AFRICAN MEDICINES REGULATORY HARMONIZATION -AMRH :

CURRENT TRENDS

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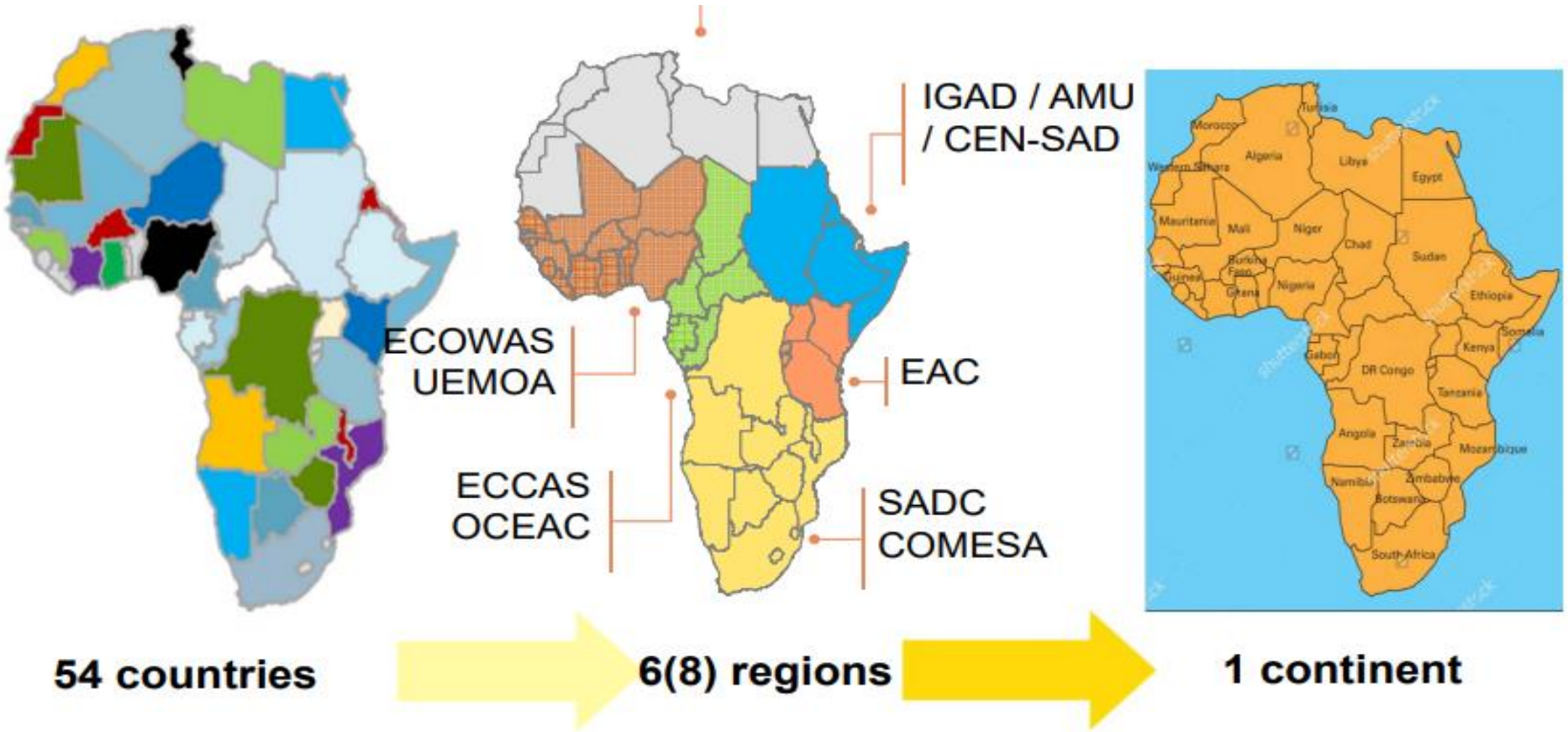
AFRICAN MEDICINES AGENCY (AMA)

- Arab Maghreb Union (UMA)
- SADC)
- East African Community (EAC)
- Economic Community of Central African States (ECCAS)
- Economic Community of West African States (ECOWAS)
- Intergovernmental Authority on Development (IGAD)



PURPOSE OF AMA Establishment

- Seeks to coordinate and strengthen continental initiatives to harmonise medical products regulation.

- Provide guidance and technical support to improve access to quality, safe and efficacious medical products.

- AMA will work within the existing continental architecture of Regional Economic Communities (RECs) and Regional Health Organizations (RHOs) to support AU Member States.

HARMONIZATION EFFORTS-REGIONAL BLOCS

- ECOWAS-ECONOMIC COMMUNITY OF WEST AFRICAN STATES.
- EAC – EAST AFRICAN COMMUNITY
- SADC – SOUTHERN AFRICAN DEVELOPMENT COMMUNITY
- ECCAS – ECONOMIC COMMUNITY OF CENTRAL AFRICAN STATES.
- IGAD – INTERGOVERNMENTAL AUTHORITY ON DEVELOPMENT

ECOWAS- Medicines Regulatory Harmonization.

MAJOR ACHIEVEMENTS

1. Established Steering Committee comprising Heads of the NMRAs.

2. Establishment of seven (7) Expert Working Groups (EWGs).

3.ECOWAS: NEW REGIONAL GUIDELINES

Medical Products Dossier Evaluation and Registration	17
Good Manufacturing Practice & Inspections	10
Clinical Trials, Pharmacovigilance and Medicines Safety	5
Quality Management System (QMS)	10
Quality Control Laboratory (QC)	4

ECOWAS-HARMONIZED GUIDELINES ON BIOLOGICAL PRODUCTS

Harmonized guidelines for biologics:

1.Quality

2.Non-Clinical

3.Clinical

EAC- Medicines Regulatory Harmonization

- EAC –MRH was established in 2012
- Six (6) countries are involved : Burundi, Kenya, Rwanda, Tanzania, Uganda and South Sudan.
- Three key areas of harmonization with lead technical working group:
  - Joint Medicines Evaluation and Registration (MER)
  - Good Manufacturing Practice Inspections (GMP)
  - Quality Management Systems (QMS)
  - Information Management Systems (IMS)
- These working groups have developed harmonized guidelines, requirements, and standards for GMP, MER and QMS which were approved by the council of Ministers in 2014.
- The EAC Secretariat and member state NRAs—in collaboration with the World Health Organization (WHO) and other stakeholders—began joint dossier assessment in 2015

SADC- Medicines Regulatory Harmonization

- SADC –MRH commenced in 2009 and was launched in 2015

- Key harmonization efforts include:
  - Development of the SADC Medicines Regulatory Strategic Framework 2015-2020
  - Adoption of the CTD format for Medicines registration
  - Regional Guidelines for medicines registration
  - ZANZIBONA Project-established as a collaborative procedure for medicines registrations between four SADC countries, namely Zambia, Zimbabwe, Botswana and Namibia.
  - The ZAZIBONA initiative has evaluated 154 product applications over 13 meetings since October 2013

North/North-eastern Africa (IGAD) - Medicines Regulatory Harmonization

- IGAD Harmonization efforts commenced as far back as 2010.

- In April 2016, the IGAD Member States signed the Khartoum Declaration.
  - Declaration was towards implementation of Regional Medicines Harmonization program.
  - To strengthen NMRAs in the region with inadequate regulatory systems.
  - To strengthen partnerships between IGAD Member States to ensure regulatory harmonization.

ECCAS- Medicines Regulatory Harmonization

- Harmonization efforts started in 2013 with the adoption of common pharmaceutical policy by member states.

- A mapping exercise was carried out in 2016 to establish the status of regulatory systems in Member States.
  - This was to help inform the AMRH project development process.

- A Steering Committee for the implementation of the MRH Project was launched in November 2016.
  - To provide oversight in the implementation of joint activities.
  - Committee to coordinate the implementation of Medicines Regulatory Harmonization.

STAGE OF HARMONIZATION PROCESS

- African ministers of health have unanimously adopted the Treaty for the establishment of the African Medicines Agency (AMA).

- It is expected to be endorsed by heads of states and governments of the African Union at their next major summit in January 2019.

CONCLUSION- AMRH Project

- The AMRH project has seen significant progress inspite of the numerous challenges and obstacles.

- It has mobilized both technical and financial resources to advance the Medicines Regulatory Harmonization in Africa.

- The program has recorded concrete milestones, especially in the EAC and SADC regions, where harmonized regulatory frameworks have been established and implemented.

CONCLUSION- AMRH Project

- However, more work is required to realize the African Union Vision, which is to establish a single African Medicines Agency(AMA).

- The establishment of the AMA will build upon the preexisting structures of the Regional Economic Communities (RECs) based the framework of the Pharmaceutical Plan for Africa (PMPA).

- More work is required to drive the AMRH implementation processes in other Regional Economic Communities, such as the North/Northern East Africa and the Central Africa.

Thank you for your attention