DIA EUROPE

IFPMA

A new agency for the new era: the African Medicines Agency and the evolution of continental regulatory systems

IFPMA supported the organization of the Africa Townhall during DIA Europe 2023, a conference aiming at driving insights into action by connecting key policy discussions with real-world knowledge and accelerating growth and performance in the drug development ecosystem. Under the conference's 2023 theme 'Advancing Health Priorities', the multidisciplinary experts gathered for the discussion, highlighting the important role of the African Medicines Agency (AMA) in the evolution of regulatory systems across the African continent. Panelists shared their thoughts on several AMA-related aspects, including the future governing board of the agency, how regulatory reliance can be facilitated, and how the AMA can deliver, including through support provided from the European Medicines Agency (EMA).

This write-up summarizes the main messagesthat emerged during the discussion.

Key take-aways on what is needed for the successful operationalization of the AMA:

1. Continue **continental progress on harmonization and convergence**.
2. Implement **efficient reliance practices**, share learnings, and improve processes.
3. Ensure **transparency of regulatory processes**, their development and implementation.
4. Maintain **clarity around the roles of regulators and all other stakeholders** at the national, regional, and continental levels.
5. Prioritize **collaboration** through the establishment of platforms that promote strong collaboration, work sharing, and the avoidance of duplication.

- **Stakeholder engagement in the operationalization of the AMA is of the utmost importance.**

  All stakeholders must be part of the process. It must be facilitated not only by regulators but also by industry, who must trust the ability for the AMA to deliver, and patients, who must have confidence in the decisions of the Agency.

- **Industry is strongly in support of the AMA.**

  Its successful operationalization has the potential to strengthen regulatory systems on the continent if stakeholders provide a conducive environment for innovation and address existing inequalities.

Nevena Miletic

Regulatory Policy Head EEMEA, Roche;
IFPMA ARN Co-Chair

Ian Hudson

Senior Advisor, Integrated Development,
Bill & Melinda Gates Foundation

Christopher Oduor Okonji

Research Officer,
African Union Commission

Margareth Ndomondo-Sigonda

Head of Health Program, AUDA-NEPAD

Samvel Azatyan

Team Lead, Regulatory
Convergence and Networks, WHO

As co-moderators of the session, **Nevena Miletic** and **Ian Hudson** set the scene with a brief recap of the current regulatory landscape in Africa and introduced the session speakers.

The history of a rising medicines agency

On behalf of Professor Julio Rakotonirina, Director of Health and Humanitarian Affairs at the African Union (AU) Commission, **Christopher Oduor Okonji** briefly outlined the history of the AMA.

Due to existing regulatory challenges faced to provide access to safe, effective, and quality medicines, medical products, and technologies in Africa, Heads of States and Government came together in 2019 during the 32nd Ordinary Session of the AU Assembly to adopt the AMA Treaty. The Treaty then entered into force on 5 November 2021, after the ratification of 15 African countries. As of April 2023, 31 countries have signed the treaty. According to the panelists, the speed at which this process unrolled demonstrates the AU Member States' high political will to end the sale and consumption of falsified and substandard medical products, and therefore to improve access to quality, safe and efficacious treatments on the continent.

Christopher Oduor Okonji and **Margareth Ndomondo-Sigonda** then outlined some of the milestones the AMA has achieved so far. These include the great progress made in the African Regional Harmonization Initiative (AMRH), a building block for continental capacity building and national regulatory system strengthening, as well as the decision to locate the AMA headquarters in the Republic of Rwanda.

Enablers and deliverables to ensure a sustainable African Medicines Agency

Discussing key enablers to ensure the sustainability of the AMA, **Samvel Azatyan** echoed Margareth Ndomondo-Sigonda's remark on the fact that since the beginning of the journey to operationalize the AMA, the continent has seen strengthened regulatory capacities. Today there are five national regulatory authorities (NRAs) that have attained WHO maturity level 3 (ML3) status (Egypt, Ghana, Nigeria, Tanzania, South Africa). The importance of African countries attaining WHO ML3 status and the support by the WHO to facilitate this is of particular importance considering that very few of the countries who have signed and ratified the AMA Treaty possess strong regulatory capacity. More countries that are at WHO ML3 or higher must be part of the operationalization of the AMA for it to be a reputable, sustainable, and strong regulatory authority.

Panelists also discussed some key 2023 deliverables for the AMA. These include a Continental Reliance Framework, pilot joint inspections of biological manufacturing facilities and recommendations, a framework for identifying experts to support various technical committee actions, and the operationalization of a Reliance Laboratory Network for vaccines released on the continent.

Martin Harvey Allchurch

Head of International Affairs,
European Medicines Agency

Dr David Mukanga

Deputy Director Africa Regulatory Systems, Bill and Melinda Gates Foundation

Bunmi Femi-Oyekan

Cluster Regulatory Lead, SSA Pfizer

Dr Boitumelo Semete

CEO, South African Health Products Regulatory Authority (SAHPRA)

A blueprint to follow

Martin Harvey Allchurch discussed how the EMA will support the AMA through lessons learned from the creation of the European Agency itself. Within five years, the EMA together with the Bill & Melinda Gates Foundation (BMGF), plan to support regulatory system strengthening at the national and regional levels, as well as the actual logistical operationalization of the AMA. He also described the expected priorities to be addressed in the next five years, which include the governance of the AMA, ensuring its operationalization and sustainability, reinforcing regulatory expertise, developing a framework for working as a network, and reinforcing the scientific expertise of the Agency and African regulators. According to Harvey Allchurch, the EMA could be considered as a model rather than a template. He stressed that actions taken to operationalize the AMA must prioritize its sustainability. This means a strong focus on trust, sustainable funding, ensuring resilient human resources, taking small achievable steps, and prioritizing stakeholder engagement.

Dr David Mukanga spoke to how the BMGF is supporting AMRH activities and the AMA's establishment. The BMGF has worked very closely with the African Union, WHO Member States and other partners to support the continent in driving harmonization of processes and adopting continental International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards by supporting NRAs in optimizing their systems. Dr Mukanga noted that the BMGF is therefore committed to supporting the vision of the AU and Member States now and well into the future. Harvey Allchurch and Dr Mukanga ended by discussing their joint podcast episode, which unpacks the journey of the AMA and foresees how, through collaboration and partnership, it will reach its full potential and purpose.

Industry perspective

Addressing what is important to industry in the operationalization of the AMA, **Bunmi Femi-Oyekan** stressed that IFPMA is strongly in support of the AMA and believes that its successful operationalization has the potential to strengthen regulatory ecosystems across the continent. This will be done through a conducive environment for innovation, and by addressing existing inequalities within Africa. She also emphasized the importance of efficient access, which will be enabled through regulatory best practices around reliance, harmonization of regulatory standards, collaboration, digitalization, and information sharing. Engaging industry early in the AMA operationalization process will be key to a smooth transition.

The role of National Regulatory Agencies

Regarding the future of the Agency's regulatory assessment processes, **Dr Boitumelo Semete** emphasized how regulators must be able to enable access to safe and effective medical products in their respective countries. Dr Semete also noted that the South African Health Products Regulatory Authority (SAHPRA) is in the process of preparing a Roadmap on how countries can reach ML4 status by 2025.

Q&A

Participants asked what the registration model within the assessment process will be like and how the AMA will ensure the uptake of review decisions.

AUDA-NEPAD's Margareth Ndomondo-Sigonda noted that assessments will generate scientific advice and recommendations for involved parties. Ahead of the assessments, AMA stakeholders are also developing tools to assist companies in updating their implementation in a more efficient and centralized manner.

Addressing a question wondering how the AMA will deal with countries that have not yet ratified the Treaty, SAHPRA's Dr Semete said that despite bureaucratic processes within countries and the fact that some have not yet ratified the Treaty as of today, feedback received from NRAs show that all countries are committed to the AMA and want to see the Agency established.

Mrs Ndomondo-Sigonda added that while not all countries will be able to ratify the AMA Treaty within the next five years, the goal is that all parties can benefit regardless.

On the topic of how industry can contribute to the operationalization of the AMA, Mrs Ndomondo-Sigonda said that it comes down to the various procedures and standards that are being developed. She stressed the importance of industry committing to eventually using the AMA regulatory procedures, adding that industry will be included in consultation processes.

To wrap up, Ian Hudson and Nevena Miletic thanked all panelists for their excellent interventions and summarized the main points made by all panelists and speakers, ending with a particular emphasis on the importance of strong collaboration toward the full operationalization of the AMA.