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
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
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
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.
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 on 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