AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMRH
African Medicines Regulatory Harmonisation Programme

AMRH Updates

July - August 2023

Greetings from the African Medicines Regulatory Harmonisation (AMRH) Joint Secretariat!

We are excited to bring you the latest edition of updates covering July to August 2023. This edition shines a spotlight on significant accomplishments during this period and offers a glimpse into upcoming events that will further bolster regulatory harmonization and support the operationalization of the African Medicines Agency (AMA).

Key Achievements during the Period

AMRH Continental Technical Committees

Good Manufacturing Practice Technical Committee (GMP TC):

The GMP TC has rolled out a plan to ensure Inspectors across the continent are engaged and involved in continental regulatory activities to facilitate efficient reliance on continental processes. In this regard, on July 10th, 2023, the TC convened its 1st meeting, bringing together 55 AU member states' GMP inspectors. This meeting introduced new developments, including recently adopted continental GMP guidelines, the Compendium of SOPs, the Continental Inspectors Playbook, and planned training programs for GMP inspections on continental processes. Over 150 inspectors from various AU RECs and NRAs attended this event. The Continental GMP guidelines and Compendia of SOPs were approved by the AMRH Steering Committee and subsequently adopted during the 9th African Medicines Regulators Conference on August 11th and August 24th, 2023, respectively.

In August 2023, the GMP TC leadership adopted a plan to roll out the 1st African GMP Inspectors Training. This initiative addresses the needs identified in a study by the AMRH on the readiness of African NRAs to conduct GMP inspections of biopharmaceutical manufacturing sites. The training is scheduled for October in collaboration with technical partners..

Evaluation of Medicinal Products (EMP) TC:

The EMP TC engaged Dissier Assessor across the continent to inform them about new developments at the continental level regarding the evaluation of medicinal products in support of AMRH and AMA on July 10th. The meeting, which brought together more than 150 dossier assessors from various AU RECs and NRAs, received feedback on the EMP TC procedure and Guidance for Priority Products.

On July 12th, 2023, the 5th meeting of the EMP TC was held virtually to review stakeholders' comments on priority products for continental assessment andthe draft continental procedure. The TC endorsed the Guidance on Eligibility Criteria for Priority Products that will be considered through Continental Assessment and Overarching Procedure. The meeting also discussed and approved the concept note on establishing a continental Technical Working Group (TWG) to lead the development of additional continental guidelines and procedures including the Continental Emergency Use Authorization (EUA) Guideline and continental procedures for evaluation of applications for registration of medical products.

The AMRH Steering Committee approved the Guidance on Eligibility Criteria for Continental Priority Products, the Overarching Procedure, the Framework for Identification of Experts, and the roadmap for piloting the continental procedure for evaluating priority medicinal products. These were subsequently adopted during the 9th assembly of the African Medicines Regulators Conference on August 24th, 2023. Implementation of the continental pilot evaluation roadmap is already underway.

In August 2023, AMRH in collaboration with the USP (PQM+) finalized a 5-year work plan for the continental Technical Working Group (TWG) on Bioavailability/Bioequivalence (BA/BE). This TWG will be established under the EMP TC to handle all matters related to BA/BE in Africa in collaboration with African National Regulatory Agencies.

Medicines Policy and Regulatory Reform (MPRR TC):

AUDA-NEPAD and Namibia Medicines Regulatory Council (NMRC) has developed a roadmap to provide technical support for the domestication of the AU Model Law on Medical Products Regulation. A technical session was convened in Namibia from August 15th to 16th, 2023, bringing together focal points within the Ministry of Health and Social Affairs and the Ministry of Justice to review the draft Bill to amend the Namibian Medicines and Related Substances Control Act. The review will also address emerging issues such as Emergency Use Authorisation, including blood and blood products as part of medical products, and a comprehensive focus on substandard and falsified medical products.

A clear roadmap for the domestication of the AU Model Law in Namibia was developed and the AUDA-NEPAD will continue supporting the entire domestication process.

African Medical Devices Forum (AMDF TC):

The AUDA-NEPAD and Africa CDC have established a Diagnostic Advisory Committee (DAC) which will work collaboratively with the African Medical Devices Forum (AMDF) to strengthen and harmonize regulatory processes for In-vitro Diagnostics (IVDs) on the continent. These efforts aim to accelerate access to diagnostics for Africa's health security.

The AMDF and DAC held a joint meeting in Dakar, Senegal, from August 15th to 17th, 2023. The meeting agreed to develop a list of IVDs for priority diseases in Africa, establish an African system for assessment and certification of IVDs, support African NRAs in registering diagnostics, promote an AU procurement mechanism for priority diagnostics, expand global price negotiation efforts, and support local manufacturing of diagnostics in Africa. For more information, visit https://africacdc.org/news-item/africa-cdc-and-auda-nepad-established-diagnostic-advisory-committee-dac-to-harmonize-regulatory-processes-for-invitro-diagnostics-ivds-and-to-accelerate-access-to-diagnostics-for-the-health-securi/

Regulatory Capacity Development (RCD TC):

The RCD subcommittee on vaccines regulatory oversight convened from July 6th to 7th, 2023, with the primary agenda of reviewing the report presented by the Independent Review Group on the designation of new Regional Centres of Regulatory Excellence (RCOREs) on vaccines regulatory oversight. Following a thorough evaluation, the meeting endorsed the development of three critical documents aimed at guiding RCOREs' operations in Africa. These documents encompass Guidelines for Operations, Guidelines for Designation and Re-designation, and a Framework for Monitoring and Evaluation of RCOREs. The subcommittee's recommendations were subsequently submitted to the AMRH SC committee for the ultimate decision-making process.

In August 2023, the following institutions attained the prestigious designation of Regional Centres of Regulatory Excellence (RCOREs) in the realm of vaccines regulatory oversight:

1. South African Health Products Regulatory Authority (SAHPRA), South Africa was designated an RCORE on National Regulatory Systems; Registration and Marketing Authorisation; Vigilance; Lot Release; Clinical Trials; Regulatory Inspections; and Licensing of Premises
2. Tanzania Medicines and Medical Devices Authority (TMDA), in partnership with the School of Pharmacy at Muhimbili University of Health and Allied Sciences (MUHAS), Tanzania was designated an RCORE on National Regulatory Systems; Registration and Marketing Authorisation; Vigilance; and Clinical Trials; Regulatory Inspections.
3. Egyptian Drug Authority (EDA), Egypt was designated as an RCORE on National Regulatory Systems; Registration and Marketing Authorisation; Lot Release; Clinical Trials; and Regulatory Inspections.
4. Food and Drugs Authority (FDA), Ghana was designated an RCORE on National Regulatory Systems; Registration and Marketing Authorisation; Vigilance; Clinical Trials; Regulatory Inspections; and Licensing of Premises.

The 9th AMRH Partnership Platform (AMRH PP)

The 9th AMRH Partnership Platform (AMRH PP) Meeting convened on July 11th, 2023, received a comprehensive update on the tangible progress on implementation of the AMRH's 5-year work plan and technical support to the AMA operationalization. Partners' unwavering support and commitments to the AMRH Workplan and AMA operationalization were discussed, including financial and technical contributions, reflecting strong collaboration.
Selected partners shared implementation experiences at various levels, from continental to national, revealing valuable insights. The meeting also discussed current gaps for 2023 strategic goals, mechanisms for enhancing clarity of roles and achieving efficiency.
The meeting also received updated on the WHO's Coalition of Interested Parties (CIP) Coordination process, demonstrating the CIP SharePoint system. Key takeaways from these discussions will be included in the AMRH PP report, guiding future actions.

National Regulatory Authorities:

On August 22nd, a meeting of 27 Heads of NRAs was held in Kigali, on the margins of the 9th African Medicines Regulators Conference (AMRC) to review the findings of a study on the maturity level and the status of implementation and/or availability of Institutional Development Plans (IDPs) for the NRAs that responded to the survey. With respect to maturity status, the results indicated that a majority of the NRAs (72%) are in maturity level 1 (ML1). Maturity level 2 and 3 accounted for 12% and 16% of respondents respectively. A large proportion of NRAs (11) indicated that they have undergone self-benchmarking assisted by WHO, with 12 indicating that they have been formally benchmarked and one (1) re-benchmarked by WHO. However, one (1) NRA indicted that no formal engagement for benchmarking has been conducted except the fact they were assisted by another NRA to assess their regulatory system against requirements of WHO Global benchmarking Tool (GBT).

AUDA-NEPAD proposed an IDP implementation tracker following the study, which was well received by the NRAs. The tracker aims to support the tracking and monitoring of progress in the implementation of IDPs and enhance collaboration among stakeholders supporting medicines regulatory systems in Africa. The tool will be implemented by AUDA -NEPAD and partner support will be mobilized to support the implementation of IDPs. Additionally, mechanisms for supporting country twinning will be put in place to enhance regulatory systems strengthening.

Regional Economic Committees:

During the recent AMRC in August 2023, the Regional Economic Communities (RECs) engaged in a substantive discussion concerning the forthcoming actions at the Continental, Regional, and national levels in the advent of the African Medicines Agency (AMA). Several key recommendations emerged from this deliberation, including:

- Minimum Package of REC-MRH Projects: A consensus was reached on the imperative of formulating a minimum package for regional MRH projects to guide alignment and design of REC projects. The minimum package will be costed to guide technical and financial support for interventions.

- Strategic and Sustainability Plans: It was strongly recommended that the RECs develop comprehensive strategic and sustainability plans. These strategic blueprints would serve as guiding frameworks to steer their operations and ensure their long-term effectiveness and sustainability. Notably, ECOWAS was encouraged to share its valuable insights and lessons learned in this domain for the benefit of other RECs.

- Evidence-Based Advocacy: To garner political support for the African Medicines Agency (AMA) Treaty and facilitate progress in countries' maturity levels, it was underscored that the RECs should adopt an evidence-based approach in their advocacy strategies and engagements. This approach entails leveraging empirical data and research to construct compelling arguments in favor of regulatory systems strengthening, harmonisation and retification of the AMA Treaty.

- Streamlining the Reliance Framework: The reliance framework, a critical instrument for fostering regulatory cooperation among nations, was acknowledged for its significance. Nonetheless, there was a call to refine and make it more practical and accessible for countries to adopt and implement effectively.

- Information Sharing and Management: In-depth discussions centered on the mechanisms for information sharing and management among the RECs. A key recommendation was that the Continental Information Management Systems (IMS) should feature an interface allowing for the automatic updating of information, thereby streamlining the process and alleviating the burden on individuals tasked with data input. Furthermore, it was stressed that the Continental IMS should actively engage with stakeholders at the country and regional level to ensure seamless coordination and the elimination of information disconnects.

Upcoming events

SCOMRA date has been announced

Abstract submission is currently open for prospective SCoMRA participants. You can submit abstracts that align with the conference's main theme, sub-themes, and specific goals. If your abstract is accepted, you will have the opportunity to present it either through oral presentations or poster sessions.

Click here to find out more

https://www.nepad.org/publication/call-abstracts

Activity	Meeting Date	Venue
AMRH PP Funders group meeting	17 Oct 2023	Virtual
Medisafe Capacity Builders & Experience Sharing meeting on SF Medical Products	2 Oct - 6 Oct 2023	Nairobi ,Kenya
Workshop on Domestication of the AU Model Law and Ratification of the AMA Treaty	31 Oct - 3 Nov 2023	Dae es Salaam, Tanazania