

The **Eighth** African Medicines Regulators' Conference (AMRC VIII)

29 - 30 June 2022 | 10:00 - 13:30 SAT



Virtual meeting

“Regulatory Landscape in Africa during the AMA and Vaccines Manufacturing Era”

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Meeting Objectives

The main objective of AMRC VIII was to take stock of progress made on the African Medicines Agency (AMA) operationalization and Partnerships for African Vaccine Manufacturing (PAVM) Regulatory Workstream with a view to provide guidance to the AU Policy Organs.

The meeting agenda was focused specifically on the following:

- Updates on the operationalization of the Treaty for establishment of AMA.
- Updates on the African Medicines Regulatory Harmonization (AMRH) support to the operationalization of AMA and adoption of recommendations.
- Consideration of the White Paper on “the African Regulatory Ecosystems during the AMA Era” and adoption of recommendations for consideration by the Conference of the States Parties to the AMA Treaty (COSP).
- Updates on AMRH support to the PAVM and adoption of AMRH TC recommendations.

Workshop Chairs

Prof Moji Christianah Adeyeye, Director General-NAFDAC & Chair of the AMRH Steering Committee

Dr Oumy Kalsum Ndao, Director General-Senegal Medicines Authority & Chairs of the AMRC Assembly

Speakers

Dr Margareth Ndomondo- Sigonda - Head of Health Programme, AUDA-NEPAD

Mrs Chimwemwe Chamdimba - Principal Policy Specialist, AUDA- NEPAD

Prof Jean Baptiste Nikiema, WHO-AFRO

Mrs. Mimi Darko, Ghana FDA CEO (representing Ghana as AMA Chair of the Bureau) and the AVAREF TC Chairperson

Dr Boitumelo Semete, CEO, SAHPRA

Dr Madické Diagne, Pharmacist-Inspector, Senegal Medicines Authority

Dr Bonaventure Chilinde, AMQF Chairperson

Mr. Wayne Muller, Chairperson, GMP TC

Prof. Eliangiringa Kaale, Muhimbili University of Health Sciences, Tanzania, Representing RCD TC

Dr Niteen Wairagkar, PAVM Secretariat

Dr Jicui Dong, LPA Unit Head, WHO

Mrs Nancy Ngum, Programme Officer AUDA-NEPAD

Ms Vanessa Msengezi, Programme Officer AUDA-NEPAD

Discussions

Day 1: PROGRESS ON OPERATIONALIZATION OF THE AFRICAN MEDICINES AGENCY TREATY

Session 1: Opening Session

Prof Moji Christianah Adeyeye, DG-NAFDAC & Chair of the AMRH Steering Committee welcomed all participants to the meeting and thanked the AMRH Secretariat for organising the meeting and getting everyone involved. She gave an overview of the AMRH Governance structure and emphasised the need for human capacity development especially with the challenges faced during the COVID-19 pandemic. She applauded the progress made by member states in ratifying the AMA Treaty with 22 countries currently ratified. She updated participants on the AMRH initiative which is composed of ten technical committees including the Good Manufacturing Practice and Regulatory Capacity Development Technical Committees that have been reactivated. Prof Moji also mentioned the four national regulatory authorities (NRAs) that have attained WHO ML3 status (Tanzania Mainland, Ghana, Nigeria, and Egypt) as a major milestone in ensuring that Africans have access quality medicines.

Dr Oumy Kalsum Ndao, Director General, Senegal Medicines Authority, Ministry of Health, Senegal & Chairperson of the African Medicines Regulators Conference (AMRC) Assembly also gave opening remarks. She welcomed all representatives to the meeting and was happy to be representing the Republic of Senegal as the current Chair of the African Union (AU). She emphasized on the importance of regional initiatives on medicines regulation. She made a commitment to support the AMRH Initiative in her capacity as Chair of AMRC and further thanked the AMRH Secretariat for organising the meeting and then declared the meeting opened. Dr Ndao gave a brief background of the AMRC as follows:

- In April 2015, the African Union (AU) Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) decided to institutionalize the biennial African Medicines Regulator Conference (AMRC) as a platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision-making processes.
- In October 2017, the AMRH Steering Committee adopted a new governance structure recognising the AMRC as the Assembly and created 8 technical committee in various fields of regulatory functions and expertise.
- Thirst meeting of the AMRC was held in October 2019 to adopt the new AMRH Governance Structure including the new terms of reference for the Technical Committees.
- In November 2021 a decision was reached by the AMRC Assembly to convene an annual meeting to facilitate decision making process. The Assembly further agreed to

have a dedicated meeting to discuss the operationalization of the African Medicines Agency.

- She further reminded participants that the reason for this AMRC Assembly was to deliberate on AMA. In addition, the meeting will discuss mechanisms to be put in place by the AMRH Initiative to support the vaccines manufacturing agenda on the continent.

Prof Jean Baptiste Nikiema, of WHO-AFRO presented the specific objectives of the 8th AMRC Assembly. The main objective of AMRC was to take stock of progress reached on AMA operationalization and PAVM Regulatory Workstream with a view to provide guidance to the AU Policy Organs.

More specifically, the meeting was expected to:

- Update on the operationalization of the Treaty for AMA.
- Update on AMRH support to the operationalization of AMA and to the PAVM.
- Discuss the White Paper on “the African Regulatory Ecosystems during the AMA Era.
- Endorse AMRH TC recommendations.

The agenda of the meeting and programme of the day was then adopted.

Session 2: Updates on the African Medicines Agency (AMA)

Mrs Mimi Darko, CEO - Ghana FDA & Chair of AVAREF TC presented on The Role of Heads of NRAs in shaping the African Regulatory Ecosystem & pointed out that Heads of NRAs could learn from EU experience in building a strong AMA. She compared the work of EMA with Regional MRH projects and highlighted the similarities of the European Medicines regulatory network with MRH-RECs and AMA. She further invited NRAs to take part in regional harmonization platforms to make use of scarce resources. She proposed the need to establish an African Medicines Regulatory Network and have a formal management group.

Mrs Chimwemwe Chamdimba, AUDA-NEPAD made a presentation on AMRH support for the operationalization of AMA including coordination of Partners support. She gave updates on the status of AMA ratification and the first meeting of the CoSP. Heads of NRAs were called upon to advocate for their countries to sign and ratify the AMA Treaty. The roles and responsibilities of AU Organs and Partners in supporting AMA operationalization was highlighted and progress on partner coordination was elaborated. The workplan on AMRH support to operationalize AMA was presented with an estimated budget of \$28 239 588 for a period of 5 years. Current financial and technical partners supporting the AMRH Initiative, and the operationalisation AMA were listed including the ongoing development of proposals for funding.

Dr Margareth Ndomondo-Sigonda, AUDA-NEPAD presented the White Paper on “The African Regulatory Ecosystem during the AMA Era”. The main purpose for producing the White Paper

was to provide a clear description of the current and future regulatory ecosystem, in Africa following the establishment of the AMA so all actors understand the vision, the division of labour, and how each component of the network (i.e. AMA, TCs, AMRH, RECs, NRAs) will contribute to the regulatory ecosystem as a whole. The White Paper also serves, amongst others, to provide options for the future ecosystem including possible approaches for AMRH to provide technical support to AMA during the initial years and to stimulate debate and consideration of the optimal approach.

The Consultation process undertaken during the development of the paper commenced with discussion with the AMRH Advisory Group on AMA (AAGA) followed by five regional consultations with Heads of Agencies (SADC, EAC, IGAD, ECCAS and ECOWAS). This was followed by endorsement by the AMRH Steering Committee. It was highlighted that despite efforts to convene the Arab Maghreb Union, there was no consultation held as the union did not respond. Eleven key issues for consideration by the AMRC Assembly were also presented including modalities for AMRH and AMA as well the need for strengthened collaboration by Heads of NRA.

The presentations for the day ended with recommendations and next step presented by Ms Vanessa Msengezi.

The Chairs made the concluding remarks and thanked all Heads of NRAs and partners for the contributions to the day and closed the first day of the conference.

Day 2 – UPDATES ON PARTNERSHIP FOR AFRICA VACCINES MANUFACTURING (PAVM)

Prof Moji and Dr Ndao gave a summary of the previous day and objectives for day 2 and welcomed all to the second day of AMRC. Mrs. Nancy Ngum also presented key highlights from the discussions the previous day including the list of agreed recommendations.

Session 1: PAVM Overview

Dr Niteen Wairagkar presented updates on the PAVM role in meeting the ambitious goal set by the AU to increase vaccine manufacturing on the African continent to meet 60% of the demand by 2040. He highlighted the important milestones so far including the Framework for Action and the project management and implementation activities of the regulatory work stream which is led by AUDA-NEPAD. He also updated on key goals for the work stream in 2022 which include the establishment of harmonised guidelines and procedures for vaccines regulatory oversight, development of Reliance NRAs Network (With AMA Reliance Labs) to support the development of frontrunner NRAs through a Reliance Framework and lastly, strengthening of vaccine regulatory regional centres of regulatory excellence (RCOREs).

Dr Boitumelo Semete, CEO of SAHPRA, presented updates on the SA Health Products Regulatory Authority's COVID-19 vaccines registration process. She highlighted the key steps of vaccine assessment starting from application to traceability/surveillance. Key highlights included- SAHPRA is a member of WHO Pharmaceuticals Inspections Cooperation Scheme and other regulators can rely on the inspection outcome by SAHPRA, she highlighted that safety is monitored across all three phases of clinical trials and with regards to assessment of data, SAHPRA requires robust evidence of the vaccine's ability to prevent infection or reduce disease severity from well-conducted phase 3 clinical trials in humans. SAHPRA may also require data considering the local disease burden or disease epidemiology for example in case of COVID-19, SAHPRA required efficacy against variants of concern. For traceability, rigorous scientific evaluation of vaccines is conducted and in the case of public health emergencies, processes are fast-tracked, and minimum required standards are aligned globally. Continuous monitoring of the vaccines also takes place during the roll out

Dr Madické Diagne, Pharmacist-Inspector, Senegal Medicines Authority presented the experience of Senegal with regards to the COVID-19 vaccines registrations process. Dr Diagne gave an overview of the institutional reforms of the NRA which involved legislation review, revival of the local pharma industry and the production of vaccines. He emphasized that vaccines are medical products that need to comply with conditions of quality, efficacy and safety and their use is therefore regulated by the NRA. Dr Diagne also highlighted vaccines that are approved and in circulation including the yellow fever vaccine which is produced in-country. Vaccines also go through a rigorous marketing authorisation process like other medical products. Like SAHPRA, the Senegal NRA also makes provision for exceptional circumstances like public health emergencies. He also highlighted the assessment process for

safety, efficacy, and clinical data for a new vaccine registration through the classic and non-classic route which has a shorter time frame and can go through joint assessment procedures. Dr Diagne also highlighted some challenges to vaccine registration of vaccines such as the need for a stronger regulatory system, human resources with the needed skills, the maturity level of the NRA and limited funding, amongst others.

Sharing the WHO's Role in Strengthening Local Production Capacity of Quality Assured Vaccines to improve access was Dr Jicui Dong, LPA Unit Head at WHO. Dr Dong expressed thanks for the invitation to speak and extended congratulations to the African NRAs for the great strides being made in medical products regulation on the continent. Dr Jong shared an overview of the areas that the WHO is supporting the strengthen Africa's capacity for local production including but not limited to; prequalification and Emergency Use Listing related specialised assistance, technology transfer facilitation, global partnerships, and collaboration. All these various initiatives are in a bid to contribute to the improvement of quality of medical products, speed up attainment of WHO EUL and PQ and enable countries to be eligible to bid for international donor funded tenders.

Session 2: AMRH Technical Committees Progress in Support of the PAVM Regulatory Workstream

Mrs. Mimi Darko, CEO Ghana FDA presented AVAREF plans in support of the PAVM regulatory workstream. The AVAREF TC met with the PAVM Secretariat to identify the support that AVAREF can give to PAVM. Mrs. Darko advised that AVAREF will support training for domestication and use of AVAREF guidelines and tools. The tools include standardized templates and guides for GCP Inspection, the submission and assessment of clinical trial applications, as well as the checklist and guides for monitoring of clinical trials on the continent. AVAREF will also support clinical trial reviews, offer scientific advice. AVAREF will additionally review AU Guidance on Expedited Approval of COVID-19 Vaccines to align with AMA objectives. Guidance documents to be developed include a Guideline on Clinical Trials for Pregnant Participants, Guideline for Clinical Trials in Pediatric Participants, AVAREF Guide for Emergency Use Authorization of medical products and Reliance, AVAREF Guide for handling safety data in clinical trials. Guidelines to be reviewed include the AVAREF Joint Review Guideline and the AVAREF Strategy and Guidance on Emergency Preparedness. Mrs Darko concluded with the agreed next steps based on the above.

Mr Bonaventure Chilinde Chair of the AMQF TC, opened by highlighting the scope of the AMQF TC. Composition of the main technical committee and established sub-committees on Bioanalytical Testing and Vaccine Lot release were also presented. Dr Chilinde also highlighted the proposed activities for the sub-committee in support of Vaccines manufacturing Initiatives including lot release for locally produced vaccine, information sharing on vaccines testing and lot release and capacity building/ training. He added that identified reliance QC Laboratories for lot release testing are from NRAs with ML3 status or close to achieving ML3

in 2022. Partners support and their areas of support were also highlighted. Partners supporting the TC include PTB/ Paul Ehrlich Institute, USP-Ghana and CEPI. Proposed strategies to achieve the objectives were also highlighted.

AMQF has committed to support PAVM as shown below:

AMQF has committed to support PAVM ambitions

● Complete ● In progress		
Key priorities for PAVM from AMQF	Plan of action to support PAVM ambitions	Progress
Drive ongoing development of continental network of national control laboratories to facilitate: <ul style="list-style-type: none"> • Appropriate quality control of vaccines and biologicals through laboratory testing • Joint lot release function of vaccines through clear continental framework • Inter-laboratory capability and capacity building and support Work with and within existing structures : WHO, RECs, NRAs to drive goals	Meeting held with AMQF committee on 26 May to discuss <ul style="list-style-type: none"> • Decision made to constitute sub-committee to drive vaccine lot release • Office bearers of sub-committee confirmed • Terms of reference approved Sub-committee priorities to perform once constituted <ul style="list-style-type: none"> • Scope activities of sub-committee • <u>Confirm</u> timeline of support and activities • Identify areas where PAVM can support activities 	<div style="margin-bottom: 10px;">●</div> <div>●</div>

Mr Wayne Muller, cGMP TC Chair also presented on the support of the cGMP TC to the PAVM. The main function of the cGMP TC is to assist AU Member States to build their GMP capabilities, provide technical advice on the development and implementation of sustainable GMP Standards in collaboration with RECs, pharmaceutical industry, and partners in support of the AU PMPA and PAVM through the AMRH Initiative and eventually AMA once operational. Mr Muller also gave an overview of specific roles and responsibilities including but not limited to supporting NRAs in identifying regulatory gaps related to cGMP inspection and developing guidelines cGMP inspection including vaccines and biologics. He also indicated that GMP-TC membership includes 17 experts representing Africa’s Regional Economic Communities

cGMP-TC commitment to support PAVM ambitions was presented as follows:

GMP-TC commitment to support PAVM ambitions

● Complete ● In progress

Key priorities for PAVM from TC-cGMP

- *Create Capacity within the African Continent and within the African Context to provide technical support talent development for Vaccine Manufacturers on the African Continent*
- Develop cGMP inspection guidelines, procedures and protocols for vaccine manufacturing plants
- Facilitate regulatory harmonisation of cGMP inspection protocols within a continental framework
- Guide, develop and establish best practice from existing structures and processes as well as aligning to WHO, ICH, PICS
- Develop Knowledge Transfer Strategies that will facilitate the Inspectors Training to conduct aligned audits
- Support the AMA (African Medicines Agency) as it is operationalised
- Serve as a platform for discussion regarding cGMP
- Work with existing structures within AU, RECs and WHO
- Joint Inspection Programs and Reliance Processes

Plan of action to support PAVM ambitions

- cGMP experts from respective regional economic communities invited to attend meeting
 - Terms of reference discussed
 - Additions and revisions accepted
- Nominees received from each REC to constitute technical committee, meeting held on 23 June
 - Technical committee reconstituted
 - Office bearers nominated
 - Terms of reference confirmed
- TC membership confirmed by AMRH steering committee
- Constituted TC to hold next meeting on 19 July
 - Determine timeline of activities
 - Constitute subcommittee on vaccine cGMP

Progress



Prof. Eliangiringa Kaale of Muhimbili University of Health Sciences, Tanzania, representing RCD TC presented on the background to the TC and outlined the TC's role to provide technical advice to the AMRH Steering Committee on human resources development needs to strengthen medicines regulatory capacities and systems in Africa. Specific objectives of the TC include amongst others, to identify and prioritize the main regulatory functions that need capacity building as well the main skills required to support the regulatory functions and to recommend comprehensive training programs and other existing resources to support the capacity building of human resources. The RCD TC is also responsible for General management of RCORE platform including M&E and designation of new RCORES.

cGMP-TC commitment to support PAVM ambitions was presented as follows:

RCD-TC commitment to support PAVM ambitions

● Complete ● In progress		
Key priorities for PAVM from TC-RCD	Plan of action to support PAVM ambitions	Progress
Strengthen and support existing RCOREs	27 May AMRH, AUDA-NEPAD, WHO and PAVM planning meeting to determine criteria for membership	●
Support development of vaccine-relevant curriculum	22 June meeting held with potential TC members	●
Determine scope of a RCORE on vaccine regulatory oversight – single RCORE or RCOREs across vaccine-specific functions: GMP inspection, biologics testing and lot release etc	<ul style="list-style-type: none"> • Terms of reference discussed • Nomination criteria & composition of technical committee determined 	
Develop and disseminate EOI for RCORE for vaccine regulatory oversight	Nominations of experts to constitute TC confirmed by AMRH steering committee	●
Evaluate applications and initiate selection process	TC Meeting scheduled for 7 July	●
Assess performance of selected RCORE against agreed upon measures of success	<ul style="list-style-type: none"> • Confirm members of technical committee • Confirm terms of reference • Vote for office bearers • Determine timeline for RCORE review and designation process 	

Closing Session:

The last session of the day was a discussion of the TC presentations and the AMRC adopted the revised ToRs & plans for AVAREF, AMQF & cGMP TCs. Prof Moji and Dr Ndao gave the closing remarks and declared the meeting closed.

Summary of recommendations:

AMRC Recommendations to the AMA Board:

1. Heads of NRAs need to allocate and release their staff to participate as experts in regional and continental activities of the TCs. This is an important success factor for both RECs and AMA interventions
2. Heads of NRAs to ensure that they put in place processes and systems to facilitate timely uptake of recommendations from their RECs, AMRH TCs and from AMA to inform their own formal regulatory decisions
3. Heads of NRAs should initiate processes to update national policies and laws to allow for recognition of or reliance on AMA and REC technical standards and product recommendations as per the AU Model Law on Medical Products Regulation
4. Heads of NRAs to create a strengthened network of reliance through AMRC -learning from the EU experience to build a strong AMA

Recommendations to the Heads of NRAs:

1. Heads of NRAs need to allocate and release their staff to participate as experts in regional and continental activities of the TCs. This is an important success factor for both RECs and AMA interventions
2. Heads of NRAs to ensure that they put in place processes and systems to facilitate timely uptake of recommendations from their RECs, AMRH TCs and from AMA to inform their own formal regulatory decisions
3. Heads of NRAs should initiate processes to update national policies and laws to allow for recognition of or reliance on AMA and REC technical standards and product recommendations as per the AU Model Law on Medical Products Regulation
4. Heads of NRAs to create a strengthened network of reliance through AMRC -learning from the EU experience to build a strong AMA
5. Heads of NRAs to have a unified continental voice and communicate information widely, such as harmonised policies and strategies to inform international stakeholders on the agenda and direction of the African continent with regards to regulatory systems strengthening
6. Heads of NRAs to identify and address in-country barriers/challenges to the ratification of the AMA Treaty and intensify advocacy efforts

Recommendations to the AMRH Secretariat

1. Agenda items for AMRC meetings to be developed in a way that motivates and attracts more participation of the HoAs to ensure their optimum contribution

2. AMRH Secretariat to ensure that TC outcomes and recommendations are communicated to Heads of NRAs through quick turnaround mechanisms such as email
3. AMRH Secretariat to explore modalities for engaging AMU/UMA to ensure they are equally engaged in the AMRC
4. AMRH Secretariat to engage AUC for guidance on the costing modalities of countries which are party to the AMA Treaty



Some of the delegates who participated in AMRC VIII

Appendix 1 – List of participants

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