeting was to gain insight on the regulatory framework of the board in light of the regional harmonization plans which have been under way for East African Community (EAC). The meeting centered on ongoing legislative changes in Kenya and the EAC with focus on the correlation of local and regional regulations & regulators, implementation of the EAC MRH guidelines in addition to local regulations and the existing post-market surveillance initiatives the country has in place.

This meeting set forth a course for ongoing discussions on better ways to harmonize local regulations, promote advocacy for regional regulations as per the EAC MRH. It also made it clear that there are shortfalls in the regulation of biotherapeutics in the country and Africa at large with need to action by players who include KAPI members.

Transport and Distribution Guidelines Review

The Kenya Association of Pharmaceutical Industry (KAPI) took part in a stakeholders consultative meeting to review the transport and distribution guidelines for pharmaceutical products in the country. This was in efforts to tame unethical practices as well as to establish good practices that will ensure product integrity throughout the entire supply chain.

The Association in accordance with its mandate engages in consultative forums to promote and foster compliance with standard good practices for the good of the end user of our products. The final draft is set to be launched by the Pharmacy and Poisons Board (PPB).

As an industry, it will be upon KAPI to establish mechanisms of advocating for compliance with the provisions and calling on the responsible agencies to enforce the provisions as outlined.

KAPI At Develop, Innovate and Advance (DIA) Meeting

KAPI Executive Secretary, Dr. Winnie Ng'ang'a represented the association at the Develop Innovate Advance (DIA) meeting in San Diego, USA from 23rd to 27th June 2019 where she participate d in a panel discussion on pharmaceutical supply chain. Her contribution was in line with the recommended best practices and challenges being faced in pharmaceutical supply chain in the country.

As an industry champion, she outlined some of the good models in pharma supply chain with specific focus on KAPI members who are setting standards in pharmaceutical supply chain i.e. supporting infrastructural capacity, workforce development, supply chain integrity and ultimately enforcing competencies of the end users who are either health care providers (HCPs) through Continuous Medical Education (CME) programs and patient advocacy groups through focused-group discussions (FGD).

"These are some ways we contribute to the pharmaceutical supply chain as major players. We are partners in the whole product lifecycle."

- Dr. Winnie Ng'ang'a

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Merry Christmas

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Happy New Year 2020!