The Third African Medicines Regulatory Harmonisation Initiative Week (3rd AMRH Week) Summary Report

5 to 9 December 2022

Accra, Ghana

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Event Page | https://www.nepad.org/event/third-amrh-week

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AMRH WEEK BACKGROUND

The African Medicines Regulatory Harmonization (AMRH) Initiative has over the last 13 years, been working to address challenges in the regulation of medical products in Africa by playing a critical role in ensuring increased access to good quality, safe and efficacious medical products. This has been addressed in mainly two ways; regulatory systems strengthening and regulatory harmonisation.

From the 5th to the 9th of December experts and stakeholders gathered the 3rd AMRH Week to unpack the ways to ensure that as the continent moves towards the African Medicines Agency (AMA), no one is left behind, partners are well coordinated, and technical capabilities are strengthened. Africa has an ambitious goal, of being able to produce its own vaccines by 2030, and the conversations at the 3rd AMRH week also centred on how to fast track this goal under the guidance of the AMRH and the Partnership for African Vaccine Manufacturing (PAVM) structures.

The AMRH Week is an event convened every two years by the AMRH Joint Secretariat, which comprises the African Union Development Agency-NEPAD (AUDA-NEPAD) and the World Health Organisation (WHO) with support from the African Union Commission (AUC). The 'week' brings together high-level African leaders and policy makers, members of AMRH Steering Committee (AMRH SC), Regional Economic Communities (RECs) the AMRH Technical Committees (AMRH TCs), the AMRH Partnership Platform (AMRH PP) as well other partners and stakeholders to showcase and celebrate the successes of AMRH as well as to reflect on progress, challenges and identify opportunities for continued improvement.

The 3rd AMRH Week took place more than two years into the pandemic, which persists and continues to pose a threat to the health and economic status of African countries. Issues such as inequitable access to vaccines are still rife as less than 25 percent of Africans are vaccinated against COVID-19. However, the pandemic has also presented opportunities for Africa. Specifically, the African Union and the Africa Centres for Disease Control and Prevention (Africa CDC) have called for the development of a framework to enable Africa to manufacture 60 percent of the vaccines it needs locally by 2040. Achieving this milestone will ensure self-reliance in the face of public health emergencies and beyond. With the launch of AMA on 5th of November 2021, the 3rd AMRH Week was even more consequential.

The AMRH Initiative is coordinating the support of multiple partners to accelerate the operationalisation of AMA. The 3rd AMRH Week presented a critical opportunity to share experiences, good practices, and innovative responses to the pandemic by African NRAs. Additionally, it presented an avenue to launch two significant reports on Africa's pharmaceutical development and progress. Specifically, the report on the analysis of the current state of development of the local pharmaceutical manufacturing and regulatory capabilities in Africa Union (AU) recognized Regional Economic Communities (RECs).

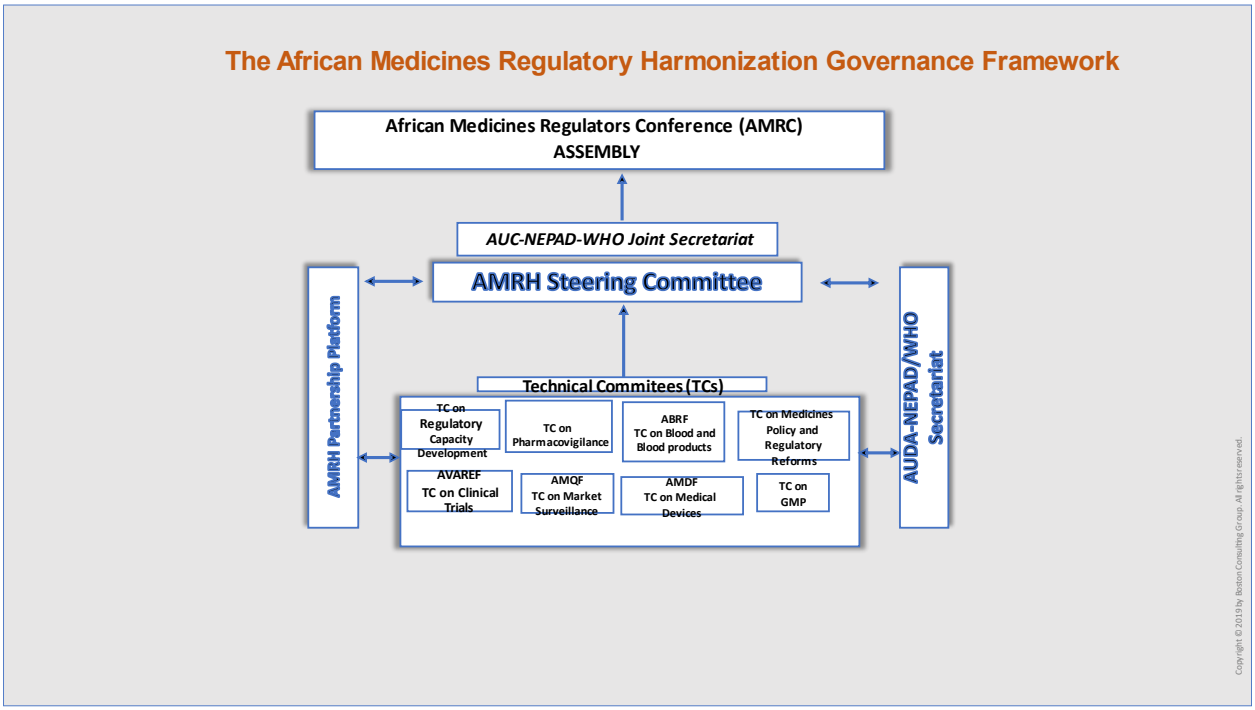
THE AMRH GOVERNANCE STRUCTURE

The AMRH governance structure was established in 2017 with a view to provide strategic direction on regulatory systems strengthening and harmonization interventions, ensure convergence and alignment at regional and continental levels, while fostering ownership by Member States, collective responsibility, mutual accountability, and sustained impact. The governance structure is comprised of the African Medicines Regulators Conference (AMRC), the AMRH SC, the AMRH TCs, the AMRH Partnership Platform (AMRH-PP) and the AMRH Joint Secretariat.

Clear roles for each entity ensure a consistent approach to governance. The AMRC is an assembly of all Heads of NRAs in AU Member States and serves as a platform for the overall decision-making in the AMRH governance framework. The AMRH Steering Committee is composed of Heads of NRAs representing the continent and RECs coordinators of MRH Programs. The Steering Committee is responsible for identifying priorities and providing strategic direction in strengthening regulatory systems and harmonization initiatives for medical products in Africa, monitoring the work of AMRH TCs and RECs MRH programs. It also provides coordination in the management of the AMRH PP, which develops resource mobilization strategies and sustainability plans for strengthening regulatory systems and harmonization initiatives for medical products in Africa.

The AMRH PP was established in 2018 as a continental platform to coordinate partner support to regulatory systems strengthening and harmonisation, minimise duplication of effort and ensure collective impact. The platform convenes both funding and technical partners supporting efforts at the continental, regional and national levels. At the global level, WHO has established the Coalition of Interested Parties (CIP) in the medical products regulatory space to effectively manage and coordinate different partners and stakeholders involved in this stream of work to avoid duplication, ensure optimal utilization of resources, and establish consensus on priority areas of intervention. The AMRH PP is the CIP Regional Steering Group for Africa.

AUDA-NEPAD, in collaboration with WHO, serves as Joint AMRH Secretariat to support the governance structure while the three institutions (AUDA-NEPAD, WHO and AUC) jointly support the work of the African Medicines Agency (AMA).



Summary of key meetings held during the 3rd AMRH Week:

Meeting of the Heads of NRAs from the East African Community (EAC) and the Intergovernmental Authority for Development (IGAD):

- The main objective of the meeting was to sensitise the Heads of NRAs of the two RECs on the proposed EAC and IGAD Reliance Framework Pilot Project to solicit their inputs on a White Paper which was presented during the meeting. It was emphasised that the EAC and IGAD Reliance Framework will serve as a regulatory pathway that applicants can rely on in submitting their dossier applications and contribute to the operationalization of the African Continental Free Trade Area (AfCFTA). The reliance framework will in addition be a trusted and transparent process that applicants can have confidence in and eventually feed into the continental framework once AMA is operational. A successful pilot is critical to assure a successful rollout of the new AMA and to continue strengthening the entire African medicines' regulatory ecosystem. The AUDA-NEPAD, the Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (MTaPS), the Gates Foundation (BMGF) and the Susan Thompson Buffet Foundation (STBF) will support the EAC and IGAD to develop and secure political endorsement for a regulatory reliance framework that enables the Ministries of Health (MoH) or NRAs of member countries to rely on each other's regulatory assessment of products for marketing authorization and/or issuance of import permits. The meeting agreed on a roadmap for the EAC-IGAD MRH Reliance Project.

The African Medical Devices Forum (AMDF) Technical Committee meeting:

- The AMDF-TC meeting reviewed their terms of reference (TORs) in alignment with the current AMRH Model, reviewed progress and new developments in WHO Global Model Regulatory Framework for medical devices including IVDs (GMRF) and in vitro diagnostic medical device (IVDs). The meeting further reviewed the five-year Strategic Plan (2022-2026) and workplan for 2023 and received commitments from AMRH Platform Partners to support the TC work. The Partners include ASLM, FIND, MSH/MTaPs, and MDRC.

The African Medicines Quality Forum (AMQF) TC meeting:

- The main objective of the meeting was to review progress and discuss new developments in support of the AU Vision for local production of vaccines and the operationalization of the AMA. The TC agreed to establish two sub-committees on Quality Management System (QMS) and Post Marketing Surveillance (PMS). The TC plan to develop a laboratory training manual was also discussed and agreed upon. In addition to the roundtable discussion on the rationale for establishment of the "Africa Continental Vaccine Lot Release Laboratory Network", the TC approved the USP offer to support a consultancy on the establishment of the Network. The assignment will include the assessment of laboratory capacity for biologics and national control laboratories. The TC also approved the plan to convene the 6th AMQF Annual Forum to be held in Kigali, Rwanda in March 2023.

Evaluation of Medical Products (EMP) TC:

- The first meeting of the EMP-TC discussed and agreed on the ToRs, elected the office bearers, agreed on next steps to operationalize the EMP-TC and the 2023 work plan. Members of the EMP-TC discussed priority products to be considered at continental level and eventually AMA once operational and agreed on the process to establish a pool of experts to start product assessment.

Good Manufacturing Practice (GMP) TC:

- The third meeting of the GMP-TC meeting reviewed progress on agreed activities for 2022 and proposed activities for 2023. The agreed GMP-TC priorities include collaboration with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), solidifying collaboration with the PAVM, the need to establish a Vaccine Manufacturing subcommittee of the GMP-TC, follow-up on training on biomanufacturing held in Cape Town in December 2022, and the need for NRAs to respond to the online NRA survey.

The establishment of a Technical Resource Group (TRG) and the need to include a consultation process with manufacturers for the guidelines to be developed was also emphasised.

The Medicines Policy and Regulatory Reforms Technical Committee (MPRR-TC):

- This was the first meeting of the MPRR-TC which deliberated on their ToRs and elected the leadership to guide the work of the TC. The AMRH Secretariat plan to develop an NRA Institutional Development Plan (IDP) Accountability Framework was presented and agreed upon as a critical tool for monitoring and evaluating progress in implementation of IDPs and coordinating partners support in strengthening medicines regulatory systems. The MPRR-TC also considered the consultant's preliminary report on evaluation of RECs Medicines Regulatory Harmonization (MRH) programs. The MPRR-TC adopted a plan to conduct an in-depth review of laws and policy instruments and qualitative assessment of Model Law domestication process (lessons learnt and best practices). The Committee agreed to identify countries to be supported on Model Law domestication process based on the agreed criteria as well as conduct country level engagements, advocacy, and capacity building on the domestication of the Model Law. The plan is to support countries to implement country level roadmaps on the domestication of the Model Law and assess the type and nature of changes to be considered in the Model Law. The Committee also agreed to conduct an analysis of innovative legal frameworks for solutions that will lead to faster adoption of reliance frameworks. Finally, the Committee discussed and agreed to identify implementation research priorities for evidence-based policy reforms.

Regulatory Capacity Development (RCD) TC:

- The third RCD-TC meeting deliberated on various items and agreed on the composition of the Vaccines Regulatory Oversight sub-committee, approved the Expression of Interest (EOI) for designation of new RCOREs on vaccines and Lot release, reviewed and approved the RCOREs performance evaluation report. The TC further approved the concept note and plans to establish the African College of Regulatory Science Professionals (ACRSP) for certification and recognition of regulatory professionals for further consultations. The TC also approved the proposed framework for the identification of experts to support various regulatory activities of AMRH/AMA. All the approved activities will be included as part of the RCD-TC workplan for 2023.

The AMRH Partnership Platform meeting:

- The seventh AMRH-PP meeting held on 08 December approved its revised ToRs to serve as African Steering Group of the Coalition of Interested Parties (CIP), agreed on the governance

structure and mechanism for coordination of partners support to AMRH on the operationalization of AMA. The meeting elected Dr David Mukanga of the Gates Foundation as Chairperson of the AMRH PP while the position of the Vice Chair was left vacant until the next meeting. The meeting further agreed on the establishment of the AMRH Funders' Group (AFG) and the Technical Partners Group (TPG) and elected Mr Vincent Tihon of Enabel and Ludovico Paganini of Swiss Medic as their respective Chairs of the two groups. The updates provided by the AMRH TC Chairs were considered to inform areas of support for the 2023 workplans.

The opening ceremony for the 3rd AMRH Week:

- The opening ceremony was officiated by a representative of the Minister of Health of the Republic of Ghana. This was followed by a keynote address & high-level panel discussion on the role of regulators in addressing African public health priorities.

The AMRH Steering Committee meeting:

- The 11th meeting of the AMRH SC was held on the 9th of December 2022 to take stock of progress attained over the year and provide direction for 2023. The meeting was also an opportunity to agree on the revised ToRs for the AMRH Governance structure including the election of office bearers. Dr Boitumelo Semete-Makokotlela, the CEO of SAHPRA was elected as Chair and Dr Adam Fimbo, DG, Tanzania Medicines, and Medical Devices Authority (TMDA), was elected as Vice-Chair representing the SADC and EAC regions respectively. The meeting also deliberated on the AMRH plans, RECs MRH Programme Evaluation Status, updates from the AMRH Partnership Platform and Technical Committees meetings on support to the operationalization of the African Medicines Agency (AMA) and vaccines manufacturing.

Agreed Next Steps and Action:

- The next Steering Committee meeting will take place in March 2023 (virtual meeting). The AMRH Secretariat will prepare an almanac for AMRH SC meetings and circulate
- The Steering Committee proposed that the Scientific Conference for Medical Products Regulation in Africa (SCoMRA) be held the week of 27 of November 2023. Proposed host countries include: Egypt, South-Africa, Rwanda. The host country to be confirmed in January 2023
- The Steering Committee was informed that the International Conference of Drug Regulatory Authorities (ICDRA) will take place in September/October 2023.
- The next AMRH Week meeting will be in 2024. Host country to be determined
- It was also proposed that during each AMRH week, the contribution of outstanding performance NRAs or regulators should be recognized
- The establishment of a new TC on Safety Monitoring should be considered

- The annual Report for 2022 should include support provided by AUDA NEPAD for the assessment and subsequent selection of the host country for AMA
- The final report of the RECs MRH Program evaluation will be available in February 2023 and should be shared with the AMRH SC
- The funder's partner group will meet in January to elect their Chair and Vice Chair and communicate the names to the AMRH Secretariat.
- The ToRs of the PP and the CIP should be aligned and updated on the website.
- A clear plan needs to be developed to cover the missing link between TCs, regional level and NRAs.
- The AMRH Secretariat should ensure ToRs and way of functioning between TCs are harmonized.
- The AMQF TC should consider establishing a continental platform to share quickly major quality issues detected such as the Gambia case to all African countries.
- The AMQF TC update should include the outcome of the roundtable discussion on vaccine lot release laboratory network.
- AVAREF should share their experience in using the MoU at the next SC meeting as it could be a good example for the other TCs.
- The EMP-TC should now be responsible for all vaccine assessments done at continental level and AVAREF should stick to its initial mandate of reviewing the CT.
- The Joint AUC-AUDA-NEPAD statement proposed by the AMQF TC should be sent to WHO for inputs based on the latest developments in the management of the Gambian case. When finalised, the AMRH Secretariat should propose the statement to the African Union with an objective to advocate for PMS, QC and to encourage countries to ratify the AMA Treaty.

ANNEX I: LIST OF PARTICIPANTS

AMRH Steering Committtee		
S/N	**Name & Organization**	**Position/Status**
	Members of SC	
1.	Dr Boitumelo Semete-Makokotlela, CEO, SAHPRA & Chair of the AMRH Steering Committee, Email: Boitumelo.Semete@sahpra.org.za	Southern Africa Head of NRA
2.	Mr Adam Fimbo, DG, Tanzania Medicines and Medical Devices Authority, TMDA & Vice Chair of the AMRH SC, Email: adamfimbo@gmail.com	Eastern Africa Head of NRA
3.	Mrs. Heran Gerba Borta, DG, Ethiopian Drug Authority, Email: hgerba@efda.gov.et	IGAD Head of NRA
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5.	Mrs Mimi Darko, CEO, Ghana FDA & Chair of AVAREF SC; Email: mimidarko66@yahoo.co.uk	Western Africa Head of NRA
6.	Mr. Richard Rukwata, Ag. DG, Medicines Control Authority of Zimbabwe (MCAZ) rrukwata@mcaz.co.zw	Southern Africa Head of NRA
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8.	Dr Bonaventure Chilinde, Director, NDQCL, Zambia Medicines Regulatory Authority, bchilinde@zamra.co.zm	Chairperson, AMQF

9.	Mr Akinyemi Abayomi Tosin; NAFDAC; abayomiakinyemi@yahoo.com	Chairperson, IMS-TC
10.	Mr Wayne Muller, SAHPRA Inspectorate, Email: wayne.muller@sahpra.org.za	Chairperson, GMP TC
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13.	Mr Khamusi Mutoti, SAHPRA, Email: khamusi.mutoti@sahpra.org.za	Chairperson, ABRF TC
14.	Dr Mrs Martha Gyansa Lutterrodt, ECOWAS- Ghana; Email: maglutt@hotmail.com	Chairperson MPRR
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21.	Dr David Mukanga; Deputy Director – Regulatory Affairs, Africa Systems, Bill & Melinda Gates Foundation (BMGF); David.Mukanga@gatesfoundation.org	Chairperson, AMRH Partnership Platform
22.	Mr Lodovico Paganini, Swiss Medic Representative; Email: lodovico.paganini@swissmedic.ch	Representing AMRH PP Funder's Group
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5	Dr Fred Siyoi	CEO, Kenya Pharmacy and Poisons Board (PPB)	Kenya
6	Mr Noel Aineplan	Manager International Affairs, Uganda NDA	Uganda
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