AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMRH
African Medicines Regulatory Harmonisation Programme

AMRH Quarterly Updates | April to August 2022

In this edition

AUDA-NEPAD Publishes a Guidance Document for the Domestication of the African Union Model Law on Medical Products Regulation

To ensure that AU member states receive adequate support to harmonise regulatory systems and improve efficiency, a Guidance Document for Domestication of the AU Model Law was commissioned by the African Union Development Agency (AUDA-NEPAD) under the AMRH initiative, with the support of the Access and Delivery Partnership (ADP), which is a global health project led and coordinated by the United Nations Development Programme (UNDP).

Malawi, Mozambique, Rwanda, and South Africa have completed the domestication process fully, while 13 other countries are in the process of domestication, bringing the countries that have domesticated in full or in part to 17. AUDA-NEPAD providing ongoing technical assistance to member states to ensure full domestication.

The guidance provides material on understanding key concepts, guidance on how to draft legislation and a chapter-by-chapter analysis of the AU Model Law, explaining the meaning of each provision and the reason for its inclusion. It also offers useful drafting suggestions. All these features will enable countries to align their regulatory laws to the AU Model Law and will not only facilitate effective regulation in each country but will also advance the goal of the harmonization of regulatory systems.

AUDA-NEPAD in its support for the operationalisation of AMA, continues to advocate for AU member states to align their medicines policies to the Model Law to ensure that they can fully benefit from being a part of AMA.

Please click the picture below for the full guidance document:

The AMQF Elects New Leadership and Members

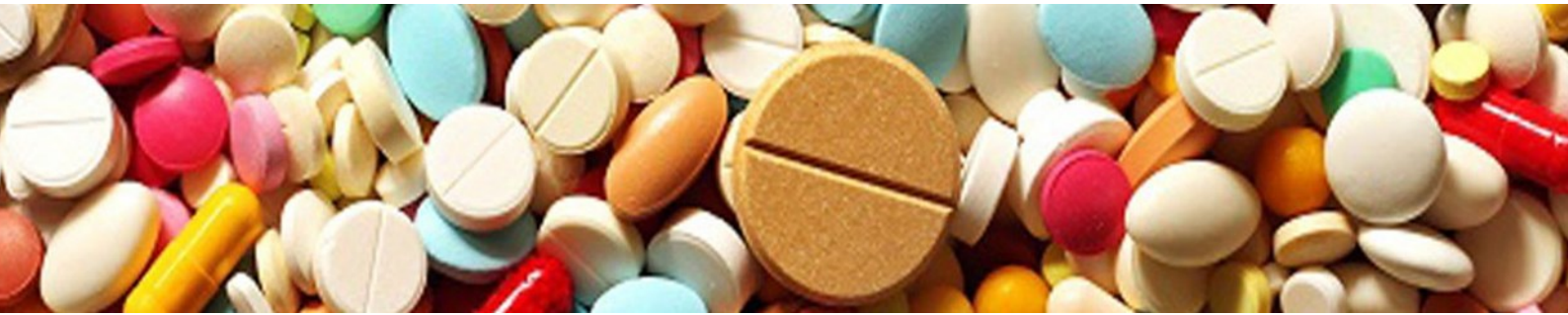
The fifth annual meeting for the African Medicines Quality Forum (AMQF) was hosted from the 4th to 6th of April 2022 by the African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), the United States Pharmacopeia Convention (USP) and the World Health Organization (WHO). Participants for this meeting included all members of the AMQF including its Technical Committee (TC), leadership from USP, AUDA-NEPAD, WHO, Regional Economic Communities (RECs), Regional Health Organizations (RHOs) as well as other partners (both current and potential) and key stakeholders.

The 5th AMQF meeting included discussions towards finalisation of the draft 2021 AMQF report including the updates on the implementation of the 2021 AMQF workplan and present this in plenary. Additionally, the TC reviewed results from 2021 ILT (Interlaboratory Testing) and alcohol-based hand sanitizers webinars and went on to discuss how NQCLs can identify platforms they can use to participate in proficiency testing. An important topic was regarding finalisation of 2022 AMQF workplan which sets the pace and tone for critical activities that support the AMRH initiative.

Some of the milestones highlighted in the meeting included:

- Frontrunner NRA engagement to attain WHO ML3/WLA is currently ongoing. Some of the activities include reviewing the NRA's benchmarking assessment reports and IDPs, identifying gaps and providing support needed and advocating with governments on the critical need for NRA to reach ML3 and WLA.
- Achieving an appropriate legislative framework using the AU model law with a timeline of December 31, 2022. Some of the activities include reviewing the AU model law to enable a full range of regulatory provisions including EUA/ EUL/ Conditional approvals.
- A continent-wide laboratory network for biologicals to be established. This milestone contains activities such as reviewing the TOR for AMQF, mapping the capacities of the current NQCLs, matching laboratories in frontrunner countries where appropriate and selecting NQCLs for support to attain WHO accreditation for vaccine testing of relevant vaccines.
- Training and talent building through RCOREs with a timeline of April 30, 2022. Some of the activities include reviewing the TOR for TCs, publishing EOIs (Expression of interest) for RCOREs on vaccines regulatory oversight and building capacities of research sites to undertake vaccine clinical trials.
- The AMQF TC also appointed new membership. Congratulations to the new committee:

Position	Name	Country
Chairperson	Bonaventure Chilinde	Zambia
Vice Chairperson	Imane Haouach	Morocco
Communication Focal Point	Hamed Sidibe	Niger
Rapporteur Anglophone	Patrick Owusu-Danso	Ghana
Rapporteur Francophone	Chiheb Ben Rayana	Tunisia
TC member	Victor Abiola	Nigeria
TC member	Ousmane Dembélé	Mali
TC member	Danstan Hipolite	Tanzania
TC member	Cyier Mayar	South Sudan
TC member	Josias Yameogo	Burkina Faso
TC member	Lavinia Mbongo	Namibia
TC member	Annette Ssenkindu	Uganda
TC member	Godeberthe Ndihokubwayo	Burundi
TC member	Matthew Kwena	Kenya
TC member	Solomon Getachew	Ethiopia
TC member	Marius Brits	South Africa



AUDA-NEPAD congratulates NAFDAC and the Egyptian Drug Authority on Attaining WHO Maturity Level 3 Status

The National Agency for Food and Drug Administration and Control (NAFDAC) and the Egyptian Drug Authority (EDA) joined the Tanzania Medicines and Medical Products Authority and the Ghana Food and Drug Authority in attaining the World Health Organisation Maturity Level 3. The WHO Global Benchmarking tool follows a rigorous assessment of NMRAs set against over 260 indicators, to establish their level of maturity. The two NRAs reached ML3 for regulation of medicines and imported vaccines (Nigeria) and locally produced and imported vaccines (Egypt), and this could not have come at a better time as the continent advances its vision to locally produce 60% of vaccines needed by 2040.

The EDA and NAFDAC have demonstrated outstanding commitment towards strengthening regulatory systems as a vehicle to facilitate access to safe, quality-assured, and efficacious medical products. It is impressive that the two Regulators also managed to make these great strides under the immense challenges that the COVID-19 pandemic presented to regulators all over the world.

AUDA-NEPAD extended letters of congratulations to both NRAs and it affirms its commitment to working closely with all regulators as they strive towards similar achievements for the betterment of Africa as we journey towards the establishment of the African Medicines Agency.

The African Medical Devices Forum (AMDF) Publishes Four Guidelines to Support Regulation of Medical Devices Including In Vitro Diagnostics (IVDS) In the African Region.

Regulatory guidelines are critical for guiding regulators and other stakeholders including manufacturers, importers, distributors to implement various regulatory processes. They give general recommendations on how to perform a specific regulatory task or provide advice on how to proceed in a particular situation. Development of regional guidelines is even more beneficial as it promotes harmonization of regulations across jurisdictions which establishes/enables a good foundation for implementation of reliance and recognition concepts, expedite regulatory decision processes, remove barriers, and ensure rapid accesses of these important health products to users.

In 2021, the African Medical Devices Regulators Forum (AMDF) through the support from WHO developed four (4) guidelines i.e. Guidelines on regulatory requirements for issuance of market authorization of medical devices including in-vitro diagnostic medical devices, Guidelines for registration of medical devices establishments, Guidelines on import and export of medical devices including in-vitro diagnostic medical devices and Guidelines for inspection of manufacturing site(s) for assessment of the quality management system of medical devices based on ISO 13485:2016. The guidelines were drafted and discussed by the respective AMDF sub working groups, which were discussed, reviewed by international experts, AMDF Technical committee and approved by the African Medicines Regulatory Harmonization Steering Committee in the last quarter of 2021. These guidelines are now available: http://www.amdfnra.org/resources.html and on https://www.nepad.org/publications and are in both English and French languages. The four guidelines are outlined below:

1. Guidelines on regulatory requirements for issuance of market authorization of medical devices including in-vitro diagnostic medical devices.
2. Guidelines for registration of medical devices establishments
3. Guidelines on import and export of medical devices including in-vitro diagnostic medical devices
4. Guidelines for inspection of manufacturing site(s) for assessment of the quality management system of medical devices based on ISO 13485:2016

To ensure that the guidelines are of benefit to the users AMDF in collaboration with WHO has organized a dissemination workshop including all regulators and regional economic communities' coordinators on 17 and 18 May 2022. The guidelines are also being shared with African Regional Economic Communities focal points and heads of National Regulatory Authorities. The guidelines are ready to be used to improve available national guidelines (adaption) or used as they are (adoption) by those NRA which do not have such guidelines. The word versions of the guidelines can be obtained by writing to WHO; Ms Agnes Kijo kijoa@who.int or AUDA-NEPAD on amrh@nepad.org. AMDF and partners will be monitoring the uptake of the guidelines through Regional Economic Communities secretariat and countries focal persons.

The AMRH Joint Secretariat Convenes African Regulators to shape the future of regulatory harmonisation at the 8th AMRC

Under the theme: 'Regulatory Landscape in Africa during the AMA and Vaccines Manufacturing Era' the Africans Medicines Regulators' Conference (AMRC VIII) was convened virtually with over 100 Heads of National Medicines Regulatory Authorities (NMRAs) , AMRH Technical Committees (TCs) and partners. Discussions for the two-day conference were centred on the African Medicines Agency Operationalisation (AMA) operationalization and Partnerships for African Vaccine Manufacturing (PAVM) Regulatory Workstream with a view to provide guidance to the AU Policy Organs.

Prof Moji Christianah Adeyeye, Director General-NAFDAC & Chairperson of the AMRH Steering Committee and Dr Oumy Kalsum Ndao, Director General, Senegal Medicines Authority, Ministry of Health, Senegal & Chairperson of the AMRC Assembly, chaired the conference and provided context and updates on progress made by African Regulators during the challenging COVID-19 era. The conference Chairs encouraged increased human capacity development as the continent moves towards accelerating the manufacturing of its own vaccines. Ratification of the AMA Treaty was also encouraged, with the number of countries steadily increasing and being on 22 ratifications at the time of the meeting. Progress was also noted on the AMRH governance structure which has supported the reactivation of the Good Manufacturing Practice and Regulatory Capacity Development Technical Committees that have been reactivated which will be pivotal TCs that will support the Partnerships for African Vaccines Manufacturing regulatory work stream which is led by AUDA-NEPAD. Significant progress has also been seen on the continent, with 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. Emphasis was placed on countries supporting each other; through on-going regional initiatives on medicines regulation and the AMRH initiative.

Discussions under AMA operationalisation focused on the need to establish an African Medicines Regulatory Network and have a formal management group to see AMA come to fruition effectively. The AMRH Secretariat continues to support the operationalisation of AMA through coordination of partner support and a concrete workplan is being finalised to support this. A White Paper on "The African Regulatory Ecosystem during the AMA Era" was drafted to provide a clear description of the current and future regulatory ecosystem in Africa following the establishment of the AMA and to provide options for the future ecosystem including possible approaches for AMRH to provide technical support to AMA

during the initial years. The consultative process on the White Paper will continue until finalised.

Regarding the vaccine AMRH Technical Committees Progress in Support of the PAVM Regulatory Workstream; several presentations were made including the key milestones reached by PAVM including the Framework for Action and the project management and implementation activities of the regulatory work stream which is led by AUDA-NEPAD. Key goals 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).

Senegal and South Africa as front runner NRAs highlighted their experiences of with regards to COVID-19 including steps of vaccine assessment starting from application to traceability/ surveillance including institutional and in-country polices supporting vaccine development. An overview of the areas that the WHO is supporting the strengthen Africa's capacity for local production includes 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.

AVAREF plans in support of the PAVM regulatory workstream were also highlighted. The AVAREF TC met with the PAVM Secretariat to identify the support that AVAREF can give to PAVM and 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.

The African Medicines Quality Forum, and the new Good Manufacturing Practice (GMP) and the Regulatory Capacity Development (RCD) TCs also presented their composition and structure, including plans to support PAVM. The role of these TCs to contributing to the vaccine manufacturing landscape in Africa and their support to the PAVM regulatory work stream is critical.

Two AMRH Technical Committees Established to support AMA Operationalisation and Vaccine Manufacturing in Africa

As part AMRH's support to the operationalisation of the African Medicines Agency (AMA), two key AMRH technical committees were the constituted between June and August 2022, namely, **the Good Manufacturing Technical Committee (GMP TC)** and the **Regulatory Capacity Development Technical Committee (RCD TC)**. Both committees play a key role in supporting the operationalisation of AMA as well as vaccine manufacturing on the African continent.

The Partnership for Vaccine Manufacturing in Africa (PAVM) was established by the African Union in 2021 to enable Africa to manufacture and supply at least 60 percent of its own vaccine needs by 2040. To see this become a reality, the importance of a strong, harmonised regulatory system cannot be over emphasized, and AMRH has since last year, been leading the regulatory workstream under PAVM.

The GMP TC is responsible for assisting AU Member States to build their GMP capacities, provide technical advice on the development and implementation of sustainable GMP Standards in collaboration with AU Member States, RECs, pharmaceutical industry, and partners.

The first meeting of the GMP TC was held on the 23rd of June 2022 and nominated members from the RECs were presented, as well as the draft terms of reference. Membership was later endorsed by the AMRC at the end of June. The second meeting was held on the 8th of August 2022 and the main key outputs included the presentation and agreement of the GMP TC Terms of Reference including detailed outline of their priorities as a TC and towards PAVM. A vaccine subcommittee was also constituted for the achievement of milestones for effective inspection of vaccine manufacturing facilities. The GMP TC also discussed plans to engage a consultant to support the work of the GMP TC focusing on drafting of guidelines, procedures, and protocols for GMP; supporting and coordinating the development of databases; coordinating partners support on GMP-TC; and supporting GMP-TC during internal and external meetings.

The **Regulatory Capacity Development (RCD TC)** is a key enabler towards regulatory excellence and attainment of WHO Maturity Level 3. The main objective of this TC is to provide technical advice to AMRH Steering Committee on human resources development needs to strengthen medicines regulatory capacities and systems in Africa. The main focus of the TC includes general management of Regional Centre of Regulatory Excellence (RCORE) platform, monitoring and renewal of existing RCOREs, determination of the need for and designation of new RCOREs and support for regulatory capacity development activities. Additionally, this TC will play a significant role in the designation of RCORECs with vaccine regulatory functions for example cGMP inspection and lot release.

An initial meeting of the RCD TC was help on 22 June 2022 to discuss the terms of reference and the role of the TC including the proposed criteria for nomination of members of the RCD-TC and to agree on next steps in the designation of new RCOREs. The RCD TC met again on the 10th of August 2022 which was a very fruitful meeting discussing and agreeing on key milestones. The TC also had the opportunity to agree on their terms of reference and had the opportunity to vote for its office bearers. During the meeting, each member also had the opportunity to present an update on the performance of their respective RCORE to date. The RCOREs outlined in detail the achievements, challenges, opportunities, and threats. This information will assist in the review process and discussion of the long-term strategy to strengthen the RCOREs framework/platform. Additionally, the process for establishment of new RCOREs was outlined and agreed upon including an expression of interest on designation of new RCOREs on vaccines and medical devices regulatory oversight. Similar to the GMP TC, the RCD TC considered the for constitution of a sub-committee on vaccines regulatory oversight to which members will be nominated.

Upcoming Events

MEETING	DATES	VENUE
African Medical Devices Forum Technical Committee leadership to attend the International Medical Devices Regulators Forum (IMDRF)	12 to 16 September 2022	Sydney, Australia
IMS Technical Committee Meeting	26 to 30 September 2022	Entebbe, Uganda
Study Tour for Unaccredited Laboratories to visit an accredited laboratory	3 to 7 October 2022	Dar es Salaam, Tanzania
GMP Technical Committee Leadership to attend the Pharmaceutical Inspection Convention of the Pharmaceutical Inspection Co-Operation Scheme -	3 to 7 October 2022	Dublin, Ireland
AMRH Partnership Platform	11 and 12 October 2022	Hybrid (Midrand, South Africa and Zoom platform)
11th AMRH Steering Committee	20 to 21 October 2022	Virtual
Ghana-FDA RCORE Fellowship Programme on Clinical Trials regulation	October-November (TBC)	Accra, Ghana
Exchange Programmes for National Quality Control Laboratories to share experiences	November (Date TBC)	TBC
Regional Centres of Regulatory Excellence Annual Meeting 2022	8 December 2022	Accra Ghana
AMRH Week 2022	5 to 9 December 2022	Accra, Ghana

Thank you to our contributors this quarter:

- AUDA-NEPAD
- WHO

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