



## AMRH Updates | January to May 2023

This **second edition** of updates from the African Medicines Regulatory Harmonisation (AMRH) Joint Secretariat to stakeholders covers the first five months of 2023.

It highlights the key achievements during the period and upcoming events on regulatory harmonization and technical support to the operationalization of the African Medicines Agency (AMA).

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# Key Achievements

## **AMRH Continental Technical Committees**

Over the past five months, the AMRH technical committees (TCs) have moved closer towards achieving their 2023 targets on supporting regulatory harmonization across the continent as a foundation to the operationalisation of the AMA. The following progress has been made by the TCs:

### **Good Manufacturing Practice (GMP TC):**

The GMP TC has developed a series of continental guidance documents and standard operating procedures (SoPs) that are essential for undertaking joint continental regulatory activities. These SoPs will be tabled by the meeting of African Medicines Regulators Conference in August 2023 after the review by the AMRH Steering Committee (AMRH SC). The draft guidelines and SoPs include:

- Guidelines for GMP inspections at continental level
- Guidelines for reliance and work-sharing that will be incorporated into the continental Reliance Framework
- Compendium of SOPs for conducting GMP inspections through joint continental processes under AMRH and eventually AMA
- Continental GMP Inspector's playbook

The TC has also assessed the capacities of twenty-five (25) African Countries to conduct GMP inspections of biomanufacturing site. This will inform capacity building initiatives in the coming months.

The GMP Sub-Committee for inspection of vaccines and other biological products manufacturing sites has been established and is operational.

### **Evaluation of Medical Products (EMP) TC:**

The EMP TC has facilitated the development of the following continental procedures and guidance documents:

- Guidance on the eligibility criteria for priority products for continental assessment which is available and published for public consultation. You can access the document on the following link: [Invitation for Comments on a Draft of the Eligibility Criteria Guidance on Priority Medicinal Products for Continental Assessment through AMRH/AMA Evaluation of Medicinal Products Technical Committee \(EMP TC\) | AUDA-NEPAD.](#)

EMP TC overarching procedure has been proposed and discussed in the 4th EMP TC meeting. This will further be developed and expected to be adopted by the EMP TC in its next meeting.



The TC has started the processes of establishing sub-committees and technical working groups to facilitate its work. The following has been accomplished:

- Concept note for establishing a continental Technical Working Group on Bioavailability and Bioequivalence. The next meeting of the TC will finalize and adopt the concept note which will assist the TC in developing requirements and assessment of bioequivalence and bioavailability data.
- Terms of Reference have been developed for the sub-committee on biologicals and vaccines and members identified. The sub-committee will have its first meeting on the 7th of June to develop its workplans and adopt its terms of reference.
- The leadership of EMP TC discussed and endorsed profiles for continental assessors. These assessors will be included in the pool of experts that will support joint regulatory activities.
- The first draft on the sustainability plan and fee structure for continental processes under EMP TC and GMP TC has been drafted. The TC will be developing the draft and consulting widely before taking it through adoption processes.

#### **African Medicines Quality Forum TC (AMQF):**

- The AMQF TC is working towards the establishment of a Reliance Laboratory Network for the continent. This is an important milestone for the continent as it will anchor the AMA regulatory activities and support local production of vaccines on the continent.
- The TC is also working towards the establishment of the Post-Marketing Surveillance (PMS) and Quality Management Systems (QMS) Subcommittees to support its activities.
- The AMRH is collaborating with PTB and Paul Ehrlich Institute to strengthen the capacity of National Quality Control Laboratories (NQCL)s on regulation of vaccine and risk-based approaches to lot release testing. In this regard a study tour was conducted for Ghana FDA, Rwanda Food and Drugs Authority, the South African Health Products Regulatory Authority, the Senegalese Pharmaceutical Regulatory Agency, AMQF Subcommittee for Vaccine Lot Release, AMQF leadership, GIZ and the South African National Control Laboratory for Biological Products to benchmark toward improving national capacity.
- The AMQF TC has initiated the development of a continental strategy on substandard and falsified medical products to guide continental interventions.

#### **Information Management Systems TC (IMS TC)**

The IMS TC is leading the development of three critical regulatory information systems in 2023 namely:

- Regulatory Information Sharing Platform (RISP) to facilitate efficient and effective information sharing among regulators and other key stakeholders. The development of the platform will be initiated in July 2023.
- Regulatory Information Sharing System (RIMS) which will facilitate regulatory information management at the continental, regional and national levels. The model RIMS has been developed and was reviewed during the May 2023 TC meeting.



- A Continental Active Pharmaceutical Ingredients (API) database which will avail information to regulators across the continent on approved APIs. The Use Case report for the database has been finalised and will inform the development of the system.
- Progress on the development of the systems was reviewed during the May 2023 TC meeting. A clear roadmap for the last half of 2023 has been developed to guide implementation.

### **Medicines Policy and Regulatory Reforms TC (MPRR TC)**

The MPRR-TC targets the review of the AU Model Law on Medical Products in 2023 to respond to new developments in the regulation of medical products continentally and globally. The following has been done in this regard:

- A justification document for the review of the Model Law has been developed and reviewed by the MPRR TC during its April meeting. The document will be presented to governance and policy organs of the AU to seek approval of the review.

An in-depth review of laws and policy instruments and qualitative assessment of the African Union Model Law Products Regulation (AU Model Law) domestication process has been initiated in partnership with the Wellcome Trust. The review will generate lessons learnt and best practices that will be used to support countries to domesticate the Model Law. An AU guidance document on Substandard and Falsified (SF) medical products is under development in collaboration with the MediSafe Project to guide Member States on SF.

The TC is also leading the development of a Framework for collaboration between the AMRH and AMA Governance Structures. This will build on lessons learnt from the ongoing regional harmonization initiatives.

A study on the country implementation of Institutional Development Plans (IDPs) has been finalized to inform support to NRA capacity strengthening initiatives. A tracker on IDP implementation has also been drafted to support monitoring of progress.

### **African Medical Devices Forum (AMDF TC):**

The following has been achieved under the AMDF:

- Guidelines for Regulation of Medical Devices for Maternal Newborn and Child Health (MNCH) Population were developed in collaboration with the Medicines, Technologies, and Pharmaceutical Services (MTaPs). The guidelines will be considered by the AMRH Steering Committee in its next sitting before submission to the AMRC for adoption.
- A concept note has been drafted to identify potential NRAs and support them towards RCOREs designation.
- A Training Needs Assessment for NRAs in premarket assessment of medical devices is being finalized. This will inform the design of training interventions.





### **Regulatory Capacity Development (RCD TC):**

- RCD Sub-Committee on Vaccines Regulatory oversight has been established which reviewed the draft Expression of Interest (EOIs) for RCOREs on vaccines.
- The EOI for vaccines RCOREs was published on 24 February 2023. It is expected that evaluation of applications will be conducted in June 2023.
- The process for identifying an expert to develop a pool of regulatory experts-this task is being implemented in collaboration with the IMS TC.
- An Interim Committee was established to lead the process of establishing the African College of Regulatory Science Professionals.

### **Regional Economic Communities Medicines Regulatory Harmonization (REC MRH) Initiatives**

The RECs have continued to make progress towards strengthening their harmonization initiatives with the view to improve access to safe, efficacious and quality assured medical products to their population. In this regard, during the last five months the following has been achieved:

#### **Economic Community for West Africa States (ECOWAS):**

- The region continues to make progress towards strengthening its partner engagement platform. Currently, the ECOWAS-MRH Partnership Platform brings together technical and financial partners monthly to discuss progress and priorities for regulatory harmonization in the regions. The AUDA-NEPAD is drawing on lessons from the ECOWAS region to convene similar platforms in all the RECs.
- The initiative to link regulatory harmonization to procurement and local manufacturing in the region is making significant progress. A meeting was convened in May 2023 to discuss the regional policy on certification of medical products. The ECOWAS pilot will provide lessons for rolling out similar interventions in other RECs and continentally.

#### **East African Community (EAC):**

- The AMRH Secretariat convened a meeting with the EAC in March to discuss the implementation of regional harmonization activities. The AMRH Secretariat is planning to initiate a Partner Coordination mechanism for the MRH programme in the region.
- USP has given access for 20 technical officers to use the US pharmacopoeia for a period of one year for free. One GMP inspection was conducted and there are plans to convene a joint dossier evaluation in June 2023.
- As part of support to RECs and NRAs, AUDA-NEPAD in 2022 initiated a study of their progress to date. To facilitate the smooth take-off of AMA, it is imperative to take stock of the progress, processes, structures, outputs, challenges, and lessons learnt through the AMRH initiative. This assessment will inform the development of a framework for better alignment of the AMRH and AMA interventions and governance. Preliminary results had been received from 4 out of 5 RECs and 4 out of 11 sampled NRAs with a view for the project to be completed in May 2023.



### **Updates on National Regulatory Authorities (NRAs)**

As part of technical support to NRAs, there is need for clear visibility into the NRA plans to achieve WHO Maturity Level 3 status and coordinate support to help NRAs address gaps and challenges identified. To achieve this, AUDA NEPAD commissioned a study to track NRA maturity status, check the availability of Institutional Development Plans (IDPs), the progress of implementation of the IDPs, including planned WHO assessment, and resources mobilized. A survey was sent to all 54 NRAs in January 2023 and as of April 2023, 25 NRAs had provided data. From the findings, a report will be prepared, and recommendations made on support to be given to the NRAs. An implementation tracker and a resource mobilization strategy will also be developed to ensure the NRAs have mechanisms in place to support resources needed for IDP implementation.

A joint mission was undertaken by the Africa Centres for Disease Control and AUDA NEPAD to NRAs (Botswana, Ghana, Senegal, and South Africa) between March and May to assess the technical, financial and operational capacity for vaccine regulatory oversight. The missions aimed at supporting the countries to finalize project proposal for support.

### **Updates on the AMRH Governance Structures:**

AMRH Steering Committee: The steering committee convened its 12th meeting from 03 to 04 April. During the meeting, progress on AMRH technical work including its support to the operationalization of the AMA was reviewed. Several key technical guidelines from the TCs were reviewed.

### **Operationalizing the AMRH Partnership Platform structures:**

The AMRH Funders Group (APG) convened its first meeting on 02 March 2023. Key outcomes of this meeting include;

- Elections of the leadership of the Funders Group: Dr Vincent Tihon of Belgian Development Agency (Enabel) was elected as Chairperson and Dr Divya Shah of Wellcome Trust was elected as Vice Chairperson for 2023 – 2024.
- The first meeting also reviewed the Funders Group Terms of Reference.

The AMRH Technical Partners Group (TPG) had its first meeting on 15 March 2023. The meeting reviewed the Terms of Reference of the TPG and partners were requested to confirm the type of technical support they are offering to the TCs so that the AMRH Workplan can be finalized and circulated.

# Upcoming events

Activity	Meeting Date	Venue
AMDF TC meeting	06 June	Virtual meeting
Evaluation of Vaccines RCOREs' EOI by the RCD Sub-Committee on vaccines	6-8 June	Cairo, Egypt
AMRH PP Meeting	11 July	Virtual
AMRH Steering Committee meeting	22 August	Kigali, Rwanda
African Medicines Regulators Conference (AMRC) Assembly	23 to 24 August	Kigali, Rwanda
AMRH PP Funders group meeting	22 September	Virtual
AMRH PP technical partners group meeting	27 September	Virtual
AMRH PP meeting	26 November	Cairo, Egypt
6th Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA VI)	27 November to 2 December	Cairo, Egypt

For questions and follow up, contact the AMRH Secretariat on [amrh@nepad.org](mailto:amrh@nepad.org)

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