REGULATORY AFFAIRS DINNER - April 2024

Theme: Regulatory Harmonization & Reliance Procedures for Health Products Security

Event Report

Background:

Access to safe, quality and effective medical products and technologies is a prerequisite to the attainment of Universal Health Coverage and Sustainable Development Goal 3: Good Health and Wellbeing. Therefore, robust, up-to-date, and coherent regulatory procedures and systems are critical elements for well-functioning health systems. The modern regulatory landscape is complex characterized by globalization of markets, complex supply chains, rapid advancements of regulatory procedures, and advanced health technologies, increasing emphasis on international cooperation in the regulation of medical products and technologies [1]. In Africa, National Medicines Regulatory Authorities (NMRAs) face numerous challenges, ranging from long registration timelines, nascent regulatory frameworks, redundancy in regulatory processes, capacity shortfalls and inefficiencies in some cases [2].

Regulatory harmonization and reliance procedures are critical in driving efficiency in the regulation of medical products and technologies in the modern regulatory landscape. To this end, interventions have been instituted with an aim of strengthening regulatory systems in Africa while also promoting efficient use of available resources towards ensuring health product security – defined as reliable access to safe, effective, quality and affordable health technologies. The African Medicines Regulatory Harmonization (AMRH) was established to promote regional integration and harmonization of regulatory procedures as well as policy alignment. The African Medicines Agency (AMA) came into force in November 2021 following ratification and depositing of treaty instruments by 15 African Union (AU) member countries [3]. AMA is designed to serve as a single credible voice on regulatory issues in Africa and to support in regulatory systems strengthening for NMRAs and Regional Economic Communities (RECs). It will also be key in controlling the influx of substandard, falsified and spurious medical products in the continent through improved vigilance functions and safety surveillance capacity. It will help to facilitate information sharing, and harmonize legislation by developing common standards and regulations.

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1. Guidance on Reliance for Regulatory Decision Making in Kenya: https://web.pharmacyboardkenya.org/download/guidance-on-reliance-for-regulatory-decision-making-in-kenya/
2. Harmonizing and Regulating Medicines in Africa: https://amrh.nepad.org/
3. The process of ratifying the treaty to establish the African Medicines Agency: perspectives of national regulatory agencies: https://academic.oup.com/heapol/advance-article/doi/10.1093/heapol/czae017/7630953

With evident delays in regulatory processes in various regulatory agencies in the continent, there is a growing need for reliance across the lifecycle of medical products and technologies regulation. Moreover, reliance seeks to optimize resource mobilization and utilization by taking into consideration the needs of regulatory systems, existing capacities, and how reliance can leverage each country's capacities to drive efficiencies. It's therefore imperative that different stakeholders have a common alignment on reliance with contextual understanding of the opportunities, challenges and required interventions to mainstream regulatory reliance in the continent towards ensuring health product security.

As an organization committed to strengthening pharmaceutical systems in Africa to guarantee reliable access to safe, effective and quality medical products and technologies for the African populace, our work focuses on:

1. **Pharmaceutical Workforce Development** where we offer professional training programs and facilitate industry peer learning & knowledge sharing engagements.
2. **Business Ecosystem Support** leveraging on internal technical capacity and industry linkages to stimulate investment & growth of Africa's pharmaceutical industry.
3. **Policy Shaping & Regulatory Systems Strengthening** through advocacy and technical support to regulatory agencies, governments and multilateral partners.

Cognizant of the inherent value of regulatory reliance and harmonization procedures in regulatory systems strengthening (RSS), we are keen on facilitating industry knowledge sharing on this procedure to improve adoption and use. On this account, we hosted a ***Regulatory Affairs Networking Dinner on April 12, 2024 at Golden Tulip Hotel Westlands – Nairobi, Kenya*** as we marked the graduation of 2024 Cohort 1 of Regulatory Affairs Trainees.

Objectives of the networking dinner were:

1. To unpack the advances in regulatory systems strengthening in the continent with a focus on regulatory reliance and harmonization processes in the continent.
2. To build a case for regulatory reliance among regulatory professionals and identify priority interventions to mainstream use of regulatory reliance.
3. To foster a health systems-approach to regulatory systems strengthening interventions with focus on health product security.

Opening Remarks

The Regulatory Affairs networking dinner commenced with welcoming remarks from Dr. Kelvin Odongo, Operations Director. He opened the ceremony by extending a gracious welcome to the delegates and expressing gratitude for their participation. He proceeded to provide everyone with the opportunity to introduce themselves, aiming to encourage networking as a mechanism of ensuring participants fostered relationships to further the aspirations of the network.

Dr. Odhiambo David gave a brief overview of African Pharmaceutical Network reflecting on the genesis of the idea of the network on the backdrop of COVID-19. He emphasized the importance of robust regulatory pathways in ensuring access to safe, quality, and effective health products. He indicated that the establishment of African Pharmaceutical Network was aimed at bringing together professionals, stakeholders and organizations working in or with an interest in the African pharmaceutical sector to collaboratively reimagine a sustainable & prosperous future for the industry in the continent.

Dr. Anthony Bernard Kodiwo – a graduate from Regulatory Affairs Cohort 1, 2024 – shared his experience during the program highlighting that having ventured into the space as a novice, he was grateful for the opportunity to put his practice to a global perspective grounded on scientific principles. He underscored the role of mentors in effectively navigating the regulatory affairs space accrediting his journey to such support. He urged graduating colleagues to actively connect with peers & mentors to further their professional journeys in the regulatory affairs space.

Guest Speakers

The Imperative for & Challenges with Regulatory Reliance & Harmonization Procedures by the Biopharmaceutical Industry – Dr. Angeline Achoka, Senior Regulatory Affairs Manager Sub Saharan Africa, AstraZeneca

Dr. Achoka introduced reliance as a process where a national regulatory authority in one jurisdiction can take into account and give significant weight to assessments performed by another national regulatory authority or trusted institution in reaching its own regulatory decision. The relying authority remains independent, responsible, and accountable regarding the decision. She outlined the adoption of risk-based approach to medicines registration, emphasizing on the utilization of work-sharing, unilateral reliance pathways, and regionalization models to enhance access to safe, quality, and effective health products. She underscored the complexity in navigating post-approval changes, a major challenge within the product management lifecycle in Africa.

She delineated the types of reliance in existence:

- Bidirectional/Horizontal reliance activities: In this pathway, regulatory bodies mutually rely on each other's assessments to make informed decisions. This is evident in various joint assessment activities, where agencies combine resources to conduct various regulatory activities.
- Unidirectional/Vertical reliance activities: In this, a regulatory authority with resource constraints leverages the expertise of a better resourced regulatory authority and trusted organization, to make informed decisions.

Underscoring the critical role of reliance in regulating health products in the modern pharmaceutical landscape characterized by limited resources, globalization, and growing public health demands, she argued that, if effectively implemented, African states and all key stakeholders stand to gain various benefits.

Dr. Angeline Achoka, Senior Regulatory Affairs Manager Sub Saharan Africa, AstraZeneca

Reflecting on various examples in her extensive experience in the regulatory affairs field, she discussed some challenges to implementation and opportunities for fostering regulatory reliance, including:

- Marketing different versions of the product in different markets
- Overly redacted inspection and assessment reports due to confidentiality laws
- Hesitancy from some assessors to use these types of pathways
- National requirements that need reassessments
- Need for agreed-upon metrics to determine if these pathways are reliable.
- Transparency on what to do when there is a safety, quality or regulatory concerns and an agency used reliance pathway in making its regulatory decisions.
- Incentives for the agency on whom another agency relies.

Dr. Achoka emphasized the pivotal role of data as the cornerstone of all reliance pathways emphasizing the importance of data in regulatory decision making as a key piece safeguarding public health.

Regulatory Reliance & Harmonization Pathways in the MD/IVD space: Opportunities & Next Frontiers – Steve Kipkoti, Senior Regulatory Affairs Manager, Medtronic

Steve Kipkoti highlighted key distinctions between the pharmaceutical and medical device industries, stressing that while both are crucial in healthcare, they diverge significantly in innovation, technology, compliance, product range, and adverse events. Medical technology share similarities with information technology in aspects such as scientific basis, innovation, intellectual property, research and development, and technology lifecycle. The regulation of a product as a medical device depends significantly on its intended use. For example, a heart rate measuring device intended for diagnosing medical conditions requires regulation while that intended for fitness and general wellness does not. Medical devices encompass a broad spectrum, ranging from simple tools like thermometers to complex robotic surgery devices.

In defining a medical device, he highlighted inclusivity of software, in-vitro reagents, implants, or appliances, noting that the scope of action may be aided by pharmacological, metabolic means, or immunological.

Steve Kipkoti, Senior Regulatory Affairs Manager, Medtronic

He discussed the steps involved in the market authorization of a new medical devices, which encompass:

- Establishing the product by identifying the intended use, indication and duration for use, and target patient population.
- Verification of the product as a medical device based on the above.
- Identifying its classification, which is a significant determinant of the regulatory pathway and level of evidence required.
- Developing valid scientific evidence such as clinical data or animal studies appropriate to the potential risk of the product.
- Preparation of pre-market submission depending on the type of device.

He underscored the importance of shared responsibility between governments and manufacturers in ensuring timely access of safe, effective, and quality medical devices. Governments are tasked with establishing and periodically revising policies and regulations to accommodate technological advancements while manufacturers must uphold quality standards during manufacturing. The regulation of medical devices is driven by factors such as an aging population, increasing chronic diseases, rapid MedTech innovation, and government initiatives to promote public well-being and reduce healthcare costs.

In Africa, the regulation of medical devices remains a challenge, with only a handful of countries having established formal regulatory processes. Most countries lack formal regulatory processes, creating opportunities to establish and develop regulatory frameworks and pathways. Within the regulatory landscape of the medical device industry, significant barriers include resource constraints, as well as the lack of political commitment. Steve Kipkoti commended the efforts of the Pharmacy and Poisons Board (PPB) in regulating medical devices, particularly noting its involvement in the Medical Device Single Audit Program (MDSAP)[4]. Through its recognition under MDSAP, the PPB can rely on audits conducted by Stringent Regulatory Authorities (SRAs) and can participate in joint audits with SRA regulators. This participation streamlines the certification process for medical technology manufacturers, enabling them to supply to SRAs more efficiently.

4. Medical Device Single Audit Program (MDSAP): https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap

The absence of common regulatory frameworks and challenges related to regulator resources impede patient access to innovative and life-saving medical devices. Kipkoti stressed the imperative to enhance government efficiency through collaborative regulatory convergence and reliance among African regulatory authorities. This entails information sharing, joint audits, and leveraging experiences to adopt international best practices, thereby reducing costs, time to market, and the risk of technical trade barriers.

He further acknowledged the absence of or limited regulations for telehealth solutions in the continent with need for multisectoral collaboration to bring these up as they were needed. In the interim he proposed the adoption of international standards and regulations as guardrails before local regulations would be in place. This he pointed to be critical to ensure that lack of regulations do not pose a risk to the public who use these technologies.

Steve Kipkoti concluded his speech by urging the delegates to be autodidactic, stressing the importance of self-learning and posing the right questions.

Dr. Juliet Konje Senior Programme Manager, Africa Partnerships & Growth U.S Pharmacopeia

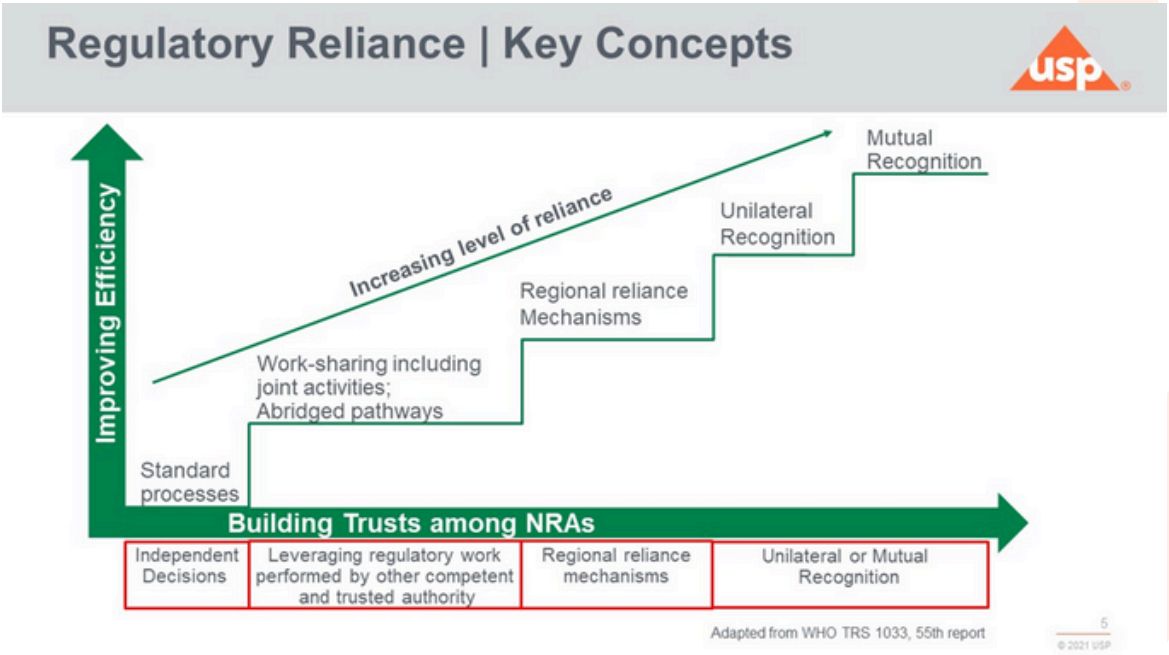
Health Product Security: Regulatory System Challenges and New Frontiers with Reliance Procedures- Dr. Juliet Konje Senior Programme Manager, Africa Partnerships & Growth U.S Pharmacopeia

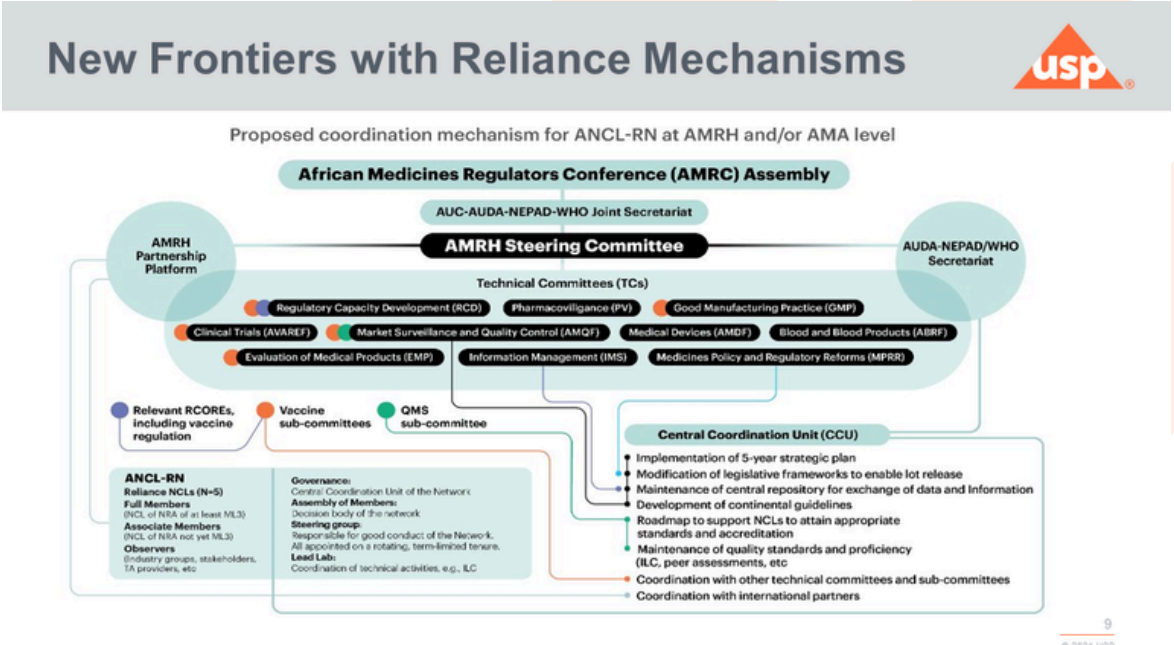
Dr. Konje commenced her speech by describing the benefits of reliance for the different stakeholders involved i.e., patients, healthcare providers, pharmaceutical manufacturers, and national regulatory authorities. Manufacturers benefit from streamlined regulatory processes, facilitating efficient management of submissions and predictable timely approvals. Patients and healthcare providers gain access to safe, effective, and quality medical products in a timely manner. National regulatory authorities are empowered to utilize resources efficiently, thereby enhancing regulatory systems.

She elaborated on the principles of reliance and stressed the importance of trust in fostering effective reliance pathways. Using the EAC-MRH pathway as an illustration, Dr. Konje highlighted the detrimental impact of mistrust on reliance pathways' efficiency.

Despite the East African Community's shared language and national anthem, the EAC-MRH initiative had not fully realized its potential due to the absence of trust among other teething challenges among member countries. When charting the path towards reliance, it's imperative to establish trust from the grassroots level. The path to reliance entails several stages, beginning with national regulatory authorities making independent decisions. This foundation extends to collaborative efforts such as work-sharing, where regulatory tasks are jointly conducted by competent authorities. Further progression involves the implementation of regional reliance mechanisms, followed by unilateral and mutual recognition agreements with stringent regulatory authorities.

She highlighted new frontiers in reliance pathways, highlighting that reliance is currently mainly focused on GMP certifications, market authorizations, and product approvals, overlooking potential benefits in other areas.





Priorities for Biopharmaceutical Industry & Regulatory Agencies' Investments to Strengthen Regulatory Reliance in Kenya & Africa: Lifecycle Approach to Regulatory Reliance – Dr. Robert Miano Superintendent Pharmacist and Qualified Person for Pharmacovigilance at Imperial Managed Solutions East Africa and Chairperson, Kenya Association of Pharmaceutical Industry (KAPI) Trade and Policy Committee

Dr. Miano kicked off his speech with an overview of WHO guidelines on good reliance practices[5] and encouraged the delegates to explore additional resources on the WHO e-learning platform. He highlighted Kenya's progress in achieving reliance, particularly through its involvement in regional harmonization initiatives like the East Africa Community Medicines Regulatory Harmonization (EAC-MRH).

Outlining initiatives undertaken by the Pharmacy and Poisons Board (PPB) to improve regulatory efficiency and reliance, he emphasized capacity building as a primary focus. These efforts include induction training for new assessors, on-the-job training, participation in assessment activities with WHO, EAC, or IGAD, and bilateral engagement with sister regulatory agencies.

Kenya employs reliance procedures for marketing authorization and emergency use authorization in various situations where:

- Product should have been evaluated and listed as a WHO Prequalified Product or Emergency Use Listed (EUL) product.
- The applicant should have granted authorization for access of assessment reports.
- Products registered by WHO listed agencies may be considered through the reliance mechanism.
- Any bilateral cooperation between Kenya and foreign governments.
- Products in which the drug substance/API used has a valid CEP or it's Prequalified by WHO.

The PPB has also adopted reliance approaches to the certification of API/FPP manufacturers and CROs/BE centers in;

- Unilateral reliance involving desk reviews for companies located in, and under the oversight of, Stringent regulatory Authorities whereby inspection reports and identified documents are reviewed under desk reviews.
- Unilateral recognition of certifications by listed/recognized NRAs/countries
- Joint inspections/Work sharing within the East African Community member states. Work sharing within IGAD member states is under establishment
- Abridged inspection

The Pharmacy and Poisons Board utilizes unilateral reliance in GMP inspections, acknowledging decisions made by other regulatory authorities or institutions to streamline its own decision-making process, particularly in emergency use authorizations. The pharmaceutical industry assumes a pivotal role in fortifying reliance by actively engaging in regulatory harmonization forums and fostering collaboration through industry associations like the Kenya Association of Pharmaceutical Industry (KAPI). They contribute to capacity building efforts by allocating resources for training programs and supporting financial needs. Additionally, they facilitate the exchange of best practices and adapt practices to suit the local context, thus contributing significantly to the enhancement of reliance mechanisms.

5. TRS 1033 - Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations: https://www.who.int/publications/m/item/annex-10-trs-1033

He urged stakeholders to actively participate in industry forums acknowledging that it is through such platforms that the industry can grow drawing on insights and perspectives from the participants. He highlighted the recently held Post Approval Changes (PAC) training that was co-hosted by KAPI and Medical Technology Industry Association of Kenya (MEDAK).

Dr. Robert Miano Superintendent Pharmacist and Qualified Person for Pharmacovigilance at Imperial Managed Solutions East Africa and Chairperson, Kenya Association of Pharmaceutical Industry (KAPI) Trade and Policy Committee

Regulatory Affairs Cohort 1, 2024 Graduating Class

Conclusion and Recommendations

The regulatory affairs networking dinner provided a valuable platform for discussing the importance of regulatory reliance and harmonization in Africa's pharmaceutical landscape as well as an avenue for industry stakeholders & professionals to network. Through insightful presentations from industry experts, it was made clear that while progress had been made in streamlining regulatory processes, there were still opportunities to optimize regulatory reliance practices and promote health product security. By overcoming concerns like mistrust, limited understanding of reliance procedures, lack of regulatory frameworks and toolkits on use of regulatory reliance and collaborative caucuses for industry and regulators the promises of reliance will be a reality. With ongoing developments to operationalize African Medicines Agency (AMA) the adoption of regulatory reliance is critical to a more streamlined, responsive regulatory environment towards ensuring reliable access to safe, effective, and quality medical products for its populace.

Recommendations:

1. **Strengthening regulatory capacity:** There is a pressing need to invest in the capacity building of national medicines regulatory authorities and pharmaceutical workforce across Africa. This includes professional capacity building programs, mentorship programs, and knowledge sharing to enhance regulatory capacity and efficiency.
2. **Advocacy for policy reform:** Continued advocacy efforts are essential to influence policy changes that promote regulatory harmonization and reliance procedures. Governments should be encouraged to prioritize the adoption of international best practices and regulatory frameworks.
3. **Promoting industry engagement:** Pharmaceutical companies play a critical role in driving regulatory reliance through active participation in regulatory harmonization forums and industry associations. Collaboration between regulatory agencies and industry stakeholders can facilitate the sharing of best practices and resources to streamline regulatory processes.
4. **Fostering trust and collaboration:** Building trust among regulatory authorities and stakeholders is paramount for the success of reliance pathways. Efforts should be made to enhance transparency, communication, and mutual recognition of regulatory decisions to foster a conducive environment for collaboration.
5. **Continuous monitoring and evaluation:** Regular monitoring and evaluation mechanisms should be established to assess the effectiveness of reliance pathways and identify areas for improvement. This includes the development of metrics to measure the reliability and efficiency of reliance pathways in facilitating timely access to safe and quality medical products. On this, there is need for research to establish the extent to which reliance is being used in the continent, their' success levels and opportunities for improvement to shape the practice dynamics.

By collaboratively working to put these recommendations into action, the future of regulatory systems in Africa and regulatory reliance as a pathway for the aspirational efficiencies will be a reality.

Regulatory Affairs Networking Dinner Participants - April 12, 2024

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