THE AFRICAN MEDICINES REGULATORY HARMONIZATION INITIATIVE (AMRH)

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Regulatory Harmonisation Background

2007: AU Decision on Pharmaceutical Manufacturing Plan for Africa (PMPA)

2012: PMPA Business Plan & AU-Roadmap on Shared Responsibility & Global Solidarity for AIDS, TB & Malaria response in Africa

2015: AU Executive Council Decision on AMRH as foundation for African Medicines Agency (AMA)

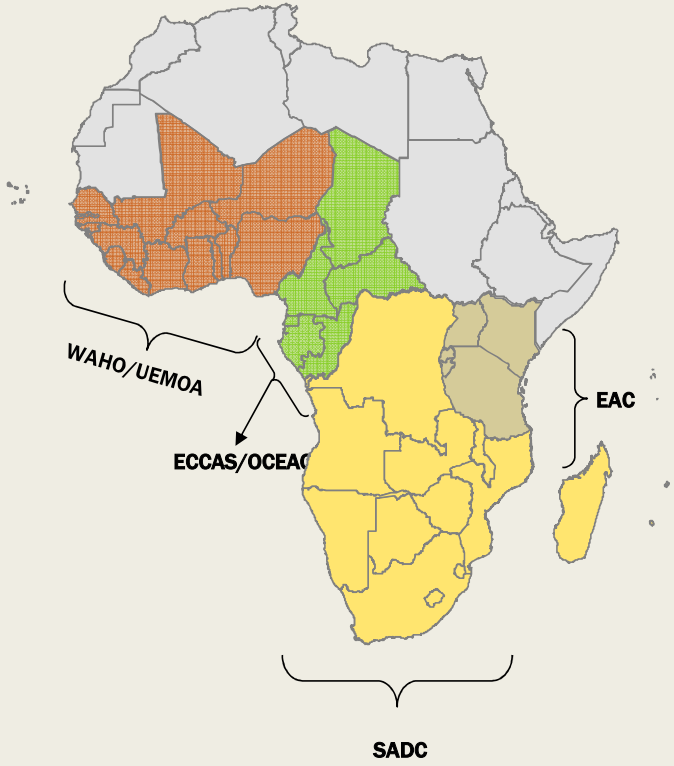
Creating an Enabling Regulatory Environment AMRH

Optimizing the African Market for new medical products and technologies

Increased access to medical products and technologies

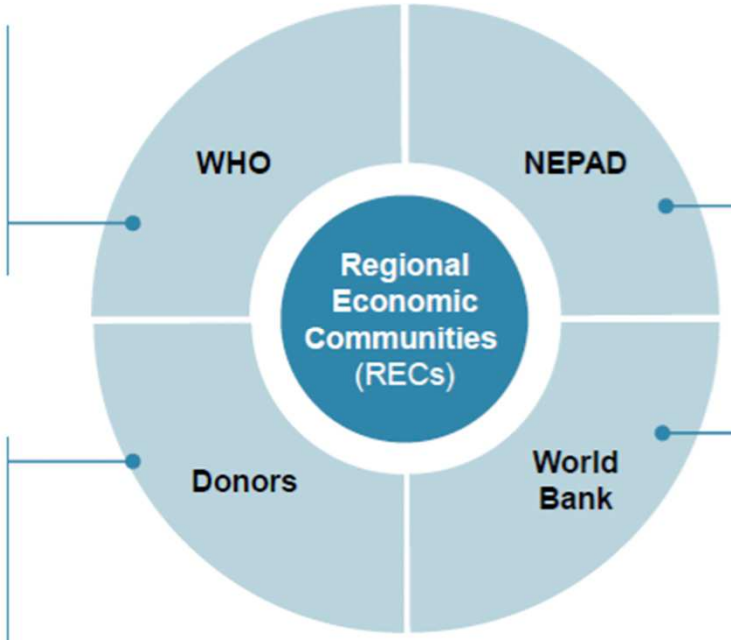
AMRH Programme Overview

- Improve the fragmented regulatory system for product registration in Africa
- Creates a platform to build African regulatory capacity by region.
- Harmonize the registration process including joint inspections.
- Currently, 85% of Sub-Saharan Africa is implementing registration harmonization process



AMRH: Core Partners and Roles

- **Leads technical support to implementation**
- **Coordinates technical support from other technical partners** (e.g. Swissmedic)



- **Leads political, advocacy, and communications efforts**
- **Coordination, and lesson sharing across RECs**

- **Provide funding or in-kind support.** Includes BMGF, DFID, US Government, GAVI, World Bank, Swiss Agency for Development and Cooperation (SDC)
- **Oversight for effective fund utilization**

- **Manages Trust Fund** and fund disbursement to recipient organizations
- **Monitors and supports local implementation**

EAC Medicines Regulation Harmonization Programme

- **Launched** on 30th March 2012
- **Purpose***: Increase access to good quality, safe and effective medicines*
- **Expected** outcomes:
  - *Harmonized Guidelines and Procedures implemented by NMRAs*
  - *Integrated Information Management System (IMS) implemented*
  - *Quality Management System (QMS) implemented by all NMRAs*
  - *Regional and national capacity to implement EAC MRH*
  - *A platform for information sharing created*
  - *Framework for mutual recognition of regulatory decision developed and implemented*

MRH: Stepwise Approach

The Pathway

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***

EAC: MRH Targets

- EAC guidelines implemented by year 3
- Registration targets
  - *18 products registered through joint assessments*
  - *75 products registered by TFDA (Tanzania Mainland), NDA (Uganda) and PPB (Kenya)*
  - *50 products registered by ZFDB (Tanzania Zanzibar), DPML (Burundi) and MOH-PTF (Rwanda)*
- Capacity built at NMRAs
  - *Assessors, GMP Inspectors trained*

MRH Progress to Date

- Harmonized requirements approved by Council of Ministers in Sept, 2014;
  - Registration, GMP and QMS
  - Effective from 1st Jan. 2015;
  - Adopted by all EAC NMRAs
- Centre of excellence established
  - MER – TFDA (TZ)
  - GMP – NDA (UG)
  - Pharmacovigilance – PPB (KE)
- Information Mgt System functional at TFDA
  - Ongoing installation to other NMRAs

EAC Procedure for Marketing Authorization established and functional since January, 2015

- 32 applications received for joint assessment; 27 evaluated
- 23 queried and 4 products registered

Joint GMP inspections conducted;

5 facilities approved

Assessors & GMP Inspectors trained

- On going joint activities

MRH: Challenges Observed

- Approval process still lengthy, although median time down to 7 months from 12 months
- Joint evaluation of applications: ongoing, but slow
- Varied capacity in terms of infrastructure, financial and human resources among EAC RAs
- Poor quality dossiers and delayed/partial responses from applicants
- Increased cost for domestic applicants
- List of priority products for registration prepared by EAC and NMRAs favoured products from outside the EA region

MRH: Expected Advantages

- Quick access to one Regional market
- More attractive for potential investors (40-60% reduction in approval times for foreign brands)
- More locally manufactured products registered (however, this is not yet the case)
- Joint medicinal product dossier assessments, GMP inspections and electronic submissions – saves time and scarce resources
- Industry responds to ONE set of queries from evaluated dossiers
- No need to prepare for individual NMRA's inspection

Thank you