



Third AMRH WEEK

5 - 9 December 2022
Accra, Ghana



MINISTRY OF HEALTH
REPUBLIC OF GHANA



World Health
Organization



Your Well-being, Our Priority.

Concept Note Agenda & Programme

Theme: The African Medicines Regulatory Harmonization - A foundation for the African Medicines Agency

Background

The African Medicines Regulatory Harmonization (AMRH) Week is an event convened every two years by the [AMRH Joint Secretariat](#) which comprises the African Union Development Agency-NEPAD (AUDA-NEPAD) and the World Health Organisation (WHO) with support from the African Union Commission (AUC). The 'week' brings together high-level African leaders and policy makers, members of AMRH Steering Committee (AMRH SC), Regional Economic Communities (RECs) the AMRH Technical Committees (AMRH TCs), the AMRH Partnership Platform (AMRH PP) as well other partners and stakeholders to showcase and celebrate the successes of AMRH as well as to reflect on progress, challenges and identify opportunities for continued improvement.

The [inaugural AMRH Week](#) took place in Kigali, Rwanda in December of 2018 and was a key moment of celebration of a decade of AMRH's success and an opportunity to align with stakeholders on the coordination and collaboration needs in the medicines regulatory space across the African continent. The event was highly successful, with participation and support from the Minister of Health in Rwanda as well as many other senior officials from AUDA-NEPAD, AUC, WHO and development partners.

Two years later, the [2nd AMRH week](#) took place under completely different circumstances, with the world being at the height of a global health crisis due to the emergence of COVID-19 as a pandemic. The event was held virtually, as many countries were abiding by forced lock down measures to contain the spread of the virus which brought on a massive loss of lives and livelihoods all over the world. Due to the circumstances under which it was held, the event which was attended by over 120 participants, focused mainly on strategies for regulatory preparedness and response during public health emergencies.

National Regulatory Authorities (NRAs) across the globe, and especially in Africa and other low- and middle-income countries faced many challenges in ensuring access to quality assured medical devices, in-vitro diagnostics, personal protective equipment (PPEs) and other health products to control COVID-19. In response to these challenges, and under the guidance of the AMRH Steering Committee, the AMRH TCs provided accelerated technical support and assistance to address some of the challenges highlighted, through coordinated efforts with the member states.

Despite these many challenges, the 2nd AMRH Week also celebrated the good work done by regulators and ethics committees in facilitating COVID-19 clinical trials reviews and subsequent approvals by NRAs, monitoring of the safety of vaccines, as well as listing of medical devices including in vitro diagnostics and manufacturers of medical devices and PPEs as part of COVID-19 response. Regulators also shared their experiences on various regulatory pathways, the use of regulatory reliance and collaboration employed to address COVID-19 challenges.

Introduction

The 3rd AMRH Week takes place more than two years into the pandemic, which persists and continues to pose a threat to the health and economic status of African countries. Many African countries are also still trying to recover from the negative economic and public health impact brought on by the pandemic. Issues to do with inequitable access to vaccines are still rife as less than 25 percent¹ of Africans are vaccinated against COVID-19.

¹ <https://africacdc.org/covid-19-vaccination/>

However, the pandemic has also presented opportunities and positive ambitions for Africa. To ensure that no one is left behind, the African Union and the Africa Centres for Disease Control and Prevention (Africa CDC) called for the development of a [framework](#) to enable Africa to manufacture 60 percent of the vaccines it needs locally by 2040, to ensure self-reliance in the face of public health emergencies and beyond. This is being done through the Partnerships for Vaccine Manufacturing in Africa (PAVM) which is being supported under its regulatory workstream by AMRH TCs to ensure this vision is accelerated and realised. The 3rd AMRH Week is also very timely, as the African Medicines Agency (AMA) came into force on the 5th of November 2021². The development, adoption by the AU Assembly and subsequent coming into force of the Treaty for the establishment of the AMA is a result of the foundation built by the AMRH Initiative as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA) policy framework³. The AMRH initiative is coordinating the support of multiple partners to accelerate the operationalisation of AMA.

This year's event will present another opportunity to share experiences, good practices, and innovative responses to the pandemic by African NRAs. Additionally, it presents an avenue to launch two significant reports on Africa's pharmaceutical development and progress. Specifically, the report on access to ARVs in selected African Countries: Local supply and production of ARVs and the report on the current state of development of the local pharmaceutical manufacturing and regulatory capabilities in Africa Union (AU) recognized Regional Economic Communities. It will therefore be an opportune time to discuss strategies to accelerate the continent's capability to produce its own vaccines and other medical products and to further highlight the importance of strategic, well-coordinated partnerships as the continent moves towards the operationalisation of the AMA.

Objectives and Expected Outcomes of the AMRH Week

General Objective

The 3rd AMRH Week will showcase how the AMRH governance structure has worked with NRAs, Regional Economic Communities (RECs) and partners collaboratively, innovatively and adaptatively during the COVID-19 pandemic to ensure access to health products and towards the operationalisation of AMA. The event will also highlight the role of AMRH TCs in providing support for local vaccine production through collaboration with the PAVM structures.

Specific Objectives

- a. To take stock of the progress made in the implementation of recommendations from the second AMRH week.
- b. To highlight regulatory response to COVID-19 by NRAs, including promoting access to diagnostics and clinical trials of vaccines and therapeutics on the continent.
- c. To articulate the strong collaboration, networking and partnerships built through the TCs of the AMRH.
- d. To strengthen and build partnerships and collective action by all stakeholders for the operationalization of the AMA.
- e. To launch a report on RECs Pharmaceutical Manufacturing Capacities on the continent.

² <https://au.int/en/pressreleases/20211109/treaty-establishment-african-medicines-agency-ama-enters-force>

³ AU Executive Council Decision, {EX.CL/Dec.857 (XXVI)} of January 2015

Expected outcome

Coordinated partnerships, increased collaboration, and strengthened commitments made among AMRH stakeholders and partners in support of regulatory systems strengthening and harmonisation efforts in Africa.

Activities during the 'Third AMRH Week'

- a. To convene the EAC and IGAD MRH HoA meeting on Reliance Frameworks Monday, 05 December 2022.
- b. To convene the AMRH TC meetings: AMQF, AMDF, GMP, MPRR, EMP, on Tuesday and Wednesday, 06 - 07 December 2022.
- c. To convene the RCD TC meeting on 06 December followed by Annual RCOREs Conference, 07 December 2022
- d. To convene the AMRH Partnership Platform (AMRH-PP) business meeting, launch a report on RECs Pharmaceutical Manufacturing Capacities on the continent, followed by the AMRH Week Opening Ceremony, on Thursday, 08 December 2022.
- e. To convene the 11th AMRH Steering Committee (AMRH-SC) meeting Friday, 09 December 2022.

Participants

Participants will include policy makers and other senior government officials, leadership of AUDA-NEPAD, AUC, WHO, and Africa-CDC, the AMRH Steering Committee members, the AMRH TC members, the AMRH Partnership Platform members, leadership of the RECs Secretariats and the REC Coordinators

Dates and Venue

The AMRH week will take place in Accra, Ghana from 5th to 9th December 2022. The event will be convened in English with simultaneous interpretation in French and Portuguese.

For more information

Email | amrh@nepad.org - Website | amrh.nepad.org -
Event Page | <https://www.nepad.org/event/third-amrh-week>

Speakers & Panellists



Hon Kwaku Agyemang-Manu

Minister of Health: Ghana & Chairperson: AMA Conference of States Parties
Ministry of Health: Ghana



Madame Nardos Bekele-Thomas

Chief Executive Officer
African Union Development Agency (AUDA-NEPAD)



H.E. Amb Minata Samaté Cessouma

Commissioner: Health, Humanitarian Affairs and Social Development
African Union Commission (AUC)



Dr Ahmed Ogwel Ouma

Acting Director
Africa CDC



Prof Julio Rakotonirina

Director: Health & Humanitarian Affairs Directorate
African Union Commission (AUC)



Ms Emer Cooke

Executive Director
European Medicines Agency



Dr Matshidiso Rebecca Moeti

Regional Director
WHO-AFRO



Prof Jean Baptiste Nikiema

Regional Advisor: Essential Medicines
WHO-AFRO



Prof Mojisola Christianah Adeyeye

Director: General
NAFDAC and Chair of AMRH Steering Committee



Mrs Mimi Delese Darko

Chief Executive Officer
Ghana Food and Drug Authority, Republic of Ghana



Dr David Mukanga

Deputy Director
Africa Regulatory Systems, Global Health Division, Gates Foundation and Chairperson, the AMRH Partnership Platform



Mr Hiiti Sillo

Head of Unit: Regulation and Safety
WHO-HQ



Dr Margareth Ndomondo-Sigonda

Head: Health Programs
African Union Development Agency (AUDA - NEPAD)



Dr Boitumelo Semete

Chief Executive Officer
SAHPRA, South Africa



Mrs Chimwewe Chamdimba

Principal Policy Specialist
African Union Development Agency (AUDA - NEPAD)



Dr Dan Hartman

Director Integrated Development
Gates Foundation



Dr Adam Hacker

Head of Regulatory Affairs
CEPI



Ms Dorothy Wambeti Njagi

African Union Commission (AUC)

Draft Program for the 'Third AMRH Week' Opening Ceremony on Thursday, 08 December 2022

Theme: The African Medicines Regulatory Harmonization - A foundation for the African Medicines Agency

| Time | Activity | Responsible person/Speaker(s) |
|---------------|--|---|
| 12:30 - 13:10 | Arrival and Registration | AMRH Joint Secretariat |
| 13:10 - 13:15 | Introductory remarks | Program Director, Prof. Mojisola Christianah Adeyeye , Director: General, NAFDAC and Chair of AMRH Steering Committee |
| 13:15 - 13:25 | Welcome Remarks | Mrs Delese Mimi Darko , CEO: Ghana Food and Drug Authority, Republic of Ghana |
| 13:25 - 13:35 | Statement | Ms Emer Cooke , Executive Director, European Medicines Agency |
| 13:35 - 13:45 | Statement | Dr David Mukanga , Deputy Director, Africa Regulatory Systems, Global Health Division, Gates Foundation and Chairperson, the AMRH Partnership Platform |
| 13:45 - 13:55 | Statement | Dr Matshidiso Rebecca Moeti , Regional Director, WHO-AFRO |
| 13:55 - 14:15 | Statement | Madame Nardos Bekele-Thomas , Chief Executive Officer, AUDA-NEPAD |
| 14:15 - 14:25 | Statement | H.E. Amb Minata Samaté Cessouma , Commissioner: Health, Humanitarian Affairs and Social Development, AUC |
| 14:25 - 14:45 | Keynote Speech and Official Opening of the AMRH Week | Hon Kwaku Agyemang-Manu , Minister of Health, Ghana & Chairperson, AMA Conference of States Parties |
| 14:45 - 15:00 | Group Photo, Coffee & Tea Break, Press Briefing | |

| Time | Activity | Responsible person/Speaker(s) |
|---------------|--|--|
| 15:00 – 15:30 | Presentation of report on RECs Pharmaceutical Manufacturing Capacities on the continent | Ms Dorothy Wambeti Njagi , African Union Commission |
| 15:30 – 17:00 | Keynote address & High Level Panel Discussion on the role of regulators in addressing African public health priorities | <p>Keynote address: Dr. Ahmed Ogwel Ouma, Acting Director, Africa CDC: The changing disease epidemiology and public health priorities for Africa</p> <p>Panel Discussion (70 min):</p> <p>» Co-Moderators: Mr Hiiti Sillo, Head of Unit: Regulation and Safety, WHO-HQ and Dr Margareth Ndomondo-Sigonda, Head: Health Programs, AUDA-NEPAD</p> <p>» Panellists:</p> <ul style="list-style-type: none"> • Prof Julio Rakotonirina, Director: Health & Humanitarian Affairs Directorate, AUC • Prof. Mojisola Christianah, Adeyeye, Chair: AMRH Steering Committee • Dr Boitumelo Semete, Chief Executive Officer, SAHPRA, South Africa • Prof Jean Baptiste Nikiema, Regional Advisor: Essential Medicines, WHO-AFRO • Mrs Chimwemwe Chamdimba, Principal Policy Specialist, AUDA-NEPAD • Dr Dan Hartman, Director Integrated Development, Gates Foundation • Dr Adam Hacker, Head of Regulatory Affairs, CEPI |



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