AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

AMRH
African Medicines Regulatory Harmonisation Programme

AMRH Updates | June 2023

The **third edition** of updates from the African Medicines Regulatory Harmonisation (AMRH) Joint Secretariat to stakeholders covers the month of June 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).

Key Achievements

AMRH Continental Technical Committees

Good Manufacturing Practice (GMP TC):

The GMP subcommittee on vaccines and biologics held its 2nd meeting on the 7th of June 2023. During the meeting, the subcommittee reviewed the first draft of the continental GMP Inspectors competency framework and training manual for theoretical and practical trainings to support continental GMP inspection pilot. The subcommittee also adopted its work plan for 2023 and identified the priorities for 2024.

The leadership of the GMP TC and the EMP TC also reviewed and finalized a roadmap which will objectively guide implementation of various planned activities to achieve the pilot for the joint continental evaluations and inspections.

Evaluation of Medical Products (EMP) TC:

The EMP TC leadership group finalised the concept note for establishing a continental Technical Working Group on Guidelines which will be constituted to spearhead development, adoption, and adaption of various continental guidelines under the EMP TC and its subcommittees. The concept note will be discussed and deliberated in the EMP TC meeting planned for 12th July 2023.

The EMP TC in partnership with the Germany's Global Health Protection Program - PharmTrain-2 in June 2023 started the drafting of a continental Emergency Use Authorization and Listing Framework to support public health emergencies preparedness and response.

The first phase of the pilot continental joint evaluations and inspections by the EMP TC and GMP TC will commence in July 2023. The first phase is expected to be concluded in March 2024 prior to full endorsement of continental procedures.

Medicines Policy and Regulatory Reforms TC (MPRR TC)

The MPRR-TC has initiated the process of reviewing the AU Model Law on Medical Products to respond to new developments in the regulation of medical products continentally and globally. A draft justification document for the review of the Model Law has been developed and will be presented to AU structures for approval.

The TC is also finalised the drafting of a Framework for collaboration between the AMRH and AMA Governance Structures. The framework builds on lessons learnt from the ongoing regional harmonization initiatives. The draft will be presented to the AMRH governance structures in August 2023 before submission to AMA governance structures for consideration.

The study to assess the implementation of Institutional Development Plans (IDPs) by National Regulatory Authorities (NRAs) has been finalised. A tracker on IDP implementation has also been drafted to support monitoring of progress and identifying priority interventions. The survey report and the tracker will be presented to the 25 Member States that responded to the survey in August 2023. The workshop will also provide an opportunity to discuss recommendations on priority interventions to support the countries as they strive to move to the next levels of maturity.

On 23 June 2023, the AMRH Team met with Namibia Medicines Regulatory Council to discuss technical support on the domestication of the AU Model Law on Medicines Regulation in the country. The two institutions have agreed to meet in August 2023 to review the draft law and develop a roadmap for the domestication of the Model Law.

African Medical Devices Forum TC (AMDF):

The AMDF TC leadership and the Secretariat met with the WHO prequalification of in vitro diagnostics team to agree on areas of collaboration. This meeting among other important matters, agreed to have the AMDF members and experts participate in the prequalification sessions starting October 2023 for purposes of converging efforts and capacity building to African regulators.

The AMRH Steering Committee in June 2023 approved a special consideration guideline for regulation of Maternal Newborn and Child Health (MNCH) medical devices which was developed by the AMDF. The AMDF TC is currently planning sensitisation webinars and trainings for use of this guidance by the African NRAs. The first webinar is planned for the 3rd of August 2023 which will be followed by a face-to-face training in September 2023 in Dar es Salaam Tanzania.

The AMRH through the AMDF TC met with the Africa Centres for Disease Control to discuss areas for collaboration and to support the establishment of the Diagnostics Advisory Group (DAG) which will collaborate with local manufacturers in Africa to support generation of performance evaluation data to be reviewed by the AMDF sub-working group to support certification of local IVDs.

Regulatory Capacity Development TC (RCD TC)

An Independent Review Group (IRG) was established by the AMRH secretariat to support the RCD TC to evaluate the Expression of Interests (EOIs) for designation as Regional Centres of Regulatory Excellence (RCOREs) for Vaccines Regulatory Oversight. The IRG was convened from 26 to 28 June 2023 to evaluate the EOIs and provided recommendations for the consideration of the RCD subcommittee. The report and recommendations will be tabled by the main RCD TC for adoption and decision on designation of new RCOREs on the 2nd to the 3rd of August 2023.

African Medicines Quality Forum (AMQF TC)

On 9 June 2023, the AMQF TC operationalised the Subcommittee on Quality Management Systems and the Subcommittee on Market Control. The AMQF Subcommittees also finalised their annual work plans for 2023 to guide their work.

Regional Ecomonic Communities and National Regulatory Authorities

ECOWAS

The second West Africa Medicines Regulatory Harmonization initiative (WA-MRH) Webinar was held on 8th June 2023 to discuss the impact of the pharmaceutical industries in the utilization of the Joint Assessment Procedures in the ECOWAS region. The aim of the webinar was to encourage pharmaceutical industries to submit medical product applications on the regional joint assessment platform to increase access to good quality, safe and efficacious medical products in the ECOWAS region.

SADC

A SADC-MRH Strategic Planning Workshop was held from 6 to 7 June in Johannesburg, South Africa, supported by GIZ. The following was achieved:

- Terms of Reference for the Forum were adopted and to be reviewed by NMRAs boards in preparation for tabling at next SADC Ministers of Health meeting in November
- An MOU for collaboration on regulation of medical products was adopted and is now undergoing national consultations in preparation for next SADC Ministers of Health meeting in November
- TORs for Implementing Agency, Governance and Transparency, Technical and Sustainability and Finance Committees were finalised and adopted. Membership and chairs for the 3 Committees was finalised and their inaugural meetings were held. The Forum Chair and Vice will be elected at next Forum meeting
- Brainstorming and identification was done of focal areas for improving Zazibona joint assessments and Inspections
- Priority areas for Year 1 and Year 2 identified were identified from the Strategic Plan.

National Regulatory Authorities:

Angola and Lesotho have recently attained semi-autonomous NMRA status and require support to initiate registration of products and licensing of premises

African Medicines Agency (AMA) Operationalisation:

The African Union Commission, in collaboration with the Government of the Republic of Rwanda, convened the Second Extraordinary Session of the Conference of States Parties (CoSP) to the AMA Treaty from 19-20 June 2023 in Kigali, Rwanda. The meeting, which AUDA-NEPAD participated in, made critical progress on the steps towards recruitment of the AMA Director General and establishment of the AMA Governing Board. The board will oversee AMA to ensure that it provides excellent scientific opinion and guidance to AU member states and the appointment of the board aims to be concluded at the end of August 2023.

AUDA-NEPAD through a dedicated task team, will continue to support the AUC in terms of the technical aspects to AMA's operationalisation.

Upcoming events

Upcoming events Quarter 3 and 4 2023

Activity	Meeting Date	Venue
AMQF Leadership Meeting	20 July 2023	Virtual Meeting
AMQF Subcommittee on Vaccines Meeting	21 July 2023	Virtual Meeting
AMQF Subcommittee on Market Control Meeting	27 July 2023	Virtual Meeting
AMQF Sub-committee on Quality Management Systems Meeting	31 July 2023	Virtual Meeting
2nd Meeting of the Interim Executive Committee on—establishment of the African College for Regulatory Science Professionals	1 August 2023	Dar es Salaam, Tanzania
RCD 3rd Meeting and Designation of Vaccines RCOREs by the RCD Technical Committee	2-3 August 2023	Dar es Salaam, Tanzania
Workshop to orient regulators in Africa through the regional economic communities (RECs) on the new AMDF guidance on regulation of Maternal New-born & Child Health medical devices and the other AMDF guidance	03 August 2023	Virtual Meeting
AMQF TC Meeting	6 August 2023	Virtual Meeting
AMRH Steering Committee Meeting	7 August 2023	Virtual
AMDF TC meeting	09 August	Virtual Meeting
10th Meeting of the Regional Economic Communities Medicines Regulatory Harmonisation programmes (RECS-MRH) in Africa	10-11 August	Gaborone, Botswana
The 5th GMP TC Meeting	15 August 2023	Virtual Meeting
To support the Namibian Ministry of Health to develop a road map to domesticate the AU Model Law	15 –16 August 2023	Windhoek, Namibia
The 1st meeting of the EMP subcommittee on vaccines and other biological products	24 August 2023	Virtual Meeting
In person technical files assessment training of regulators in Africa through the regional economic communities (RECs) on the new AMDF guidance on regulation of Maternal New-born & Child Health medical devices	12 – 14 September 2023	Dar es Salaam, Tanzania

Upcoming events

Upcoming events Quarter 3 and 4 2023

AMQF TC Leadership Meeting	6 December 2023	Virtual Meeting
NRAs meeting on IDP implementation	22 August	Kigali, Rwanda
African Medicines Regulators Conference (AMRC) Assembly	23 and 24 August	Kigali, Rwanda
Workshop on Domestication of the AU Model Law and Ratification of the AMA Treaty	11-15 September 2023	Dar es Salaam, Tanzania
AMRH PP Funders group meeting	22 September	Virtual
AMRH PP technical partners group meeting	27 September	Virtual
AMQF Exchange Program	2—6 October 2023	Rabat, Morocco
AMRH PP meeting	26 November	Cairo, Egypt
SCOMRA VI	27-29 November	Cairo, Egypt

For questions and follow up, feel free to contact the AMRH Secretariat on amrh@nepad.org