**‘The AMRH Week’**

# 10-14 December 2018

**Kigali, Rwanda**

## CONCEPT NOTE

## 1. Introduction

The African Medicines Regulatory Harmonization week known as the “AMRH Week” stems from more than a decade’s leveraging on investments made in regulatory systems strengthening (RSS) and harmonization efforts in Africa. National Governments have been regulating medical products with a view to promote and protect public health against hazards associated with use of substandard and falsified (SF) medical products. Many African countries have had to grapple with challenges to effectively regulate the pharmaceutical sector ranging from outdated laws or inadequate legal frameworks; human and financial resources limitations; lack of elaborate infrastructure; and poor coordination of regulatory activities; just to mention a few. As a result, Partners have collaborated to assist in strengthening and improving regulatory systems and facilitating regional harmonization schemes to ensure that countries comply with internationally recognised standards.

As a result of investments from governments and partners, Africa has witnessed a sharp increase in the number of organisations involved in medicines regulatory systems strengthening interventions on the continent. No doubt that Africa stands to benefit as this number continues to grow and niche streams of work emerge. However, there would be need to strengthen-ordination to effectively harmonise the different interventions. Inter-organisation strategy could be ambiguous without proper mechanisms in place, and the limited human and financial resources are taking a knock as they get thinly spread, thereby reducing the expected impact of the interventions. This has often resulted in the duplication of similar work by different organisations in Africa.

In 2007, the African Union (AU) Conference of Health Ministers (AUCHM) responded to the AU Assembly Decision 55 (Assembly/AU/Dec.55 (IV) taken during the Abuja Summit in January 2005 which mandated the African Union Commission (AUC) to develop the Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the NEPAD Agency. A direct off-spring of this mandate was to establish the African Medicines Regulatory Harmonization (AMRH) initiative, to be implemented as part of the PMPA framework, to address challenges faced by National Medicine Regulatory Authorities (NMRAs) in Africa. As a result, the AMRH initiative was established in 2009 to provide leadership on the African continent in creating an enabling regulatory environment for pharmaceutical sector development within the ambit of the PMPA framework.

The AMRH initiative focusses on addressing gaps in medicines regulatory systems and enhancing capacity in key regulatory functions at national and regional levels. These gaps include; weak or non-coherent legislative frameworks, sluggish medicine registration processes and subsequent delayed approval decision, inefficiency and limited technical capacity, among others. The work of AMRH is guided by three focus areas; (i) policy alignment (ii) regional integration and harmonization (iii) and human and institutional capacity development. AMRH achieves these through implementation of Medicines Regulatory Harmonization (MRH) projects at regional level through the Regional Economic Communities (RECs) and Regional Health Organizations (RHOs). The impact of this approach trickles down to the national level, thereby benefitting AU Member States by providing guidance to NMRAs to determine priority areas of action for medicines regulatory strengthening and harmonization in Africa.

## 2. AMRH Success Story

Over the past decade, the AMRH initiative has made significant progress in strengthening regulatory systems and facilitating harmonization initiatives by working with regional economic communities (RECs) and regional health organizations (RHOs) in supporting African countries. Some of the success stories include;

### 2.1. Implementing Regional Harmonization (MRH) Programs

MRH has, and still is, implementing MRH Programs in the East African Community (EAC), Southern African Development Community (SADC) and the Economic Community of West African States (ECOWAS) with a view to harmonise technical standards; conduct joint review of dossier applications and inspection of manufacturing sites to facilitate faster approval of medical products. Furthermore, collaborative efforts on medicines regulation have started in the Economic Community of Central African States (ECCAS) and Intergovernmental Authority on Development (IGAD).

### 2.2. Promoting regional collaborative procedures and protocols

AMRH has strengthened implementation of regional collaboration and reduced drug approval timelines. A study has shown that regulatory review timelines for a number of branded medicines has reduced from 1–2 years to a median of 7 months, representing a reduction of 40 – 60% as a result of joint dossier assessments initiated by the MRH project in EAC.

### 2.3. Operationalising the AMRH performance indicators

Following development of the AMRH Implementation Tool Kit and Monitoring and Evaluation (M&E) Framework, a pilot was successfully conducted in 2016 in all the six (6) EAC Partner States, results will be published soon. An online M&E portal is currently being built to automate data collection, analysis and reporting.

### 2.4. Development of African Union (AU) Model Law

The AU Model Law on medical products regulation was developed to ensure effective regulation of medical products and technologies and promote harmonization. In January 2016, the AU Model Law was endorsed at the 26$^{th}$ AU Heads of State and Government Summit. A total of 12 AU countries have utilized the AU Model Law to review/amend national medicines laws.

### 2.5. Enhancing fight against Sub-Standard and Falsified (SF) medical products

Through the AMRH Initiative, the Organization of Coordination for the Fight against Endemic Disease in Central Africa (OCEAC) was supported to develop the Plan of Action against counterfeit medicines for the region. The African Medicines Quality Forum (AMQF) has been established as a continental Technical Working Group to address the challenge of prevalence of Substandard and Falsified (SF) medical products on the continent.

### 2.6. Strengthening capacity in core regulatory functions

Designated a total of Eleven (11) Regional Centres of Regulatory Excellence (RCOREs) in Eight (8) different regulatory functions across Africa in order to enhance regulatory

capacity and promote knowledge exchange through existing institutions and expertise to ensure sustainability.

### 2.7. Operationalising a 'Pool of Regulatory Experts'

Established a pool of Eighty (80) African experts in key regulatory functions to provide technical support and capacity building in medicines regulatory systems strengthening and harmonization. The pool of experts is a technical resource for supporting AU Member States and RECs.

### 2.8. Establishing AMRH Partnership Platform

Established the African-chapter of the WHO Coalition of Interested Partners (CIP), the AMRH Partnership Platform which aims to improve coordination of different partners and stakeholders in the regulatory systems strengthening and harmonization work in Africa.

### 2.9. Alignment of RSS initiatives and networks with AMRH and transition into AMA

The AMRH Initiative has embarked on alignment of regulatory systems strengthening networks and harmonization efforts across the African continent. The alignment efforts include bringing together initiatives such as the African Vaccines Regulatory Forum (AVAREF), Pan African Harmonization Working Party on Medical Devices and In-Vitro Diagnostics (PAHWP) and the Network of Official Medicines Control Laboratories–Africa (NOMCoL-Africa), just to mention a few.

### 2.10. New AMRH Governance Framework

In September 2017, the new AMRH Governance Framework was endorsed by the Steering Committee for Medical Products Regulatory Systems Strengthening and Harmonization Initiatives in Africa known as 'AMRH Steering Committee'. This is composed of; the African Medicines Regulators Conference (AMRC); the AMRH Steering Committee, the Continental Technical Working Groups (TWGs), the AMRH Partnership Platform and the AMRH Secretariat. The AMRH serves as a foundation and a critical step towards establishment of the African Medicines Agency (AMA) as per AU Executive Council Decision of January 2015.

### 2.11. Development of a Treaty for Establishment of the AMA

The AU Executive Council in January 2015 recognized the need to strengthen the capacity for regulation of medical products in Africa, and the harmonization of medicines regulatory systems as a foundation for the establishment of a single regulatory Agency for Africa within the framework of the PMPA. The Council endorsed the establishment of AMA and requested the African Union Commission (AUC), the NEPAD agency and the World Health Organization (WHO) in collaboration with other stakeholders to define the scope of the medicines or medical products that would be covered by the work of the AMA, and to work out detailed modalities, institutional framework, legal and financial implications, of the establishment of the AMA

Under the leadership of AMA Task Team, the AUC, NEPAD Agency and WHO Joint Secretariat facilitated the development of the AMA Treaty in consultation with regulators and legal experts from AU Member States. The AMA Treaty was adopted by African Ministers of Health in Geneva, Switzerland in May 2018 and will be presented for endorsement to the AU heads of State and Government after review by African Ministers of Justice.

## 3. Justification for 'AMRH Week'

The AMRH initiative has entered into a review phase since February 2017, assessing past performance and exploring strategies to galvanise the momentum and ensure financial sustainability and ownership. This provides an opportunity for partners and stakeholders to take-stock of the work of AMRH on the continent and reflect on the past decade of implementation, as well as align expectations going forward to ensure that AMRH work becomes more sustainable, and to strengthen coordination and collaboration in the medicines regulatory space.

The 'AMRH Week' for 2018 will therefore be ***officially launched in Kigali, Rwanda under the able leadership of H.E Paul Kagame, President of the Republic of Rwanda and African Union (AU) Chairperson, in collaboration with AUC Commissioner of Social Affairs and the Chief Executive Officer of NEPAD Agency.***

The event which will bring together partners and stakeholders, will highlight the current status of AMRH, review its form and shape with a view to re-energize the on-going alignment of work in the medical products regulatory space.

Specifically, AMRH Week will focus on on-going work around alignment arrangements of different partners, stakeholders, networks and similar initiatives towards the AMRH. This is a critical step towards harmonization and eventual establishment of AMA. In addition, the week-long event will serve as a platform for further consultation and discussion on strategic direction that the AMRH Initiative should be taking, as well mechanisms for better coordination of RSS and harmonization efforts in Africa that will foster ownership, collective responsibility and mutual accountability.

The launch of 'AMRH Week' in Kigali is an opportune platform to convene the EAC Heads of NMRA Forum; the RECs Secretariats responsible for coordination of regional programmes; the EAC MRH Program Steering Committee meeting; the PAHWP as a continental Technical Working Group; the AMRH PP; and the AMRH Steering Committee meeting on medical products regulatory systems strengthening and harmonization initiatives in Africa.

## 4. Objectives and Expected Outcomes of the 'AMRH Week'

The main objective is to demonstrate the AMRH success story and leverage critical synergies between relevant interventions and processes.

### 4.1. Specific Objectives:

a) To convene the EAC Heads of NMRAs Forum and the RECs meeting on Management and Monitoring of MRH Projects, on Monday, 11 December 2018;

b) To convene the EAC MRH Programme Steering Committee on Tuesday, 11 December 2018;

c) To convene the first meeting of the Pan African Harmonization Working Party as a continental Technical Working Group and the AMRH Partnership Platform (AMRH_PP) business meeting on Wednesday, 12 December 2018;

d) To launch the 'AMRH Week" on 10th December as part of the 4th Steering Committee meeting on regulatory systems strengthening and harmonization initiatives in Africa which will be held from 13-14 December 2018.

### 4.2. Outcomes

a) Common understanding and appreciation of alignment and transitional arrangements towards AMA.

b) AMRH PP and the 1st Pan African Harmonization Working Party Technical Working Group meetings convened.

c) AMRH week officially launched during the 4th Steering Committee meeting on regulatory systems strengthening and harmonization initiatives in Africa.

d) Knowledge on AMRH implementation model popularized and political advocacy secured.

## 5. Participants

Expected participants will include executives from AU organs namely the African Union Commissions, Pan African Parliament, NEPAD Agency and Regional Economic Communities; Chief Executive Officers of National Medicines Regulatory Agencies; UN Agencies, Multilateral and Bilateral Partners, International Partners; Policy Makers and experts from the AU Member States and RECs, Development Partners and Stakeholders, leadership and experts from the EAC Secretariat; Members of the AMRH Partnership Platform and Members the AMRH Steering Committee.

Stakeholders, Members of the AMRH Partnership Platform and AMRH Steering Committee

## 6. Dates and Venue

The AMRH week will take place in Kigali, Rwanda from 10-14 December 2018 at a venue to be communicated.

## 7. Agenda Opening Ceremony/Launch AMRH Week (draft)

**Theme: Regulatory harmonization – a building block of the African Medicines Agency**

**10 December 2018**

| Time | Session | Speakers |
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| 08.00 – 09.00 hrs | Arrival and Registration | AMRH Secretariat |
| 09.00 – 09.10 hrs | Welcome Remarks | Program Director, Minister of Health, Republic of Rwanda |
| 09.10 – 09. 20 hrs | Statement | Director BMGF |
| 09.20 – 09. 30 hrs | Statement | NEPAD CEO |
| 09.30 – 09.40 hrs | Statement | Commissioner for Social Affairs |
| 09:40. – 10.00hrs | Keynote Speech and Official Launch of AMRH Week | AU Chair/President of Republic of Rwanda |
| **10:00. – 10.30hrs** | **Group Photo, Coffee & Tea Break, Press Briefing** | |
| 10.30 – 11.30 hrs | Panel Discussion of the theme | Co-Moderator – Head-ISTI, NEPAD Agency & Director Africa CDC<br>- Regional Director WHO AFRO<br>- Director World Bank |

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| | | - Chair, AMRH Steering Committee |