AMRH Newsletter

Quarter II: April - June 2018

AFRICAN MEDICINES REGULATORY HARMONIZA

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African Union Ministers of Health adopt treaty for the establishment of the African Medicines Agency

African Ministers of Health meeting as a Working Group of the Specialised Technical Committee on Health, Population and Drug Control unanimously adopted the Treaty for the establishment of the African Medicines Agency (AMA) on 19th May 2018 in Geneva, Switzerland. .

AMA seeks to ensure the coordination and strengthening of continental initiatives to harmonise medical products regulation, provide guidance and technical support to improve access to quality, safe and efficacious medical products and health technologies on the continent. AMA will work within the existing continental architecture of Regional Economic communities (RECs) and Regional Health Organizations (RHOs) to support AU Member States.

"The African Medicine Agency is a key element of the architecture for harmonisation of continental, institutional, scientific and regulatory resources to improve access to safe, efficacious and quality medicines" said Ambassador Ajay Kumar Bramdeo, the Permanent Observer of the African Union to the United Nations Office at Geneva.

The African Medicines Agency will promote the adoption and harmonization of medical products regulatory policies and standards, and scientific guidelines,

and coordinate existing regulatory harmonization efforts in the RECs and RHOs. It will further provide regulatory guidance, scientific opinions and a common framework for regulatory actions on medical products, as well as priority and emerging issues and pandemics.

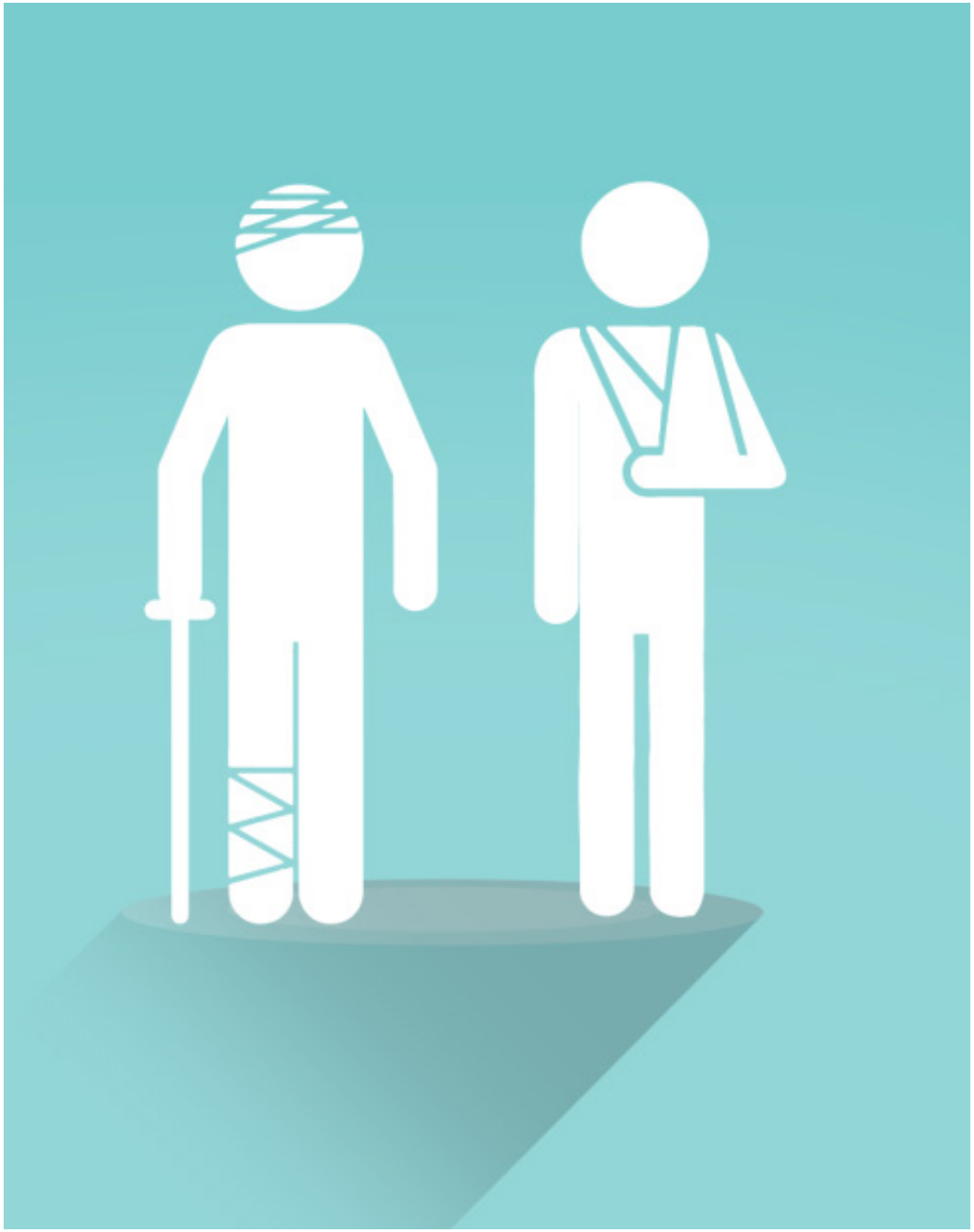
The Specialised Technical Agency will also provide regulatory guidance and provide technical assistance on regulatory matters to countries that lack the capacity and resources to do so. It will further provide guidance on regulation of clinical trials on medical products and health technologies.

"It is increasingly becoming evident that no single country has enough resources and capability to efficiently and effectively regulate the whole supply chain system alone in this globalised world. AMA thus occupies a distinct position to leverage various regulatory assets and capabilities to improve access to safe, effective, good quality and affordable essential medicines and health technologies" said Gugu N. Mahlangu, Director-General at Medicines Control Authority of Zimbabwe who also Chairs the AMA Taskforce.

The new institution will also lead the establishment and strengthening of Regional Centres of Regulatory Excellence in order to develop the capacity of medical products regulatory professionals. Other key mandates will include the promotion of international cooperation and partnerships for the mobilization of financial and technical resources. The agency will promote and advocate for the use of the AU Model Law on Medical Products Regulation in Member States and RECs to facilitate regulatory and legal reforms at continental, regional and national levels.

Through AMA, systems to monitor, evaluate and assess the comprehensiveness of national medical products regulatory systems will be further enhanced to ensure efficiency and effectiveness. The Agency will also play a lead role in the event of a public health emergency across the continent, where new medical products are to be deployed for investigation and clinical trials.

In such cases, AMA will be responsible for mobilising regulatory expertise across the continent and beyond to provide scientific opinions in consultation with affected Member State National Medical Regulatory Agencies



IGAD initiates a Regional Approach to Medicines Quality Surveillance

Launching a five-day meeting on 25 June 2018 in Addis Ababa, Ethiopia, the Intergovernmental Authority on Development (IGAD) took key steps to strengthening pharmacovigilance and post-marketing surveillance systems for medicines marketed in Djibouti, Eritrea, Ethiopia, Kenya, Somalia, South Sudan, Sudan and Uganda; with specific attention to cross-border points.

Four key outputs aimed at expanding access to quality-assured medicines in IGAD member states were achieved;

1. **Establishment of a Regional Expert Working Group on Pharmacovigilance & Post-Marketing Surveillance.**
2. **Recommendations for a regional cross-border pharmacovigilance system.**
3. **Recommendations for implementation of a regional post-marketing surveillance strategy and related guidelines.**
4. **A regional protocol for studying the prevalence of substandard and falsified medicines at selected IGAD cross-border sites, targeting products used in maternal & child health, family planning, tuberculosis, and HIV & AIDS programs.**

Participants at the IGAD meeting in Addis Ababa, Ethiopia

Participants in the meeting include representatives from medicines regulatory authorities in IGAD countries as well as technical assistance experts from Promoting the Quality of Medicines (PQM) program, NEPAD AGency and World Bank (WB). IGAD is partnering with the PQM program for technical support in recognition of its global experience in strengthening medicines quality assurance systems.

The meeting was chaired by Ato Yehelu Denekew, Director General of the Ethiopian Food, Medicines, and Healthcare Administration & Control Authority (EFMHACA). Inaugurating the proceedings, Dr. Denekew emphasized that unregulated substandard and falsified medicines circulating in IGAD member states are, "…a serious public health threat which, if not prevented and controlled, will undermine confidence in public healthcare systems and programs." He further added that as chair of IGAD, Ethiopia supports efforts to study the prevalence of Substandard and Falsified (SF) medicines in cross-border areas. This will help the region develop necessary regulatory actions and interventions to control this problem.

Fatuma Adan, Senior Regional Program Coordinator in IGAD's Health & Social Development Division, called on the participants to review and finalize draft terms of reference for a Regional Expert Working Group on Pharmacovigilance and Post-Marketing Surveillance and submit to the heads of the National Medicines Regulatory Authorities (NMRAs) for ratification and approval.

Timothy Nwogu, PQM Principal Program Manager, remarked that approaching pharmacovigilance and post-marketing surveillance from a regional perspective is more than a question of cooperation.

"IGAD is fostering harmonization, and moving towards work-sharing and principles of mutual reliance," he specified.

Zazibona Assessors meeting discusses 11 new applications

Zazibona assessors meeting discussed a total of 11 new applications during its 19th session that took place in Lusaka, Zambia from 11 – 15 June 2018. Out of the 11 new applications, 6 were for biological applications i.e. 4 new biological applications (4 strengths of 1 product reviewed using Article 58 procedure) and 2 biosimilar applications.

During the same meeting, regulators benefitted from the EMA training session which focussed on assessment of biosimilars and reliance based on reports generated by EMA in the assessment and approval of biological products for the purposes of granting marketing authorisation of the same product when applications are submitted to the respective countries.

The 10th Zazibona Heads of Agency meeting was also organized in association with the 19th meeting of assessors, on 14-15 June 2018. Among the matters discussed included update on assessment activities, update on inspectorate activities, feedback from the SADC Regulators Forum, updates on Zazibona membership, coordination of Zazibona activities, targets and progress on assessments and inspections, financing of Zazibona activities and schedule and preparations of meetings for rest of the year.

The success of Zazibona has attracted interest from other countries to join the initiative. This will further accelerate joint dossier assessments.

Continental platform approach to improve coordination of medicines regulatory work

Participants at the 1st AMRH Partnership Platform meeting at NEPAD Agency Head Office in Johannesburg, South Africa

There is a lot of work being implemented in medicines regulatory systems strengthening in Africa. According to Dr Mike Ward, World Health Organization (WHO) Coordinator for Regulatory Systems Strengthening (RSS), one of the biggest challenges of this work has been the lack of coordination of different partners and stakeholders. He was speaking during the first African Medicines Regulatory Harmonization Partnership Platform (AMRH-PP) meeting which took place in Johannesburg, South Africa on 11 April 2018.

“The proposed establishment of this AMRH Partnership Platform is a milestone on medicines regulatory systems strengthening and harmonization in Africa”, Dr Ward said.

Dr Ward said that the only way to succeed in this work is if we take a coordinated approach. WHO is already implementing the global Coalition of Interested Parties (CIP) and there are lessons that the African chapter of the WHO-CIP can learn, as well as best practices and vice versa. He further pointed participants to the fact that since the AMRH-PP is the Africa chapter of the WHO-CIP, it must align with the global platform’s principles, values and concepts and the various partners and stakeholders must be agreeable to these aspects.

Dr Andreas Seiter, Global Lead for Private Sector in Health at the World Bank (WB) indicated that this kind of broader partnership approach is a model of how business is done nowadays and it should occur more naturally in modern times.

"No single institution or organization can call the shots and make all the decisions regarding the work on medicines regulatory systems strengthening in Africa', Said Dr Seiter.

Dr David Mukanga said that the Bill and Melinda Gates Foundation (BMGF) strongly supports the WHO-CIP concept which allows recipients of regulatory systems strengthening support to come together around shared goals and ideas, plan together, draw lessons from each other, leverage each other's strengths, execute together, as well as jointly promote continental convergence of systems and processes to truly realize the idea of harmonization.

"The extension of the WHO-CIP principles to the Africa region through the AMRH-PP is timely as the work expands and the foundation is fully supportive of this idea", Dr Mukanga said.

He also stated that as this journey of continental coordination of partners and stakeholders is beginning through the AMRH-PP, this is also the right time to develop clear goals and targets bearing in mind the priorities at regional and country level, so that the work of the AMRH-PP can easily be measured at the end of the year to see how it is performing.

Head of Health Programs at the NEPAD Agency, Margareth Ndomondo-Sigonda indicated that there is a lot of interest from the African Union (AU) leadership to see AMRH advance and eventually transition in to the African Medicines Agency (AMA). Challenges of duplication of efforts in medicines regulatory systems strengthening and harmonization in Africa exist and these will be dealt with through effective coordination of this work through the AMRH-PP.

"NEPAD Agency's role is to facilitate effective coordination of this platform in alignment with AU policies and WHO internationally accepted standards and practices', Mrs Sigonda said.

During the meeting, it was announced that a total of 53 applications were received from different organizations and institutions expressing interest to join the AMRH-PP following the publicized call for Expression of Interest (EOI). The deadline for receiving applications was 15 March 2018. The method for for reviewing the received applications was through the use of inclusion and exclusion criteria to determine suitable members of the AMRH-PP. As a result, from the received 53 applications, 25 were accepted as members and 28 were not accepted. The applicants will soon be officially notified of this outcome. It was also announced that three (3) members of the AMRH-PP will represent the platform in the Steering Committee (SC) meetings.

Strengthening EAC M&E structures and capacity

Countries in the East African Community (EAC) benefitted from a capacity building training to equip their key personnel in the medicines regulatory system structures with knowledge in data collection on Monitoring and Evaluation (M&E) indicators related to the African Medicines Regulatory Harmonization (AMRH) M&E Guidelines. The training was organized by NEPAD Agency and the EAC Secretariat and took place in Nairobi, Kenya from 21–23 May 2018.

The main objective of the training was to improve the capacity of countries in the EAC region to monitor AMRH M&E performance indicators and eventually evaluate the outcomes and impact. Eventually, this will contribute to harmonizing and strengthening national regulatory systems for medical products in the region. The data will also be used periodically to determine the status of performance of National Medicines Regulatory Agencies (NMRAs) in the region. In addition, the training is also a step in the right direction towards strengthening existing structures and capacity within member states to collect, collate, analyse and utilise data on the selected AMRH indicators for informing policy and practice.

The data from M&E will be very useful in decision making and also identifying gaps that require special prioritization to advance the medicines regula-

tory strengthening and harmonization work in the EAC region. During the training, pilot data collected since 2014 in the EAC region was validated and this information will contribute to finalizing the EAC report, as well as highlight available baseline information and data sources for selected AMRH indicators for alignment and harmonisation. Baseline information is critical for tracking impact over time.

The training was attended by National Medicines Regulatory Officers (NMROs)/M&E focal points from NMRAs. Other representatives from regional bodies participated as observers as follows;, Intergovernmental Authority on Development (IGAD) and Organisation for the Fight against Endemic Diseases in Central Africa (OCEAC).

New AMRH Governance Framework endorsed at 2nd Steering Committee meeting

The newly revised governance framework of the African Medicines Regulatory Harmonization (AMRH) program was endorsed at the 2nd Steering Committee (SC) on Regulatory Systems Strengthening and Harmonization Initiatives in Africa. The 2018 work plan and quarter one progress report of the AMRH program were also presented to the SC members for feedback and comments. The 2nd SC meeting took place in Johannesburg, South Africa at the NEPAD Agency Head Office from 12 – 13 April 2018.

After the meeting, the necessary documents will be finalized to align with the comments and feedback received from SC members.

During the opening of the meeting, the Interim Chair of the SC Prof. Moji Christianah Adeyeye mentioned that the foundation of this meeting is to realize the vision of the AMRH in Africa and that is to ensure that African people have access to essential, quality, safe and efficacious medical products and technologies.

The Steering Committee meeting on regulatory systems strengthening and harmonization was attended by key partners and stakeholders in Johannesburg, South Africa

"As the Steering Committee, our mandate is to provide the strategic direction to ensure that the AMRH vision in Africa is achieved", Prof. Adeyeye said.

Head of Industrialization, Science, Technology and Innovation (ISTI) at the NEPAD Agency, Prof. Aggrey Ambali provided an overview of the expected outcomes of the 2nd SC meeting, as well as an outline of the specific objectives. He re-emphasized the fact that NEPAD Agency remains committed to serving the SC in its capacity as Secretariat to advance the work on medicines regulatory systems strengthening and harmonization in Africa.

World Health Organization (WHO) Global Lead – Regulatory Networks and Harmonization, Dr Samvel Azatyan presented progress report on WHO technical support to Regional Economic Communities (RECs) and programs implementation in Africa related to Medicines Regulatory Harmonization (MRH). World Bank (WB) Global Lead for Private Sector in Health, Dr Andreas Seiter provide insight on available financing for RECs MRH programs in Africa.

Progress on other initiatives, networks alignment with AMRH

The SC meeting also considered key points developed at the AMRH Partnership Platform and these were endorsed to facilitate establishment of the platform and its operational model as the Africa chapter aligned with the global WHO Coalition of Interested Parties (WHO-CIP). Furthermore, the SC meeting received updates from representatives of the United States Pharmacopoeia (USP), WHO and Paul Ehrlich Institut (PEI) and WHO to bring the SC members to speed on how the initiatives led by these organizations, as well as networks are aligning with the AMRH Initiative in the spirit of harmonization.

USP gave an update on how the Network of Medicines Control Laboratories in Sub-Saharan Africa (NOMCoL–SSA) is transforming to establish the African Medicines Quality Forum (AMQF) and how the AMQF is transitioning to align with the AMRH Initiative in a push to address challenges of poor-quality medicines; help ensure African people have access to safe, effective, quality-assured medicines. WHO presented on-going progress on collaboration and harmonization of the African Vaccines Regulatory Forum (AVAREF) and the AMRH Initiative, as two Pan-African Initiatives well positioned to improve the governance of medicines regulatory systems strengthening and harmonization work in Africa to achieve end-to-end programme impact. PEI highlighted aspects of regulation of blood and blood products in Africa and how their added value is being anchored on the strong foundation of the AMRH Initiative and its structures on the continent. All the alignment efforts contribute to the proposed future establishment of the African Medicines Agency (AMA) on the continent.

During the meeting, Prof. Moji Christianah Adeyeye was elected as Chairperson of the SC with Dr Kaimba Cyriaqueluc appointed as Vice Chairperson by a majority vote. The Chair and Vice Chair of the SC are elected from among the Heads of the National Medicines Regulatory Authorities (NMRAs) and are allowed to serve for a non-renewable term of two years.

Steering Committee meeting in session - participants adopted the new AMRH governance framework

AFRICAN MEDICINES REGULATORY CONFERENCE (AMRC) ASSEMBLY

AMRH Partnership Platform

African Union | World Health Organization | NEPAD TRANSFORMING AFRICA

AUC - WHO - NEPAD

JOINT SECRETARIAT

Steering Committee on Regulatory Systems Strengthening and Harmonization in Africa

TECHNICAL WORKING GROUPS

APAG TWG on Pharmacovigilance	**FBRA** TWG on Blood & Blood Products	**PAHWP** TWG on Medical Devices & Diagnostics	**AVAREF** TWG on Clinical Trials
AMQF TWG on Post-marketing Surveilance	TWG on Regulatory Capacity Development	TWG on Medicines Policy and Regulatory Reforms	TWG on Good Manufacturing Practices

SECRETARIAT NEPAD

ZAZIBONA Assessors Meeting

20-24 August 2018, Harare, Zimbabwe

ECOWAS GMP Inspectors Training

27-31 August 2018, Accra, Ghana

BILL & MELINDA GATES foundation | WORLD BANK GROUP | World Health Organization | African Union | NEPAD TRANSFORMING AFRICA

UPCOMING EVENTS

1st ECOWAS MRH Steering Committee Meeting

16-18 July 2018, Cape Verde

Eastern Mediteranean Drug Regulatory Authorities Conference (EMDRAC)

17-19 July 2018 - Salalah, Oman

NMQCL Managers training on utilization of QC Guidelines and Manuals

23-27 July 2018, Bamako, Mali

Seminar on Health Statistics

24-26 July, Accra, Ghana

1st African Medicines Quality Forum Meeting

06-10 August 2018, Accra, Ghana

EAC MRH Steering Committtee Meeting

28-31 August, Nairobi, Kenya

18th International Conference of Drug Regulatory Authorities (ICDRA) and AMRH Partnership Platform Side Event

03-07 September, Dublin, Ireland

Steering Committee of the African Vaccines Regulatory Forum (AVAREF)

23-29 September, Entebbe, Uganda