AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

10th Steering Committee (SC) on Regulatory Systems Strengthening and Harmonization Initiatives in Africa

(AMRH SC)

Virtual Meeting held on 22 April 2022

Background and summary:	The 10th AMRH SC was held on 22nd April 2022 to deliberate on progress on the white paper on 'African Regulatory Ecosystem in the AMA Era' and a Workplan for Partners support to operationalise the African Medicines Agency (AMA) . The meeting also deliberated on updates on vaccine manufacturing in Africa and alignment of procurement and REC regulatory assessments. These discussions will feed into the AMRC Assembly, to be held on 23 to 24 May 2022.	
Participants:	AMRH Steering Committee members; Chairs of AMRH Technical Committees; Resource Persons; Partners and AMRH Joint Secretariat. The list of participants is attached as **Annex 1.**	
Meeting Presentations	Detailed meeting presentations to be shared separately	
Agenda Item No.	**Key Points, Observations & Discussion**	**Agreed Actions**
Session 1 **1.1 Introduction, Brief Remarks & Adoption of the Agenda** **1.2 Minutes of the 9th AMRH Steering Committee meetings** **1.3 Matters arising from minutes of the 9th AMRH Steering Committee meeting** **1.4 AMRH Calendar of Activities for 2022**	1. Prof Mojisola Adeyeye, Chair of the AMRH SC welcomed all members of the SC to the 10th AMRH SC Meeting. The agenda of the 10th AMRH SC was adopted by members of the SC. Prof Moji then gave brief remarks which included the need for accelerated vaccine manufacturing on the continent. She emphasized the need for Heads of National Regulatory Authorities (NRAs) to play a role in advancing the Pharmaceutical Manufacturing Plan for Africa (PMPA) and Partnerships for African Vaccine Manufacturing (PAVM) in build up to the operationalization of the AMA as a strong regulator will mean a strong AMA. Prof Moji also emphasized the key roles of the African Medicines Regulators Conference (AMRC) and the AMRH Steering committee to provide a strategic and technical oversight on regulatory systems strengthening and harmonization efforts on the continent. 2. Dr Margareth Ndomondo-Sigonda presented on matters arising from the 9th AMRH SC which included: ○ Updates on implementation of RECs MRH Projects	Updates on matters arising for the 9th AMRC SC meeting were endorsed with the following additions: ➢ Additional TCs to be included for AMA support – IMS and AMDF ➢ A new RCORE on regulatory digitalization was proposed and agreed upon for the Secretariat to work on ➢ IMS and RCD TCs to consider designation of an RCORE on digitalisation of NRAs processes

	○ Updates on AMRH TCs which will be prioritised to support the implementation of AMA ○ Updates on regional centres of regulatory excellence (RCOREs) and their role in support of PAVM including the need for their expansion. A summary of the 2019-2022 RCORE evaluation report was also presented. ○ Updates on the 5th Scientific Conference on Medical Products Regulation in Africa (SCoMRA V) & the 7th AMRC were also given including the endorsement of the annual AMRC meetings. ○ Updates on WHO Global Coalition of Interested Partners (CIP) and the alignment with the AMRH Partnership Platform as the Africa Chapter was also provided. ○ Progress on alignment of regional joint assessments, procurement and local production initiatives was presented as separate agenda item. 3. Mrs. Vanessa Msengezi presented the AMRH calendar of activities including their funding sources as provided in **Annex II**. The calendar is to be updated as new activities may be recommended.	➢ AMRH SC meeting summary and updates to be disseminated on the website ➢ The full AMRH website/portal expected to go-live by 31 July ➢ AUDA-NEPAD to share the full RCORE evaluation report of 2019-2020 ➢ The calendar of activities was endorsed by the SC.
Session 2: **2.1 African Vaccine Manufacturing – mRNA Tech Transfer Experience & Progress-South Africa Case Studies** **2.2 Vaccines Regulatory Oversight: Experience from the Egyptian NRA**	1. Prof Petro Terblanche, MD of Afrigen Biologics and Vaccines presented on mRNA Technology Transfer & Training Hub-A public/private partnership consortium to advance mRNA vaccine development and manufacturing for LMICs. The initiative underscores the need for equity in access to COVID-19 vaccines which will be achieved through strong partnerships. Prof Terblanche also highlighted the key regulatory activities of the hub and spokes, including planned deliverables and various key partners and stakeholders in the process. 2. Dr Dalia Abdouhussein gave an overview of the Egyptian NRA experience in vaccine regulation. The EDA has been recognised by WHO as an ML3 vaccine producing country. Dr Dalia presented plans underway for local vaccine manufacturing and international certifications that are being pursued by the authority.	➢ PAVM and AMRH Secretariats to ensure the AVAREF, GMP, AMQF and RCD TC provide the needed support on vaccines regulatory oversight. ➢ Expand role of RCOREs to include vaccine regulatory oversight as part of support to PAVM Framework ➢ Establish a continental platform for continuous interaction between manufacturers and regulators

2.3 Progress in the implementation of PAVM regulatory workstream	3. Dr Niteen Wairagkar presented updates on the ambitious goal that has been set by the AU to increase vaccine manufacturing on the African continent to meet 60% of the demand by 2040 and the role of PAVM in this. He gave updates on the taskforce structure of the regulatory workstream as well as updates on the bold program of the PAVM. He emphasized the need for strengthening the AVAREF, GMP, AMQF and RCD TC to support vaccines regulatory oversight.	and document best practice (lessons from Afrigen and SAHPRA interaction)
Session 3: **3.1 Updates on Workplan and Partners Coordination in support of operationalization of the African Medicines Agency (AMA)** **3.2 Draft White paper on 'African Regulatory Ecosystem in the AMA Era'**	Mrs. Chimwemwe Chamdimba presented the updates on the workplan to support AMA operationalization including coordination mechanism. The role of the AMRH Advisory Group on AMA (AAGA) and the Secretariat in support of AMA operationalization was highlighted. Plan to conduct the partner mapping exercise was emphasized and the need for the Secretariat to provide monthly updates to partners. She also presented the key changes made to the white paper on 'African Regulatory Ecosystem in the AMA Era' after REC consultations with IGAD, SADC, ECOWAS and ECCAS. The changes were approved for further presentation to the AMRC.	➢ The SC provisionally approved the White Paper-recommendations for submission to the AMRC Assembly, pending consultations with RECs that have not provided inputs i.e. EAC and AMU. ➢ The SC further approved the AMA Operationalisation work plan for partners support. ➢ The WHO-HQ representation on AAGA to read – Samvel Azatyan or Abraham Kahsay
Session 4: Progress on alignment of regional assessments and procurement	➢ Mrs. Rachelle Harris presented on procurement levers for improved access to quality assured medical products based on a study of 21 countries to explore ways to support and enhance procurement decisions on quality assured medicines. Key findings and recommendations were also highlighted including a request for an interim technical committee (or working party) to support the processes needed to improve the procurement of quality assured medicines.	➢ SC endorsed the establishment of an ad-hoc technical committee on procurement. ➢ The ad-hoc TC to review use or replace the terminology-prequalification to avoid confusion with the same when

	➢ An Ad-hoc TC was proposed to provide technical guidance on the process. A combination of regulatory and procurement experts was proposed to support development of policy framework, harmonized guidance, development of the database design and the design of REC certificates to validate suppliers.	used under the WHO prequalification program
Session 5: Proposed Next Steps, AOB, Closing the meeting	Mrs Vanessa Msengezi presented the proposed next steps as indicated in Annex III. Prof Moji thanked members of the SC, resource persons, partners and AMRH Joint Secretariat for their participation and contributions. She closed the meeting at 13:48	

ANNEX I: LIST ON PARTICIPANTS

S/N	Name & Organization	Position/Status
	Members of SC	
1.	Prof. Moji Christianah Adeyeye; Director General, NAFDAC, Email: cm.adeyeye@nafdac.gov.ng	Chairperson of AMRH Steering Committee; ECOWAS NMRA
2.	Mrs. Sakhile Dube Mwedzi; SADC MRH Project Implementing Agency; Email: sakhi.vee@gmail.com	REC Secretariat
3.	Dr Fatuma Adan and Dr Anthony Martin Toroitich, IGAD Secretariat; Email: Fatuma.Adan@igad.int	REC Secretariat
4.	Ms Jane Mashingia, EAC Secretariat, mashingiaj@eachq.org	REC Secretariat
5.	Mrs. Heran Gerba Borta, DG, Ethiopian Drug Authority, hgerba@efda.gov.et	IGAD NMRA
6.	Dr David Mukanga; Senior Programme Officer – Regulatory Affairs, Africa Systems, Bill & Melinda Gates Foundation (BMGF); David.Mukanga@gatesfoundation.org	Chairperson, AMRH Partnership Platform
7.	Dr Bonaventure Chilinde, Director, NDQCL, Zambia Medicines Regulatory Authority, bchilinde@zamra.co.zm	Chairperson, AMQF
8.	Mr Akinyemi Abayomi Tosin; NAFDAC; abayomiakinyemi@yahoo.com	Chairperson, IMS-TC
9.	Dr Paulyne Wairimu, Pharmacy Board Kenya, pwairimu@pharmacyboardkenya.org	Chairperson, AMDF TC
10.	Mr Adam Fimbo, DG, Tanzania Medicines and Medical Devices Authority, TMDA, adamfimbo@gmail.com	Eastern Africa NMRA
11.	Prof Bouchra Meddah, Morocco NMRA, bouchra_meddah@yahoo.fr	Northern Africa NMRA
12.	Dr Dalia Abdouhussein, Egyptian Drug Authority	Northern Africa NMRA
13.	Dr Boitumelo Semete-Makokotlela, CEO, SAHPRA, Boitumelo.Semete@sahpra.org.za / Dr Christelna Reynecke, COO, SAHPRA, christelna.reynecke@sahpra.org.za	Southern Africa NMRA

14.	Mr. Richard Rukwata, Ag. DG, Medicines Control Authority of Zimbabwe (MCAZ), rrukwata@mcaz.co.zw	Southern Africa NMRA
	AMRH Joint Secretariat	
15.	Dr Samvel Azatyan; WHO HQ, Email: azatyans@who.int	
16.	Prof Dicky Akanmori, WHO-AFRO, akanmorib@who.int	
17.	Mr. Abraham Gebregiorgis Kahsay; WHO HQ; Email: gebregiorgisa@who.int	
18.	Dr Margareth Ndomondo-Sigonda; Head, Health Unit; AUDA-NEPAD; Email: margarets@nepad.org	
19.	Mrs. Chimwemwe Chamdimba; Principal Programme Officer; AUDA-NEPAD; Email: Chimwemwe.chamdimba@nepad.org	
20.	Dr Janet Byaruhanga; Senior Public Health Officer; AUDA-NEPAD; Email: janetb@nepad.org	
21.	Mr. Paul Tanui; Senior Programme Officer; AUDA-NEPAD; Email: paulk@nepad.org	
22.	Mr. Jean Fidele Bationo, Senior Programme Officer; AUDA-NEPAD	
23.	Mrs Vanessa Msengezi; Project Management and Advocacy Officer; AUDA-NEPAD; Email: vanessam@nepad.org	
24.	Mr. Anthony Kapeta; Legal Officer, AUDA-NEPAD; Email: akapeta@nepad.org	
25.	Victoria Prudence Nambasa, AUDA-NEPAD; Email: victorian@nepad.org	
26.	Ms Nthabiseng Moiloa, Programme Officer, AUDA-NEPAD; Email: nthabisengm@nepad.org	
27.	Ms Mercedes Leburu; Programme Officer, AU-3S, Email: mleburu@nepad.org	
	AMRH Partners and Resource Persons	
28.	Prof Petro Terblanche, MD Afrigen Biologics Ltd, SA	
29.	Dr Niteen Wairagkar, PAVM Secretariat	
30.	Suhail Dada, PAVM Secretariat	
31.	Rachelle Harris, BMGF	
32.	Chantelle Genovezos, Hyphagroup	
33.	Freda Kissi, USP	
34.	Christelna Reynecke	
35.	Imane Haouach	

ANNEX II: AMRH CALENDAR OF ACTIVITIES, 2022

MEETING	DATES	VENUE	FUNDING SOURCE
AMRC Assembly Meeting	23-24 May	Virtual	BMGF
Technical Consultation Meeting of the AMA Governing Board and COSP	30-31 May 2022	Virtual	AUC
Regional sensitization and consultative workshops for NRAs to address challenges on use of AU Guidance on expedited COVID-19 vaccine approvals	May and September	Virtual	GIZ
Joint Action Group Meeting	May	Virtual	BMGF
AMRH Partnership Platform	2 June	Virtual	BMGF
Ghana-FDA and UG SPH RCOREs annual Fellowship Programme on Clinical Trials regulation	June (TBC)	Physical-Accra	GIZ
Regional sensitization and consultative workshops with African regulators, RECs and other stakeholders by identified experts on AMDF guidelines	June and September	Virtual	GIZ
RCOREs Annual Meeting 2022	13- 15 July	Physical-Zanzibar	GIZ
MEETING	DATES	VENUE	FUNDING SOURCE
11th AMRH Steering Committee Meeting	28 July	Virtual	BMGF
Pilot training of NQCLs based on WHO's Global Regulatory Competency framework and NEPAD's Body	July	Physical location to TBD	GIZ

of knowledge for Africa Medicines Regulatory Professionals.			
Study tour for 3 laboratories to visit Accredited labs.	September	Physical location TBD	GIZ
Exchange programmes for sharing of experiences and expertise-AMQF	September	Physical location TBD	GIZ
3rd AMRH Week (with AMRH SC, RECs, TCs and partners meetings)	Physical-Mombasa	31 October – 4 November	TBC

ANNEX III: AGREED ACTION POINTS & NEXT STEPS

	Next Steps	Responsible Leads
1.	A total of 8 AMRH TCs approved to support AMA Operationalization and vaccines regulatory oversight namely AVAREF, GMP, AMQF, PV, RCD, MPRR, IMS and AMDF. ToRs to be reviewed and workplans to be worked on	AMRH & PAVM Secretariats
2.	IMS TC to consider digitalization of NRAs	IMS TC
3.	AMRH SC updates to be disseminated on the website	AUDA-NEPAD
4.	The full AMRH website/portal to be ready to go-live by 31 July	IMS TC
5.	AUDA-NEPAD to share with the SC the full RCORE evaluation report of 2019-2020	AUDA-NEPAD
6.	Continental platform for continuous interaction between manufacturers and regulators and document best practice (lessons from Afrigen and SAHPRA interaction)	AMRH Secretariat
7.	White paper- recommendations to be finalized in preparation for AMRC, provisionally approved by SC, RECS that have not provided input to do so in for the white paper to be finalized	AMRH Secretariat
8.	Review representation of WHO-HQ in AAGA composition to include Samvel Azatyan replacing Hiiti Sillo	AUDA-NEPAD
9.	Establish Ad-Hoc technical committee on procurement and review the terminology- 'prequalification' to avoid confusion with the WHO prequalification program	AMRH Secretariat