12–15 & 18 SEPTEMBER 2023
23 OCTOBER 2023

5TH AFRICA REGULATORY CONFERENCE

CONFERENCE REPORT

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Table of Contents

The 5th Africa Regulatory Conference (AfRC) was

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- The AfRC has established itself as a platform for stakeholders to share insights, experiences, and best practices in navigating the regulatory landscape in Africa, bringing together key stakeholders active in the field, including National Regulatory Authorities (NRAs) and pharmaceutical manufacturers.

- Over four days of discussions (12-15 September 2023) and two satellite sessions (18 September and 23 October), the conference featured panel discussions, keynote speeches, and interactive Q&A moments, creating a dynamic and engaging environment for knowledge exchange.

- Participants had the chance to learn from each other and explore potential collaborations to address common challenges and opportunities in the regulatory field. The conference welcomed over 600 registered participants per day.

Emphasizing the need for collaboration among stakeholders to advance regulatory science, reliance, and convergence, the AfRC aimed to contribute towards building a robust regulatory ecosystem that ensures the availability of safe, effective, and quality medicines and vaccines for the people of Africa, ultimately leading to improved health outcomes and better access to healthcare for all.

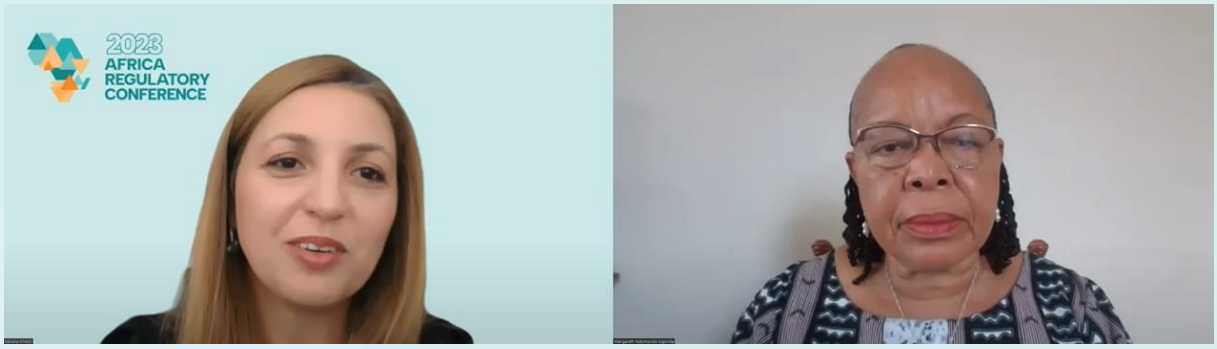
This report outlines key takeaways and recommendations from each session of the 5th Africa Regulatory Conference.

Day 1

HOW CAN THE REGULATORY ECOSYSTEM IN AFRICA BE STRENGTHENED?

Building on the notion that the regulatory landscape in Africa is changing rapidly, the first day of the conference - divided into two tracks - outlined how to register medicinal products effectively and easily at national level and how to improve the clinical trials ecosystem in Africa.

In her welcoming and opening remarks, **Margareth Ndomondo-Sigonda**, Advisor on the African Medicine Regulatory Harmonization and the African Medicines Agency (AMA) for the African Union Development Agency (AUDA-NEPAD) and the African Union, addressed the changing regulatory landscape in Africa and outlined key initiatives undergoing on the continent to improve it.



In the picture: Nevena Miletic, Regulatory Policy Head Eastern Europe, Middle East & Africa (EEMEA), Global Regulatory Policy, F. Hoffmann La Roche and Margareth Ndomondo-Sigonda, AMRH/AMA Advisor to AUDA-NEPAD & AUC

As stressed by Ndomondo-Sigonda, the COVID-19 pandemic exposed Africa's vulnerabilities in ensuring access to vital drugs, vaccines, and health technologies. This reality has called attention to the need for a **new Public Health Order** for the continent to be able to protect itself against the threat of infectious diseases and expand the manufacturing of vaccines, diagnostics, and therapeutics. The Africa Centres for Disease Control and Prevention (CDC) has been entrusted with this responsibility and has been working to promote the prevention and control of diseases in Africa through several initiatives, including:

- **The Partnership for African Vaccines Manufacturing (PAVM)** - An off-shoot of the New Public Health Order formed to strengthen the African vaccine manufacturing

ecosystem. It sets Africa on the path to locally manufacture 60% of the continent's routine immunization needs by 2040.

- **The Framework for Action (FFA)** – Prepared under the supervision of the PAVM and the Africa CDC, it puts forward the key diagnostic findings on the current vaccine manufacturing environment in Africa. It further recommends programs to unlock Africa's potential to grow and scale vaccine development and manufacturing over the next two decades.
- **The African Medicines Regulatory Harmonization (AMRH) Initiative** – Established in 2009 to address weak and/or outdated laws coupled with fragmented regulatory systems on the African continent using regional structures.
- **The African Medicines Agency (AMA)** - A proposed specialized agency of the African Union (AU) intended to facilitate the harmonization of medical regulation and therefore improve access to quality, safe, and efficacious medical products in Africa.

These initiatives – which all build on the firm foundation of the Pharmaceutical Manufacturing Plan for Africa (PMPA) – have been initiated to ensure that the African continent has the resources and capabilities to build the correct local frameworks for regulation of vaccine manufacturing. The key pillar – and ultimate aim – is therefore to streamline and harmonize regulatory processes, guidelines, procedures, and standards of practice across the continent.

Track 1 - **Navigating the maze: Simplifying the path to efficient national registration of medicinal products**

Facilitated Regulatory Pathways (FRPs) – National Regulatory Authorities (NRAs) are under mounting pressure to improve performance and facilitate timely access to safe, effective, and quality medicines as well as other health technologies. This task has become more challenging due to globalization, increasingly complex technologies, and growing public expectations. Nowadays, there are several tools available to NRAs and industry to facilitate regulatory decisions (e.g., initial approval and post approval changes), ensuring timely access to quality-assured products in countries and good regulatory-decision making. Using the concept of **collaboration, reliance, and work-sharing** between NRAs, Facilitated Regulatory Pathways such as Collaborative Registration Procedures (CRPs) and Joint Assessment Procedures (JAPs) are tools that if applied can facilitate NRAs and industry in making the best with their available resources and time, reducing duplication of efforts, workload and ultimately accelerating the assessment and registration of their products in countries in the region.

Implementing collaboration and reliance mechanisms – Today, the major challenges and weaknesses of the African regulatory system are the lack of a centralized submission and tracking system; the lack of resources; and the lack of jurisdiction power. Africa has seen developments in implementing efficient national registration pathways, ensuring accelerated assessment procedures for selected therapies. However, to further enhance regulatory reliance and strengthen the foundation of the soon to be operationalized African Medicines Agency (AMA), further simplifying the path to efficient, national registration of medical products is key. This can be achieved by streamlining the different initiatives active on the continent to bring about greater alignment and efficiency in regional operating models.

Participants and panelists were asked to identify the biggest opportunity to strengthen FRPs and CRPs in Africa:

Implementing the way forward - The AMA is an unprecedented opportunity to improve regulatory reliance, local production, and speed up access to medicines and vaccines across the continent. Clarifying the scope and responsibilities of national, regional, and continental regulatory layers and avoid duplication of work is essential to ensure medicinal products are registered effectively and easily. Regional Economic Communities should develop regional legally binding frameworks to ease the establishment of a centralized procedure to assess, approve, and register medicines. At the same time, NRAs should implement such regional provisions and guidance at the national level. Finally, the industry is committed to raising awareness and engaging for a more systematic use of CRPs and JAPs.

Track 2 - **Clinical trials and research ecosystem in Africa: Optimization for the future**

Building on the World Health Assembly (WHA) Resolution 75.8 on Strengthening clinical trials, this track explored how the Resolution is important to identify best practices, generate quality evidence, and foster international collaboration to **make Africa an attractive destination for clinical trials**.

Working toward strengthening clinical trials - The COVID-19 pandemic highlighted thousands of low-quality clinical trials. Addressing this issue, the WHA Resolution 75.8 outlines actions for Member States, national authorities, non-state actors and the WHO to enable well-designed and implemented trials globally. To support clinical trial capacity development in areas in need and facilitate addressing key barriers, some of the solutions envisioned include:

- Building a framework for improving clinical trial capabilities and infrastructure.
- Using protocol design to ensure quality of research.
- Integration of randomized controlled trials (RCTs) into healthcare delivery.
- Bridging data gaps in under-served populations.
- Clarifying roles of national and international stakeholders.
- Facilitate inter-agency and multilateral coordination.

Underlining the importance of convergence and harmonization to strengthen clinical research in Africa – Today, although Africa is 20% of the global population, only 3% of global clinical trials happen on the continent. This number has been increasing in the past years (from less than 100 in 2003 to more than 2500 in 2021) but supporting and implementing the development of clinical trial capacity is of utmost importance. This is especially true given the importance of clinical trials for both pandemic preparedness and R&D improvement. To achieve such a goal, a sound regulatory framework is critical.

Collaboration to boost clinical trial capacity – There are good examples of both private and publicly coordinated trials that were crucial in finding solutions to face the COVID-19 pandemic. Having a good view on countries' epidemiology through high quality sites and labs could potentially help boost clinical trial capacity in the future for many other diseases burdening the continent. Such an efficient infrastructure will also attract investments from the private sector and make clinical trials self-sustaining. Moreover, as local partners are critical to making programs cost-effective, partnerships with several stakeholders including governments and academics across Africa should be implemented.

Ethics and regulatory oversight – The industry and other partners have been making efforts to build clinical trials capacity in ethics and regulatory oversight through initiatives such as the Clinical Trial Community African Network, which collects regulatory and ethics information for African clinical trialists, and the WHO African Vaccine Regulatory Forum (AVAREF). AVAREF connects NRAs and ethics committees from African countries, providing regulatory and ethical advice on clinical trials' design, coordinating NRAs and ethics committees for timely and efficient reviews, and working with NRAs to achieve clinical trial oversight maturity according to the WHO benchmark.

LEARN MORE:

- **RECORDING** FROM DAY 1
- **PRESENTATIONS** FROM DAY 1

Day 2

How can regulatory collaboration help achieve a patient-centric impact?

On its second day, the AfRC explored how regulatory reliance has been implemented in Africa, and discussed challenges, lessons learned and opportunities for further advancements. During track 4, speakers described how reliance can be applied to handling of post approval changes (PACs) and outlined best practices to do so.

Track 3 - **Reaching regulatory maturity through reliance: Lessons learned on the African continent**

The importance of regulatory reliance – As the world faces growing health challenges, the importance of using all available resources to their full extent has become increasingly important. Regulatory reliance can help increase the efficient use of resources while avoiding duplication of efforts. It can also help accelerate access to safe and quality health technology and reduce inequalities that exist across countries and continents. By doing so, regulatory reliance reduces uncertainty for R&D-based pharmaceutical manufacturers and helps improve convergence in regulations across regions.

Best practices and practical implementation – The vast majority of the WHO Member States (70%) still have regulatory systems that are considered nonfunctioning according to international standards. Considerable efforts still need to be made in terms of building regulatory systems and making sure that they can oversee, control, and monitor medical products entering each country. As regards Africa, many NRAs are adopting reliance pathways and there are several examples of reliance and work-sharing already happening on the continent, including the AMRH, the AMA, and the AVAREF Technical Committee. Efficient implementation of regulatory reliance allows for the acceleration of access to safe, effective, and quality medical products, while ensuring earlier approval and access to innovation. Industry and NRAs can apply reliance as a tool to streamline the development and management of regulatory submissions and be more efficient with resources. Regular exchanges between NRAs and the industry can be valuable in capturing learning and aligning operations.

Track 4 - **Optimizing regulatory frameworks for management of post-approval changes (PACs) to benefit patients**

Benefits of post-approval changes (PACs) and regulation imperative – Changes to approved licenses are essential to maintain the continuous supply of high-quality medicines and vaccines; support continuous innovation and improvement of facilities, manufacturing methods, process controls and analytical techniques; and address unmet medical needs through accelerated product development and registration process. However, since every change made to a medicinal product that has already been licensed may impact the quality, safety, and efficacy of the product itself, this kind of regulation is one of the most important elements of regulation of vaccines by NRAs. To facilitate this process, countries are encouraged to establish national guidelines to manage PACs. Moreover, alignment with international standards is deemed crucial to drive convergence and facilitate reliance. A common regulatory understanding of risk-based approaches and risk-based classification of changes is essential for PACs management, harmonization, and convergence of regulation, as highlighted in the ICH Q12 Guidelines on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management and the WHO Guidelines on procedures and data requirements for changes.

Management challenges – PACs pose challenges to NRAs and industry because of the wide variety of regulations around the globe, the unpredictable timelines for approval that lead to duplication of efforts, delayed submissions, and unpredictable change implementation periods. Transparent communication and coordinated dialogue amongst all stakeholders, including manufacturers, is imperative for successfully managing PACs. To address the global challenges of diverse regulatory frameworks, recommendations include:

- Use of reliance mechanisms as a tool through the entire life-cycle of a medicine or vaccine.
- Converged submission requirements for PACs.
- Flexible market implementation to ensure supply continuity.
- Adoption of risk-based approaches and adherence to PAC classification and timelines.

At the same time, the responsibility of the final regulatory decision on the approval of PACs shall remain with the receiving NRAs.

Read more on the Joint Position from EFPIA, IFPMA, and Vaccines Europe on PACs management.

LEARN MORE:

- **RECORDING** FROM DAY 2
- **PRESENTATIONS** FROM DAY 2

Day 3

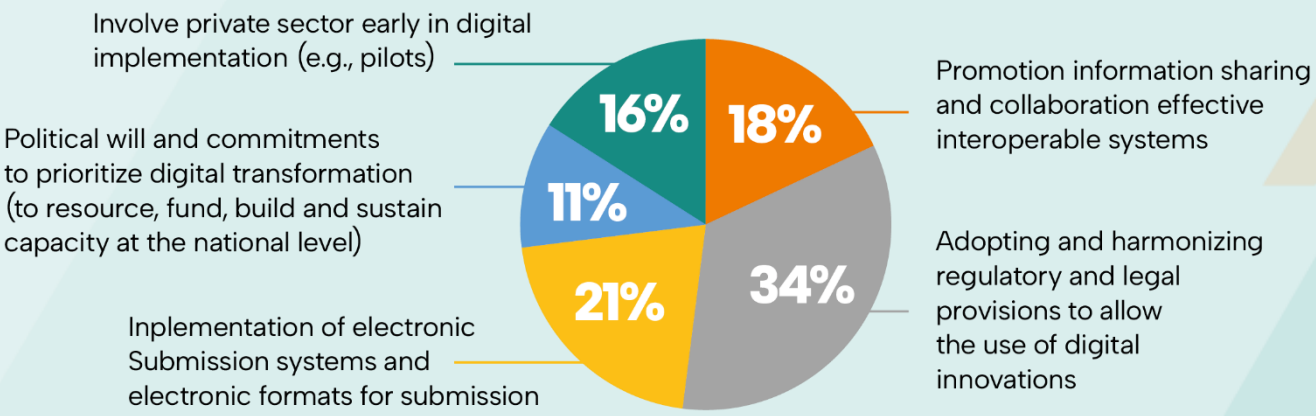
How can Africa pioneer regulatory system innovation and digitalization?

The third day of the AfRC first delved into the role of digitalization and centralized Regulatory Information Management Systems (RIMS) to streamline dossier submissions and assessments as well as to foster regulatory reliance. Track 6 particularly focused on how regulatory agilities worked during the COVID-19 pandemic and prompted discussions on the best way to implement them as standard practices to respond to future emergencies.

Track 5 – **Regulatory Digitalization: Looking at new trends for a modern Agency**

Digitalization as the backbone of work-sharing and regulatory reliance – The world is currently witnessing a paradigm shift from static, paper-based regulatory submissions toward harmonized, structured data standards, and cloud-based submissions that enable continuous data assessments and increase reliance approaches. In Africa, progress in this regard is being made on the foundational steps, including e-submissions and the electronic Common Technical Document (eCTD). Thanks to the National Regulatory Authorities and Regional Economic Communities' advancements in digital innovations and eCTD deployments, digitalization is well underway in Africa.

Participants and panelists were asked to identify their key priorities for the digitalization roadmap for the next two years:



Benefits of digitalization

- Acceleration of access to data and its assessment with higher speed and efficiency, which in turn allows optimal collaboration and faster decision-making.
- More harmonization and alignment, enabling access to historical information as well as creating connections between pharmacovigilance, submission platforms, and holistic regulatory oversight.
- More comprehensive and efficient reviews, facilitating reliance, and benefiting patient access.
- Digitalization can improve information management and allow easy access to all previously submitted information. Industry is committed to partner with agencies and stakeholders to support the African digitalization roadmap through forums and pilots.

No reinventing the wheel – Thanks to the many examples of efforts towards digitalization happening globally, Africa has a wide pool of examples on which to build its roadmap. It is necessary to broaden the best practices across the continent by actively supporting the African Medicines Regulatory Harmonization (AMRH)'s endeavors towards AMA operationalization and a successful implementation of a centralized regulatory information management system and eCTD for all African NRAs. **The AMA can indeed have a great role in connecting all stakeholders** on the continent and regulatory ecosystem layers (national, regional and continental levels) through a strong, interoperable digital health infrastructure. The agency has the potential to leapfrog the most innovative solutions, bridging disparities in access to care and helping achieve universal health coverage (UHC), making Africa one of the most efficient and modern regulatory systems in the world.

Track 6 – **Ability of regulatory systems to incorporate innovation and change**

Regulatory agilities during a crisis – The COVID-19 pandemic disrupted medicinal product development, production regulation, and distribution. As such, stakeholders were experiencing a lot of pressure to develop COVID-19 products and ensure patient access to other medicines. This reality led to NRAs and the biopharmaceutical industry employing regulatory agilities, accelerated development, and authorization of safe, effective COVID-19 vaccines and treatments.

IFPMA's research project "Medicinal product development and regulatory agilities implemented during the early phases of the COVID-19 pandemic: Experiences and implications for the future- an industry view" highlights best practices resulting from the pandemic and outlines which regulatory agilities should be integrated into standard normative processes for better pandemic preparedness. It also provides a regulatory basis to help streamline regulatory processes and reduce duplication.

Participants and panelists were asked to select the top three regulatory agilities for potential implementation during normal regulatory processes and procedures:

32%

Promote joint regional initiatives, incorporating reliance, for assessment of medicines and vaccines

25%

Institutionalize use of e-submissions and e-documents, e.g. e-CPP

13%

Implementation of virtual meetings with NRAs

13%

No samples required in support of post-approval changes

12%

Collaborative hybrid virtual inspections

5%

Remote monitoring of clinical trials

As a result, the use of reliance, digitalization, e-tools, and collaborative hybrid virtual inspections stand out as areas for implementation and growth. Regulatory agilities have the possibility to accelerate processes and, building on quality, safety, and efficacy requirements, they will benefit patients.

Lessons learned – Regional trends show that during the COVID-19 pandemic, NRAs in Africa used regulatory reliance and digital tools, such as electronic Certificate of Pharmaceutical Product (eCPP) and virtual/hybrid inspections. There was a lot of collaboration, with the WHO African Vaccine Regulatory Forum (AVAREF) and the International Coalition of Medicines Regulatory Authorities (ICMRA) playing a significant role in facilitating international collaboration and regulatory harmonization. However, there were still some challenges related to Africa's regulatory systems' fragmentation, limited digital infrastructure in some areas, and limited human resources.

Stakeholders' recommendations – Regulatory agilities implemented during the COVID-19 pandemic are useful to prepare for and respond to future health emergencies. To integrate them in normal regulatory processes and ensure a more efficient response, industry recommends:

- An increased use and institutionalization of **electronic tools**.
- **Interoperability across regulatory systems** to ensure that all countries and populations fully benefit from digital infrastructure.
- Increased **use of risk-based approaches, reliance, transparency, and responsible data-sharing** amongst National Regulatory Authorities, as well as a holistic regulatory dialogue.
- Prioritizing PACs management to allow fast manufacturing and supply.

Generic and biosimilar medicines associations recommend to African regulatory agencies to take stock of the guidelines developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). At the same time, NRAs welcome any approach, such as regulatory reliance, that would facilitate rapid applications' review and access to lifesaving tools. Together, industry and regulators can ensure a robust supply chain to deliver them.

LEARN MORE:

- **RECORDING** FROM DAY 3
- **PRESENTATION** FROM DAY 3

Day 4

Transforming the Regulatory ecosystem in Africa

The fourth day of the Conference featured a fireside chat on the importance of strong regulatory systems for patients. In addition, different stakeholders discussed the role of the New Africa Public Health Order to create a sustainable ecosystem for the biopharmaceutical industry. Stakeholders finally focused on how to join forces to successfully operationalize the AMA.

Fire side chat with patients: Why are strong regulatory systems important for patients and how are African patients engaging in regulatory activities?

During this fireside chat, patients' representatives elaborated on how patients can benefit from stronger regulatory systems and highlighted the importance of their active engagement throughout the entire life cycle. This includes regulatory and treatment development processes, which has been also emphasized in a recent report by the Council for International Organizations of Medical Sciences (CIOMS).

During the chat, it was also highlighted that:

- The entire spectrum of drug development processes requires **cooperation and coordination with patient communities** at national, regional, and global levels.
- NRAs, as well as industry, need to ensure that patients and patients' organizations are well represented in advisory committees, and provided with adequate skills, knowledge, and opportunities to meaningfully contribute to every stage of the regulatory process.
- There is an increasing need to draw on patient knowledge and experience in order to understand the day-to-day use of medicines, what it is like to live with a specific condition, and how care is administered. This input helps to improve discovery, development, and evaluation of new effective medicines.

Track 7 – **The Africa New Public Health Order: Creating a sustainable ecosystem for the biopharmaceutical industry**

This segment brought together experts from the industry, NRAs, and non-governmental organizations (NGOs), who stressed the importance of regulatory structures to promote a sustainable business environment for the biopharmaceutical industry.

A sustainable local manufacturing landscape – Pharmaceutical manufacturing in Africa is still at a nascent stage, with the continent having limited and concentrated manufacturing capacity for therapeutics and a publicly driven vaccine market. Since health product manufacturing and innovation provides a sizeable opportunity on the African continent, the Africa CDC has put forward its commitment to meet the goal of ensuring that **60% of health products required by Africa are produced locally by 2040.** This would allow the continent to achieve health security, prevent falsified and counterfeit medicines from entering the market, and ensure more equitable access to medicines. With that goal in mind, there is an urgent need to guarantee Africa's self-reliance through increasing its ability to develop, manufacture, and trade essential health products that help prevent, diagnose, alleviate, and treat local medical needs. To meet the ambitions of the continent and develop a sustainable local manufacturing landscape, several strategic priorities and drivers of the transition can be implemented, including:

- **Ensuring healthy markets** for locally produced health products.
- **Strengthening of the local R&D ecosystem** through facilitation of intellectual property (IP), technology transfer, increase of R&D capabilities and capacity.
- Establishing and sustaining long-term **public-private partnerships** (PPP), including with industry.
- Strengthening and **harmonizing regulatory activities** across the continent.
- Incubating and **scaling-up capacity and infrastructure,** including digital and technology solutions**,** of local manufacturing and supply chains in a streamlined manner.

Track 8 – **Powering up: Uniting stakeholders for a successful African Medicines Agency operationalization**

Considering the progress of the AMRH, as well as the latest developments on the operationalization of the AMA, the experts discussed the ways through which the AMA brings solutions to a variety of regulatory challenges currently faced by the continent.

Guiding principles to the successful AMA – To ensure the success of the AMA, all stakeholders must be guided by transparency and reliability. Respecting regulatory timelines and employment of information management systems is necessary to ensure equitable use of resources, capacity building, timely communication amongst stakeholders, cooperation at all levels, as well as sustainable funding mechanisms.

Participants and panelists were asked to share a key focus area that should be prioritized to ensure that the establishment and operationalization of AMA is successful.

Convergence and harmonization – The AMA is gaining momentum in actively shaping the continental regulatory ecosystem. Once fully operational, the Agency will not replace the Regional Economic Communities (RECs) and NRAs but rather **coordinate and complement** certain aspects of the continent's regulatory processes. The treaty establishing the AMA already gained 27 ratifications, and although not all African countries are officially supporting the Agency, their NRAs remain an important component of the regulatory ecosystem and must participate in regulatory harmonization and systems strengthening. **Regulatory harmonization** is imperative to align policies with global standards and ensure scientific evidence-based regulatory decision making that leads to accelerated, transparent, streamlined, and predictable review processes spanning the full product lifecycle of medicinal products.

Collective impact and benefits can be achieved only if stakeholders at all levels improve inter-agency cooperation and join forces in shaping the continental regulatory ecosystem. Further, adoption of digital and technology solutions, as well as sustainable funding mechanisms are fundamental to ensure an efficient and effective operationalization of the AMA.

LEARN MORE:

- **RECORDING** FROM DAY 4
- **PRESENTATIONS** FROM DAY 4

Satellite session

Pharmacovigilance expertise: The importance of collaboration and learning

Following World Patient Safety Day on 17 September, the first AfRC satellite session brought together experts from African regulatory bodies, NGOs, and the industry, with the aim of improving the understanding of the current landscape of collaborations in the field ***of pharmacovigilance (PV) and reliance****. This exercise built on the lessons learned from the COVID-19 pandemic and facilitated the sharing of best practices from ongoing PV activities in several African countries, such as South Africa. Experts took the floor to highlight the efforts and responsibility of all stakeholders to improve safety and elevate the voices and engagement of patients at all levels and stages of treatment development.*

The evolving medicinal products' landscape in Africa – The medical products' landscape is evolving at a remarkable speed in the African continent, with new pipelines of medicines being introduced faster and, often, with limited safety data. While major challenges in PV surveillance persist, there are initiatives targeting a continental end-to-end safety surveillance systems, such as the African Union Smart Safety Surveillance (AU-3S). Such initiatives have the potential to:

- Improve medicines and vaccine safety for patients in Africa and globally.
- Strengthen PV expertise among national and continental stakeholders.
- Enable African ownership.
- Increase confidence and trust in public health safety.

TRAININGS

- Strengthening internal capacity
  - Benefit-risk assessment
  - Signal detection skills & capabilities
  - ICSR assessment & feedback provision

ACCESS TO TOOLS

- Signal detection system
- Joint Signal Management Group
- Med Safety App
  - Promote ADR/AEFI reporting
  - Interactive – feedback
  - Language translations

COLLABORATION

- Use of big data compared to single country's data
- Opportunity to learn from others
- Strengthened existing collaboration with EPI
- Sharing of data in real-time – expedite case investigation and causality assessment

AWARENESS

- Launch of the Med Safety App
- Increased visibility on social media, TV, and radio
- Training of healthcare professionals in partnership with EPI

SPONSORSHIP

- Prioritization of pharmacovigilance activities e.g., training
- Opportunities to increase human resources

Strategies & Benefits of AU-3S initiative

What the pandemic showed and how to move forward – The COVID-19 pandemic significantly expanded the spectrum of challenges related to PV, mainly due to decreased PV reporting and resources. Moving forward, increased collaboration and harmonization lead to improved systems resilience and enable successful tracking of major public health challenges.

Good Pharmacovigilance Practices – Examples from Kenya's, Uganda's, and Ghana's NRAs demonstrated the impact of Qualified Person for Pharmacovigilance (QPPV) trainings in advancing skills of local and international pharmaceutical companies' representatives, improving effectiveness of PV reporting. As the PV regulatory requirements continue to evolve, progress and important changes for safe medication use need to be considered. Despite diversity in PV practices in the region, valuable examples of collaboration are noticeable. However, there is the need to further accelerate the implementation of Good Pharmacovigilance Practices (GPP) requirements at national levels to ensure harmonized and effective PV systems across the continent. Strengthening countries' vigilance capacity and the involvement of the pharmaceutical industry in safety monitoring and collaboration within the continent is critical for stronger and more efficient PV systems. With promising developments in safety, increased focus on operational aspects of PV management by marketing authorization holders (MAHs) and QPPV needs to be upheld. As the future of PV in Africa is rapidly evolving, promising developments in safety must be followed closely.

LEARN MORE:

- Recording from the Satellite session on pharmacovigilance expertise
- Presentations from the Satellite session on pharmacovigilance expertise

Satellite session:

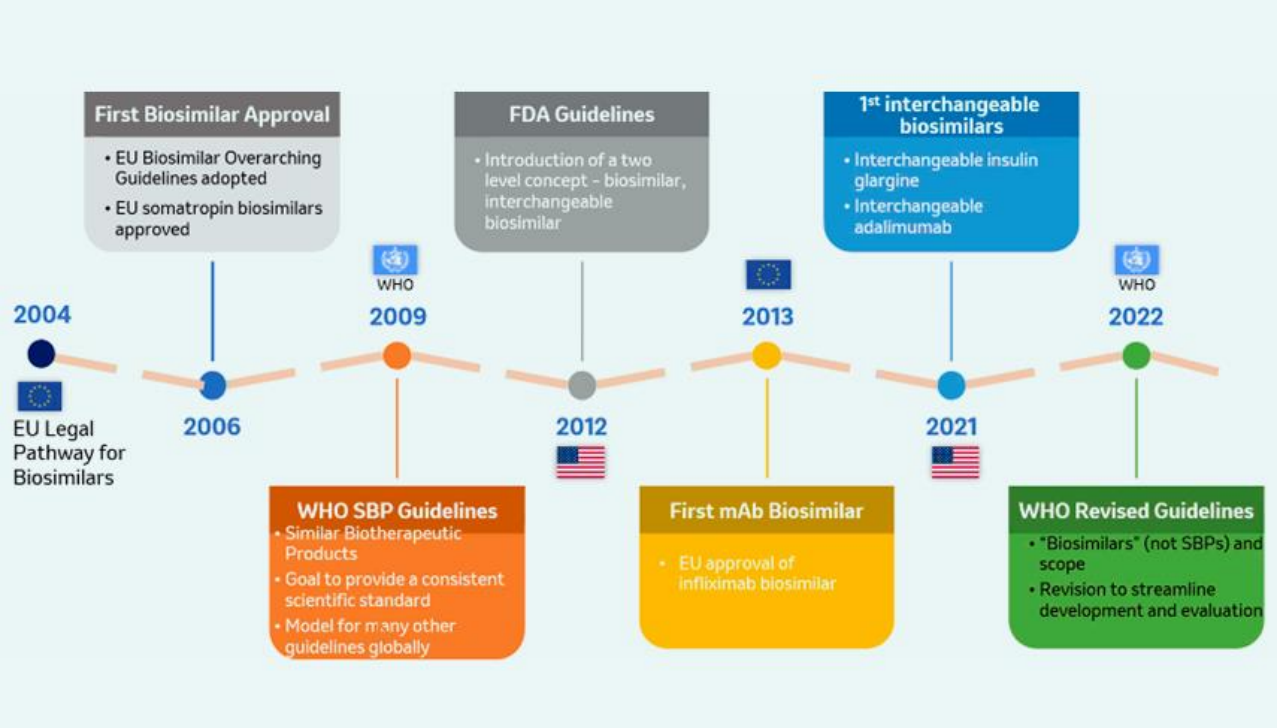
How can the regulatory landscape on biosimilars be navigated?

On 23 October 2023, the second AfRC satellite session welcomed two leading experts, representing the WHO and industry, who provided an overview of the biosimilars regulatory landscape. The session explored topics such as traceability and interchangeability, as well as the evolution of the definition of biosimilars, and highlighted the importance of precise and tailored data to allow for better decision-making and ensure patients' access to medical products and therapeutics.

Implementation of the WHO Guidelines (GLs) for Biosimilars and monoclonal antibodies (mAbs) – There has been significant progress in countries' adoption of the WHO GLs on Biosimilars, which contributed to establish a harmonized regulatory framework for biosimilars and to increase regulatory convergence at the global level. A WHO-led survey identified four leading obstacles in the guidelines' implementation, related to reference products (RP), lack of resources, inadequate quality of biosimilars, as well as biosimilars' interchangeability, naming, and labelling. As reflected in discussions from previous satellite session, the speakers accentuated the value of **pharmacovigilance** for establishing safety and efficacy of interchangeability of biosimilars, in the context of global implementation challenges.

Revision of the WHO guidelines – The 2022 GLs revision carries on several benefits, such as the guidelines' extended scope, updated term for RP, notable changes in the section on quality, as well as changes in the clinical, non-clinical, and safety sections. The revised GLs also provide more flexibility and inclusion of exemplary cases that allow countries to align with internationally recognized terminology.

Milestones in biosimilar regulatory process



Although the revision marks a substantial step forward in the regulatory landscape of biosimilars, there needs to be a clear and aligned definition that allows healthcare professionals and patients to fully understand the concept of biosimilars. The IQVIA's 2022 report on the Impact of Biosimilar Competition shows a significant maturation of the biosimilars market and increasing competition amongst biosimilars in Europe, with the number of biologic molecules with a biosimilar doubled in the past five years. However, not all regions of the world are served equally - this calls on understanding the needs of African patients, monitoring increasing market competition in Africa, as well as enhancing engagement with African biosimilar manufacturers and NRAs.

LEARN MORE:

- Recording from the Satellite session on regulatory landscape on biosimilars
- Presentations from the Satellite session on regulatory landscape on biosimilars

CONCLUSIONS

After outlining the main discussions and exchanges from the 5th African Regulatory Conference, in this section we summarize the key takeaways for each track and the satellite sessions. Please refer to the above summary, the recordings, and the presentations to learn more details about each takeaway. The list below will prove useful to track progress in the implementation of the recommendations provided during the 5th AfRC.

Track 1:

- The ongoing harmonization initiatives in Africa are the basis for further collaboration. Work-sharing and reliance led to more efficient use of resources and faster product registrations.
- The Joint Assessment Procedures (JAPs) provide several advantages, such as shorter timelines, generally predictable appointment, and assessment meetings, as well as greater flexibility to assess products.
- It is important to clarify the scope and responsibilities of the national, regional, and continental regulatory layers in the African regulatory ecosystem to avoid duplication and redundancy. Continental Technical Working Groups and Technical Committees are working to support such clarification.
- To ensure a consistent and sustainable approach, regional provisions and guidance should be appropriately implemented at the national level.
- There are several efforts undergoing in Africa to establish common procedures for variations handling, to propose sustainable financing models, as well as to set up common digital platforms for submission, collaboration, and follow-up.
- The industry is committed to continue raising awareness and advocacy for a more systematic use of JAPs and CRPs.

Track 2:

- The number of clinical trials in Africa has increased from less than 100 in 2003 to more than 2500 in 2021.
- There is a great opportunity to continue growing the clinical trial and research ecosystem in Africa, including capacity building in ethics and regulatory oversight.

- The WHO implementation of the WHA 75.8 Resolution on Strengthening clinical trials aims to address best practices for clinical trials – in terms of design and implementation - and to generate quality evidence, while improving international coordination, prioritization, and links with health policy.
- An efficient clinical trial infrastructure is fundamental in Africa for improving both pandemic preparedness and R&D capacity.

Track 3:

- Reliance is the “21st century regulatory tool” that benefits both patients and public health.
- As many African agencies are already adopting reliance pathways, regular exchange between NRAs and the industry is crucial to capture learnings and harmonize operations.

Track 4:

- Post-approval changes (PACs) pose challenges to NRAs and the industry due to wide variety of regulations around the globe, with unpredictable timelines for approval that lead to duplication of efforts, delayed submissions, and unpredictable change implementation periods.
- International standards are key to harmonization and convergence. The WHO has worked on the development of useful guidance on PACs that can be adopted by Member States and promoted implementation workshops. Aligning with the WHO’s standards will drive convergence and facilitate reliance.
- A common regulatory understanding of risk-based approaches and risk-based classification of changes is essential for PACs management, as highlighted in the ICH Q12 and WHO guidelines on procedures and data requirements for changes.
- Reliance is a tool that can be used through the entire life-cycle of a medicine or vaccine. The responsibility of the final regulatory decision on the approval of the PAC still lies with the receiving NRA.
- Transparent communication and coordinated dialogue amongst stakeholders are critical elements for success.

Track 5:

- Digitalization is well underway in Africa, thanks to the NRAs and RECs advancements in digital innovations and eCTD deployments.

- There is no need to “reinvent the wheel” to improve regulatory digitalization in Africa. It is possible to broaden the best practices across the continent by actively supporting the AMRH’s endeavors toward the eCTD and a centralized regulatory information management system through the AMA.
- A step-wise approach to the digitalization journey is key to sustainable solutions. Foundational steps are critical for the AMA to participate in the future of regulatory digital transformation.
- The AMA can leapfrog to the most modern solutions, avoiding pitfalls, outdated and siloed technologies others previously experienced.
- Industry is committed to partner on the digitalization roadmap for the continent and calls on agencies and stakeholders to work together towards this goal through forums and pilots.
- There should not be a 2-step Africa. The AMA can connect all stakeholders in the continent and regulatory ecosystem layers. A strong, interoperable digital health infrastructure has the potential to help close disparities in access to care and help countries achieve their universal health coverage goals.

Track 6:

- Initially, the primary goal of regulatory agilities was to ensure rapid access to safe and effective products to combat the pandemic. Now there is an opportunity to review and incorporate regulatory agilities within normal regulatory processes to promote innovation & advancement in regulatory systems.
- The use of reliance, digitalization, e-tools, e-documentation, and collaborative hybrid virtual inspections stand out as areas for implementation and growth.
- Regulatory agilities have the possibility to accelerate processes, yet commitments to quality, safety and efficacy must be maintained for the benefit of patients.

Track 7:

- Increased local production will assist in ensuring more equitable access to medicines in Africa.
- The drivers for developing a sustainable local manufacturing landscape include private and public sector partnerships; effective funding models; strengthening and harmonizing regulatory activities across the continent; building capacity in a streamlined manner.
- Securing the existing local supply chain routes to prevent counterfeiting are also equally critical.

Track 8:

- Cross-sectoral cooperation and collaboration is crucial for a successful operationalization of the AMA.
- The cooperation among all actors and stakeholders should be guided by the following practices: transparency and reliability, reliance, harmonization of regulatory policies, NRAs capacity building, timely communication, interagency collaboration, digital and technology solutions, and sustainable funding mechanisms.

Satellite session I:

- Considering the pace of pharmacovigilance (PV) regulatory evolution, changes for the safety of us of medicines should be considered.
- Despite diversity in approaches for PV regulation, there has been collaboration and focus on safety across countries.
- There should be a practical focus on both the operational aspects of PV management conducted by Marketing authorization holders (MAHs) as well as the role of Qualified Persons Responsible for Pharmacovigilance (QPPV) in individual countries.
- Africa' s promising developments in PV safety need to be closely followed.

Satellite session II:

- Updating the concept of biosimilarity is essential, as therapeutic technologies are constantly advancing and the regulatory landscape is evolving.
- A clear and aligned definition is needed to allow healthcare professionals and patients to fully understand the concept of biosimilars.
- Access to precise and tailored data is required to improve decision-making and ensure patients' access to medical products and therapeutics in Africa.

ADDITIONAL RESOURCES

Speakers' biographies, the recordings of each session, and related presentations are available on the AfRC website here.

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