

**10th Meeting of the Steering Committee on Regulatory Systems
Strengthening and Harmonization Initiatives in Africa
(AMRH SC)**

Concept Note, Agenda & Program

Virtual Meeting
22 April 2022

Prepared by:
AMRH Secretariat
09 March, 2022

1. Introduction

The COVID-19 pandemic has accelerated the African Union (AU) plans to ensure sustainable supply of medical products to her people. The African continent has not been spared from supply chain challenges especially so because of its heavy reliance (>70%) on pharmaceuticals imports. It is in realization of these challenges that the AU is revitalizing its Pharmaceutical Manufacturing Plan (PMPA) Policy Framework with a view to encourage research and development and local production of the needed medical products and commodities on the continent. In addition, the AU is catalyzing vaccines manufacturing through the Partnership for African Vaccines Manufacturing (PAVM) Framework. The target of the PAVM framework is to pool the needed expertise, infrastructure, and resources to ensure that Africa produces 60% of the vaccines needed by the African population by 2040.

The role of national regulatory agencies (NRAs) in advancing the PMPA and the PAVM Frameworks cannot be overemphasized. It is in recognition of this that the African Medicines Regulatory Conference (AMRC) was adopted as 'an AU Platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision-making processes' in April 2015¹. The AMRC serves as the Assembly of the AMRH since 2017. During its 7th meeting held on 24-26 November 2021, the AMRC agreed to have annual meetings to deliberate on issues of common interest including a dedicated meeting on the establishment of the African Medicines Agency (AMA).

Following the coming into force of AMA on 05 November 2021, the AUDA-NEPAD in collaboration with the African Union Commission (AUC) convened a technical consultation meeting with partners on 03 December 2021 to discuss modalities of supporting the operationalization process. Given that the AMA Conference of the State Parties (COSP), the highest policy making organ of AMA is not yet operational, it was agreed that the existing African Medicines Regulatory Harmonization (AMRH) governance structures specifically the AMRH Partnership Platform be used as a mechanism for partners engagement. The aim is to ensure a well-coordinated partner support and a smooth AMA take off leveraging on the AMRH foundation.

The AMRH Advisory Group on AMA (AAGA) has been established to guide on operationalization of AMA. The AMRH Secretariat has been strengthened to coordinate the AMA operationalization process. A White Paper on 'African Regulatory Ecosystem in the AMA Era' and a Workplan for Partners support to operationalise the AMA have been developed by the Secretariat and subjected to stakeholders' consultations for inputs. The 10th AMRH SC meeting is being held to deliberate on progress and the way forward.

2. Proposed Agenda:

- 2.1. Opening the meeting
- 2.2. Matters arising from the 9th SC meeting
- 2.3. Updates on operationalization of the African Medicines Agency (AMA)
- 2.4. Draft White paper on 'African Regulatory Ecosystem in the AMA Era'
- 2.5. Draft Workplan on Partners support to Operationalize AMA
- 2.6. Proposed Next Steps
- 2.7. AOB
- 2.8. Closing the meeting

¹ The African Union Specialized Technical Committee on Health, Population and Drug Control (STC-HPDC) in April 2015

3. Draft Program of Work for the 10th AMRH Steering Committee Meeting
22 April, 2022
10:00 – 12:30hrs SAT

TIME	ACTIVITY	Moderator/Speaker
FRIDAY 22 APRIL 2022		
09:30-10:00	Zoom Line open for participants to log in	AMRH Secretariat
10:00-11:00	SESSION I: OPENING & RECAP ON THE 9TH AMRH SC MEETING	
	Introduction, Brief Remarks & Adoption of the Agenda --(10 minutes)	Prof Mrs Moji Christianah Adeyeye; Chairperson-AMRH SC
	Minutes of the 9 th AMRH Steering Committee meetings --(10 minutes)	Prof Mrs Moji Christianah Adeyeye; Chairperson-AMRH SC
	Matters arising from minutes of the 9 th AMRH Steering Committee meeting --(15 minutes)	Margareth Ndomondo-Sigonda, AUDA-NEPAD
	AMRH Calendar of Activities for 2022 --(15 minutes)	Vanessa Msengezi, AUDA-NEPAD
	Discussion and adoption of recommendations --(10 minutes)	ALL
11:00-12:00	SESSION II: UPDATES ON AMA OPERATIONALIZATION	
	AMA Progress --(10 minutes)	Margareth Ndomondo-Sigonda, AUDA-NEPAD
	The white paper on 'African Regulatory Ecosystem in the AMA Era' --(20 minutes)	Hudu Mogtari & Chimwemwe Chamdimba, AUDA-NEPAD
	Partners support on operationalization of AMA --(20 minutes)	Nancy Ngum & Paul Tanui, AUDA-NEPAD
	Discussion and adoption of recommendations--(30 minutes)	ALL
12:00-12:30	SESSION III: NEXT STEPS, AOB & CLOSING	
	Next steps	Vanessa Msengezi, AUDA-NEPAD
	AOB & Closing	Prof Mrs Moji Christianah Adeyeye; Chairperson-AMRH SC
END OF AMRH SC MEETING		

4. Meeting documents

- 4.1. 9th AMRH SC meeting
- 4.2. Matters arising from minutes of the 9th AMRH SC meeting
- 4.3. The draft White Paper on 'African Regulatory Ecosystem in the AMA Era'
- 4.4. The Partners Workplan for Operationalization of AMA
- 4.5. Others documents to be shared in the form of presentations during the meeting