The African Medicines Regulatory Harmonization (AMRH) Initiative

Prof Moji Christianah Adeyeye, FAAPS, FAS
Director General, NAFDAC
Steering Committee Chair, AMRH

NEPAD Planning and Coordinating Agency

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OUTLINE

- Background & Context
- Key Accomplishments, Challenges & Lessons Learnt
- How will the AMRH-AMA Vision be financed?
Lack of access to quality, safe and efficacious medicines is a key contributing factor to these health problems. Partly due to general lack of local pharmaceutical manufacturing or tools to work with, and weak medicines regulatory systems including the supply chain control.
Background & Context...

2005: AU Decision 55 on Development of the Pharmaceutical Manufacturing Plan for Africa (PMPA) within the NEPAD Framework

2007: AU Ministers Decision on PMPA
2012: PMPA Business Plan &
2015: AU Executive Council Decision on AMRH as foundation for African Medicines Agency (AMA)

Creating an Enabling Regulatory Environment---AMRH

Increased access to medical products and technologies

Pharmaceutical sector development (Optimizing the African Market for new medical products and technologies)

Source: AMRH/NEPAD Agency July 2016
Background & Context...

55 | African Union Member States

1.13 billion
Number of people on the African Continent

Regional economic communities recognised by African Union

"achieve access to safe, effective, quality and affordable essential medicines and vaccines for all".
AMRH Overview

Is a partnership initiative formalized in 2009 and launched in the East African Community countries in 2012 (Tanzania, Uganda, Kenya, Burundi, Rwanda)

Partnership includes African countries (regulatory authorities) and regional blocs, NEPAD, AUC, PAP, WHO, Gates Foundation, DFID, PEPFAR/USG, GAVI, World Bank

Aims to improve the fragmented regulatory system for product registration in Africa by changing from a country-focused approach to a collaborative regional and simplified one

Stepwise approach - start by harmonizing and streamlining technical requirements for product registration, leading to increased and timely product access

Creates a platform to build African regulatory capacity by region
AMRH Overview

Regional regulatory platforms
- Harmonized standards (technical requirements / guidelines)
- Joint and regional dossier assessments / GMP inspections
- Work sharing / pooling of resources
- Streamlined decision-making processes

- Reduced registration cycle time... ...starting with generics ...extending to other product categories (NCEs, vaccines, diagnostics)
- Extending to other regulatory functions over time (clinical trials, safety surveillance, etc.)
- Extending to other African regional blocs

Source: AMRH/NEPAD Agency
July 2016
African Union Vision

55 countries ➔ 5 regions ➔ 1 continent

Source: adapted from AMRH/NEPAD Agency July 2016
AMRH Strategic Direction V2 (2016-2020)

**Vision**
African people have access to essential medical products and technologies

**Mission**
Provide leadership in creating an enabling regulatory environment for pharmaceutical sector development in Africa

### Strategic Direction 1: Policy Alignment & Regulatory Reforms
**SO:** Enhanced policy coherence in RECs and member states for public health and pharmaceutical industry development

**Targets**
- At least 3 regions have adopted regional policies and legal frameworks for regulation of medicines by 2020
- At least 25 countries have domesticated the Model Law on Medical Products regulation by 2020 – West Africa Pilot
- At least 3 regions have implemented Innovative GMP Certification Schemes by 2020

### Strategic Direction 2: Regional integration and harmonization
**SO:** Increased use of harmonized policies and regulatory frameworks by member states

**Targets**
- MRH projects implemented in 5 RECs by 2020
- AMRH project scope expanded to clinical trials oversight, PMS, PV, medical devices and diagnostics in 5 regions by 2020
- MRH M&E framework implemented in 3 regions by 2020
- At least 2 regional medicines agencies established by 2018

### Strategic Direction 3: Human and institutional capacity development
**SO:** Increased human and institutional capacity for regulation of medical products and technologies

**Targets**
- 15 regional centres of regulatory excellence operational by 2020
- Curricula on Regulatory Science in alignment with Global Competency Framework by 2018
- 10% increase in the number of regulatory experts in Africa by 2020

### Strategic Direction 4: Enabling Environment: Coordination, partnership and resource mobilization
**SO:** Effective execution of programmes on regulation of medical products and technologies

**Targets**
- Scientific & Regulators conferences convened biennially
- At least 4 functional Technical/Expert Working Groups (TWGs) by 2018:
  - PRR
  - RCD
  - GMP
  - Clinical Trials & Ethics ; Alignment with AVAREF
- AMRH transitioned into AMA by 2018
Key Accomplishments
Key Accomplishments

Targets

• At least 3 regions have adopted regional policies and legal frameworks for regulation of medicines by 2020

• At least 25 countries have domesticated the Model Law on Medical Products regulation by 2020 – West Africa Pilot X

• At least 3 regions have implemented Innovative GMP Certification Schemes by 2020

By end of 2018

- 2 RECs/RHOs (EAC & CEMAC-OCEAC) adopted regional policies frameworks on regulation of medical products

- 14 countries domesticated the AU Model Law

- 2 RECs implementing regional GMP schemes
# Key Accomplishments

## Targets

- MRH projects implemented in 5 RECs by 2020
- AMRH project scope expanded to clinical trials (CT) oversight, PMS, PV, medical devices and diagnostics in 5 regions by 2020
- MRH M&E framework implemented in 3 regions by 2020
- At least 2 regional medicines agencies established by 2018

## By end of 2018

- RECs MRH Governance structure operational (Steering Committee, Expert Working Groups, Harmonized Guidelines (registration, GMP, QMS, IMS), standard operating procedures, REC MRH Project Management Tools
- 3 RECs (EAC, SADC, ECOWAS) implementing MRH projects
- PV, CT & Medical Devices added as part of AMRH Programme
- M&E Framework endorsed by AMRH Steering Committee for operationalization in all RECs implementing MRH Projects
- EAC and ECOWAS in the initial stages of establishing regional medicines agencies
Key Accomplishments

Target

• 15 regional centres of regulatory excellence operational by 2020
• Curricula on Regulatory Science in alignment with Global Competency Framework by 2018
• 10% increase in the number of regulatory experts in Africa by 2020

By end of 2018

- 11 RCOREs operational in different fields of regulatory expertise
- RCOREs curricula aligned with Global Competency Framework
- Review to be conducted in 2019
Key Accomplishments

Target

- Scientific & Regulators conferences convened biennially
- At least 4 functional Technical/Expert Working Groups (TWGs) by 2018:
  - Policy and Regulatory Reforms
  - Regulatory Capacity Development
  - GMP
  - Clinical Trials & Ethics; Alignment with AVAREF
- AMRH transitioned into AMA by 2018

By end of 2018

- 3 scientific and regulators conference conducted since 2013
- February 2017, new AMRH Governance Framework
- Eight continental TWGs at different levels of functionality; AVAREF serves as TWG on clinical trials oversight under the new AMRH Governance Structure
- Treaty for establishment of AMA endorsed by Ministers of Health and Ministers of Justice & Legal Affairs for consideration by the AU Summit in February 2019
Key Accomplishments (cont’d)

**Milestone 1**
Established governance framework (systems and structures) for harmonization of regulatory standards at regional and continental levels such as Technical Working Groups and Steering Committees and regional and continental levels.

**Milestone 2**
Regulatory capacity for marketing authorization, GMP inspections and clinical trials oversight strengthened.

**Milestone 3**
Improved legal frameworks for regulation of medical products using the AU Model Law as a reference guide.

**Milestone 4**
Improved reliance amongst countries e.g. in the EAC region, a lead country for registration of products, GMP inspections, pharmacovigilance e.t.c; provides technical leadership in the coordination of joint regulatory activities.

**Milestone 5**
Shorter approval timelines for products assessed through the RECs e.g. ZAZIBONA (median 9 – 10 months) compared to the time to market authorization for products assessed in the individual countries and subsequent improved market access by manufacturers.
AMRH Governance Framework...

African Medicines Regulators Conference (AMRC)

ASSEMBLY

AUC-NEPAD-WHO Joint Secretariat

AMRH Steering Committee

Technical Working Groups (TWGs)

AMRH Partnership Platform

NEPAD/WHO Secretariat

- TWG on Regulatory Capacity Development
- AVAREF TWG on Clinic Trials
- APAG TWG on Pharmacovigilance
- AMQF TWG on Market Surveillance
- FBRA TWG on Blood and Blood Products
- PAHWP TWG on Medical Devices
- TWG on Medicines Policy and Regulatory Reforms
- TWG on GMP
5 Key Challenges

1. **REG. CAPACITY**
   Varying levels of regulatory capacity among countries participating in a regional platform for harmonization of medical products regulation with subsequent delayed national decision making by some countries following approval of jointly assessed products.

2. **FRAMEWORKS**
   Inadequate legal framework for regulation of medical products.

3. **GUIDELINES**
   Varying guidelines and standards for registration of medicines, quality management systems and information management systems across RECs.

4. **TECH. CAPACITY**
   Limited technical capacity to manage and coordinate MRH Programs at national, regional and continental levels.

5. **RESOURCES**
   Availability of resources to undertake a fully-fledged regional medicines regulatory harmonization project & its sustainability.
Lesson 1
Regional integration and harmonization of policies, guidelines and standards of practice is critical for building national regulatory capacity through work sharing, information sharing, twinning programs e.t.c..

Lesson 2
Management, monitoring and evaluation tools for RECs MRH Programs is important to ensure accountability for results.

Lesson 3
Clear Governance structures involving national Heads of NMRAs and experts is key for ownership and leadership.

Lesson 4
Need for advocacy at all levels e.g. Policy makers, parliamentarians, health care professionals, industry.

Lesson 5
Need for effective coordination of partners and resource mobilization.
Thank you!