The African Medicines Regulatory Harmonization (AMRH) Initiative: Update on Continental Progress

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A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
PRESENTATION OUTLINE

1. Background & Context
2. The AMRH Initiative Model
3. Achievements, Challenges & Lessons Learnt
4. New AMRH Governance Framework & Alignment of Regulatory Networks & Forums
5. AU Vision for AMRH
**BACKGROUND & CONTEXT**

- **55** | African Union Member States

- **1.13 billion** | Number of people on the African Continent

- **8** | AU Recognised Regional Economic Communities

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**AGENDA 63 GOALS**

1. A High Standard of Living, Quality of Life and Well-Being for all Citizens
2. Healthy and well nourished Citizens

“achieve access to safe, effective, quality and affordable essential medicines and vaccines for all”.

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BACKGROUND & CONTEXT...

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

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

2012: PMPA Business Plan

Creating an Enabling Regulatory Environment---AMRH

Increased access to medical products and technologies

Source: AMRH/NEPAD Agency July 2016
- 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, AUDA-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

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

**The Pathway**

**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**
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Key Accomplishments

Milestone 1
Established AMRH governance framework (systems and structures) for medical products regulatory systems strengthening and harmonization networks & forums

Milestone 2
Regulatory capacity: 11 RCOREs designated for different regulatory functions e.g. MA, GMP inspections, PV & Clinical trials oversight

Milestone 3
17 AU Member States domesticated AU Model Law on Medical Products Regulation, Increased # of Autonomous Agencies e.g ECOWAS (10/15), EAC (5/7)

Milestone 4
Increased # of ISO 9001:2015 EAC (3); ECOWAS (5)

Milestone 5
Shorter approval timelines for products assessed through the RECs e.g. EAC, SADC-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.

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AMRH Governance Structure

African Medicines Regulators Conference (AMRC)

AMRH Steering Committee

Continental Technical Working Groups (CTWGs)
- TWG on Regulatory Capacity Development
- APAG TWG on Pharmacovigilance
- AMQF TWG on Market Surveillance
- FBRA TWG on Blood and Blood products
- TWG on Medicines Policy and Regulatory Reforms
- TWG on GMP

AMRH Partnership Platform

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5 Key Challenges

1. **REG. CAPACITY**
   - Varying levels of regulatory capacity among participating countries in a regional harmonization project.

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. **RESOURCES**
   - Availability of resources to undertake a fully-fledged regional medicines regulatory harmonization project & its sustainability.

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

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5 Lessons Learnt

Lesson 1
Regional integration and harmonization of policies, guidelines and standards of practice as a vehicle for building national regulatory capacity e.g. 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

1. 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 Pharmaceutical Manufacturing Plan for Africa.

2. Endorsed the establishment of the African Medicines Agency (AMA); and

3. Requested the AUC, AUDA-NEPAD and 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.
AFRICAN MEDICINES AGENCY

55 COUNTRIES
8 REGIONS
1 CONTINENT

A decade of regulatory harmonization
Thank you!