The African Medicines Regulatory Harmonization: Continental Progress Update

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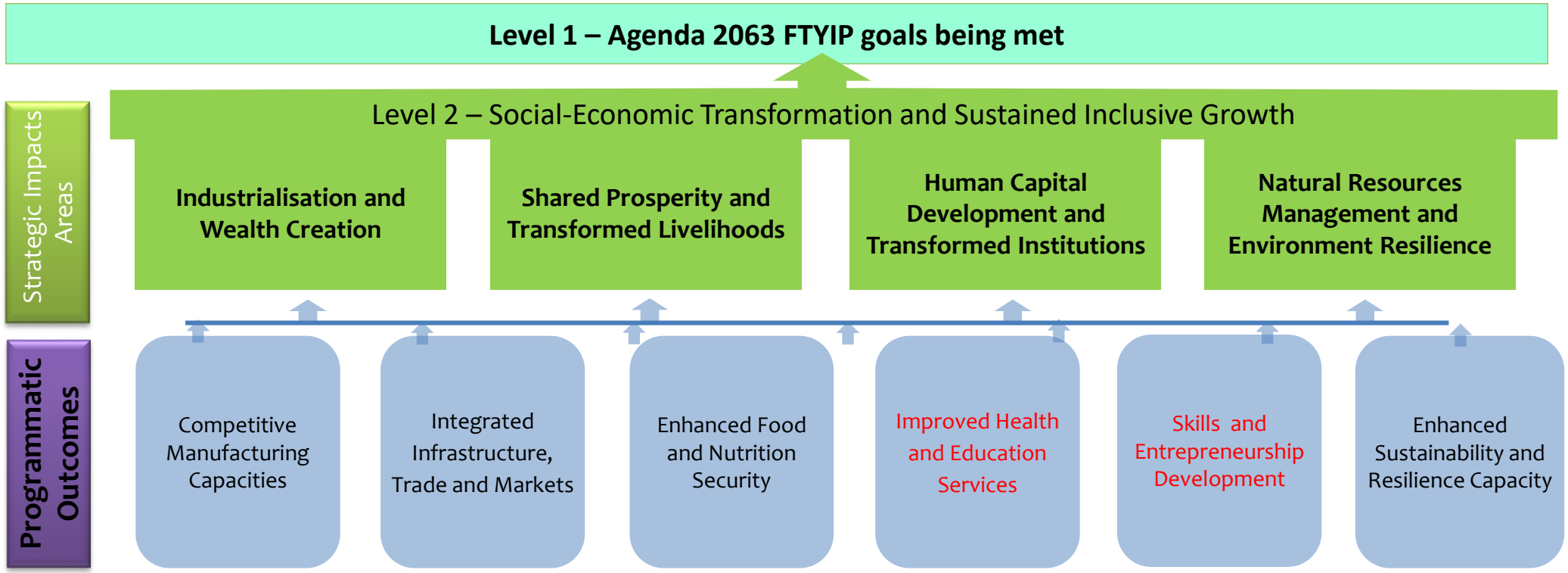
NEPAD Agency Mandate

- Facilitating & coordinating implementation of continental and regional priority programmes & projects
- Mobilising resources & partners in support of implementation of Africa's priority programmes & projects
- Conducting & coordinating research & knowledge management
- Monitoring & evaluating the implementation of programmes & projects
- Advocating on the AU and NEPAD vision, mission and core principles/values

Agenda 2063 Aspirations	Agenda 2063 Goals mapping			
1. A Prosperous Africa, based on Inclusive Growth and Sustainable Development	**Goal 4:** Transformed economies and Job creation	**Goal 1:** A high standard of living, quality of life and wellbeing for all citizens	**Goal 2:** Well educated citizens & skills revolution underpinned by science, technology & innovation	**Goal 7:** Environmentally sustainable and climate resilient economies and communities
	Goal 5: Modern agriculture for increased production & productivity	**Goal 3:** Healthy and well-nourished citizens		
	Goal 6: Blue/Ocean economy for accelerated economic growth			
2. An Integrated Continent, Politically United, based on the Ideals of Pan Africanism and the Vision of Africa's Renaissance	**Goal 8:** A United Africa (Federal or Confederate)		**Goal 9:** Continental financial and monetary institutions established and functional	
	Goal 10: World class infrastructure criss-crosses Africa			
3. An Africa of Good Governance, Democracy, Respect for Human rights, Justice and Rule of Law		**Goal 11:** Democratic values, practices, universal principles of human rights, justice & rule of law entrenched	**Goal 12:** Capable Institutions and transformative leadership in place	
4. A Peaceful and Secure Africa	**Goal 13:** Peace, security and stability is preserved		**Goal 15:** A fully functional and operational African Peace Security Architecture	
	Goal 14: A stable and peaceful Africa			
5. Africa with a Strong Cultural Identity, Common Heritage, Values and Ethics		**Goal 16:** African cultural renaissance is pre-eminent		
6. An Africa whose Development is people-driven, especially relying on Potential offered by its Women & Youth & well cared for Children		**Goal 17:** Full gender equality in all spheres of life		
		Goal 18: Engaged and empowered youth and children		
7. An Africa as a Strong, United & Influential Global Player & Partner	**Goal 19:** Africa takes full responsibility for financing her development		**Goal 20:** Africa as a major partner in global affairs & peaceful co-existence	
Consolidated NEPAD Agency priority impact areas	**Industrialisation and Wealth Creation**	**Shared Prosperity and Transformed Livelihoods**	**Human Capital Development and Transformed Institutions**	**Natural Resources Management and Environment Resilience**



Services

- Analytics (GIS, Foresight), STI and Knowledge support
- Evidence-based planning; Policy research and
- Impact assessment, M&E and learning
- Brokering financing and financing partnerships (including quality of financing and development of domestic financing)
- Brokering and leveraging technical partnership and alliances
- NEPAD Flagship projects and programmes

AMRH Background

2005: AU Decision55 on Development of the Pharmaceutical Manufacturing I Africa (PMPA) within the NEPAD Framework

Increased access to medical products and technologies

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

Creating an Enabling Regulatory Environment---AMRH

2007: AU Ministers Decision on PMPA

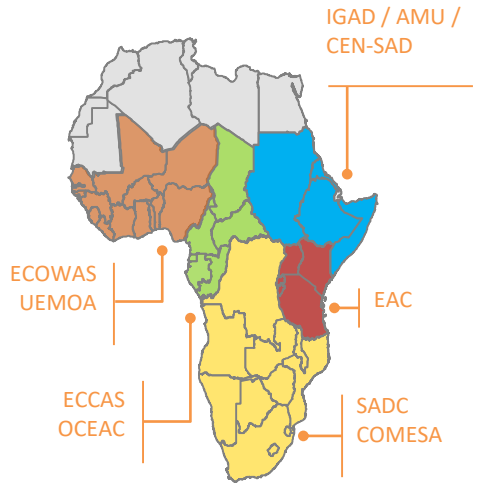
2012: PMPA Business Plan &

AU-Roadmap on Shared Responsibility & Global Solidarity for ATM response in Africa

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

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**



The Pathway

Regional regulatory platforms

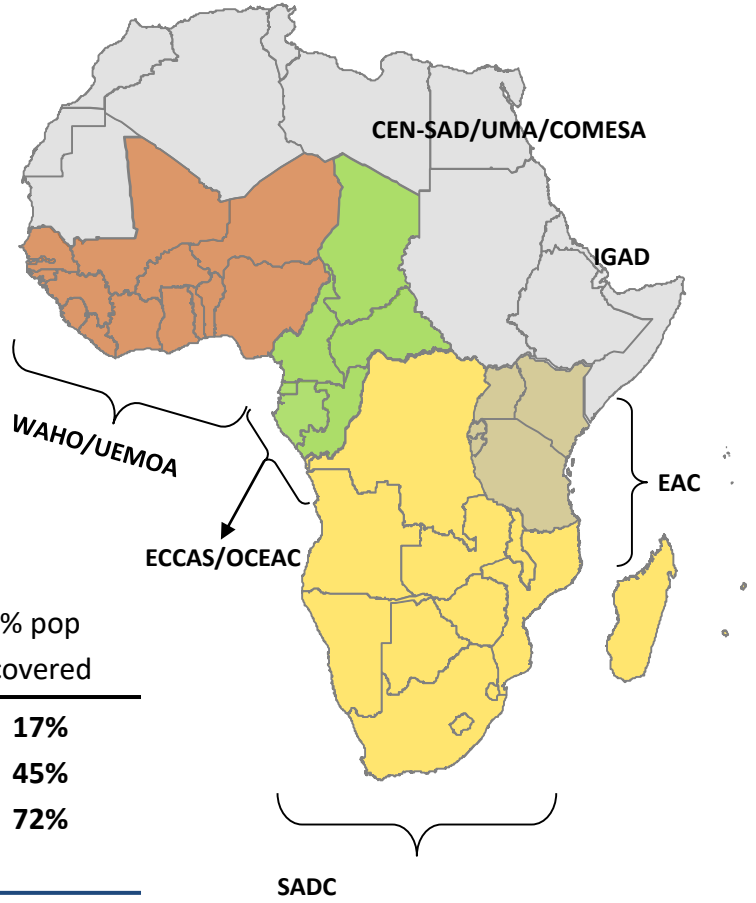
- Harmonized standards (technical requirements / guidelines)
- Joint and regional dossier assessments /GMP inspections
- Work sharing / pooling of resources
- Streamlined decision-making processes

- ***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***

> 85% of Sub-Saharan Africa covered with medicines registration harmonization (MRH) Projects at different levels

REC progress

REC	Status	Comments
EAC	Implementation	Launched March 2012
CEMAC-OCEAC	In progress	Launch Nov. 2016
WAHO/UEMOA	Implementation	Launched Feb 2015
SADC	Implementation	Launched July 2015
IGAD	Project Preparatory Phase	2016/2017



Completed or in-process RECs	Countries covered	Total members*	% pop covered
EAC & OCEAC	12 (20%)	11	17%
EAC, OCEAC, ECOWAS	26 (46%)	26	45%
EAC, OCEAC, ECOWAS, SADC	41 (74%)	41	72%

EAC Pharmacovigilance Project,
AVAREF alignment with AMRH on clinical trials ethics and regulatory oversight

AU Model Law on Medical Products Regulat on

7 Things you need to know about the African Union (AU) Model Law on Medical Products Regulat on

Legislat ve framework aimed at guiding AU Member States and Regional Economic Communit es (RECs) in harmonising medical products regulatory systems

Developed as a result of the partnership between the African Union Commission (AUC), NEPAD Agency, Pan-African Parliament (PAP) and other key cooperat ng partners

Offi cially endorsed by African Heads of State and Government at the African Union (AU) Summit in Addis Ababa, Ethiopia in January 2016

The AU Model Law is available in four (4) different languages; English, French, Portuguese and Arabic to ensure that it is appreciated across African countries that speak different languages

Contributes to the AU Pharmaceut cal Manufacturing Plan for Africa (PMPA) and the Roadmap for Shared Responsibility and Global Solidarity for the AIDS, TB and malaria response in Africa

Strengthens nat onal Laws on medical product regulat on and promotes autonomous Nat onal Regulatory Authorit es (NRAs). AU Member States are at liberty to domest cate and adapt the AU Model Law to ensure alignment with their Const tut onal principles and legal systems

Sat sfies World Health Organizat on (WHO) best pract ces on medical products regulat on and is aligned with WHO recommendat ons and internat onal safety and quality standards

NEPAD TRANSFORMING AFRICA

AMRH
African Medicines Regulatory Harmonisation Programme

Regional Centres of Regulatory Excellence (RCOREs)

NEPAD TRANSFORMING AFRICA

AMRH African Medicines Regulatory Harmonisation Programme

What is the role of RCOREs?

RCOREs will produce regulatory workforce in Africa by performing the following roles:

1. Providing academic and technical training in regulatory science applicable to different regulatory functions and managerial aspects.
2. Contribute to skills enhancement through hands-on training, twinning and exchange programmes among NMRAs.
3. Encourage practical training through placement in pharmaceutical industry.
4. Execute operational research to pilot-test innovations and interventions to inform best practices for scale up to other NMRAs.

What is an RCORE?

A Regional Centre of Regulatory Excellence (RCORE) is a designated institution or partnership of institutions with specific regulatory science expertises as well as training capabilities. This initiative was established by the NEPAD Agency's AMRH programme to fill an existing gap and address the regulatory capacity challenges experienced by National Medicines Regulatory Authorities (NMRAs) and the pharmaceutical industry in Africa.

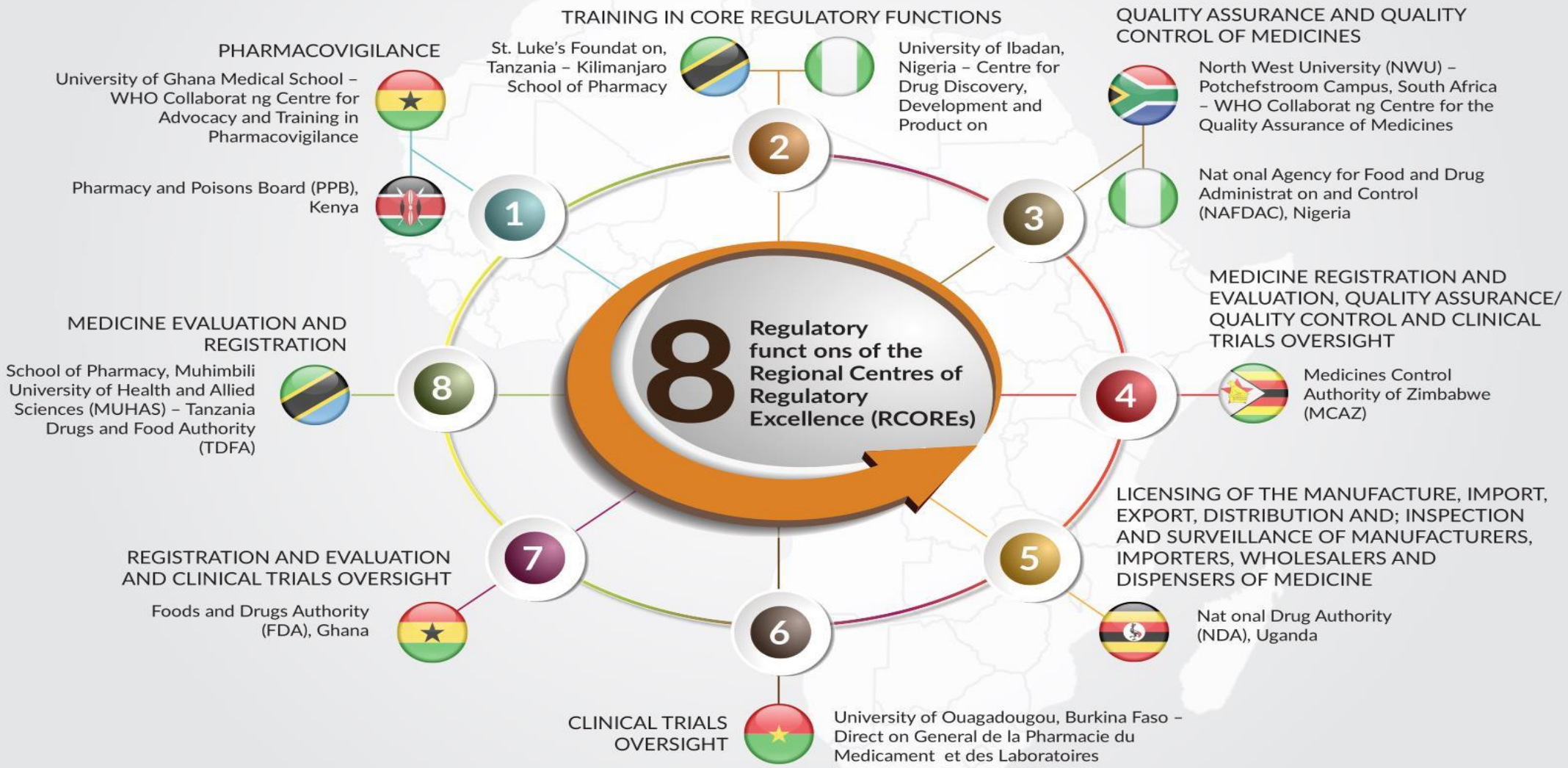
How To Become a Designated AU RCORE

Your country and/or institution can become part of the AU RCORE. Just follow these four steps to get designated:

1. **APPLICATION**
   Submit an expression of interest to the NEPAD Agency
2. **ASSESSMENT**
   Assessment of expression of interest, short-listing and audits shall be conducted accordingly
3. **SELECTION**
   Based on the eligibility criteria, selection will be done accordingly
4. **PERFORMANCE EVALUATION/ REVIEW**
   The performance of the registered RCORE shall be monitored continuously

Regional Centres of Regulatory Excellence (RCOREs)

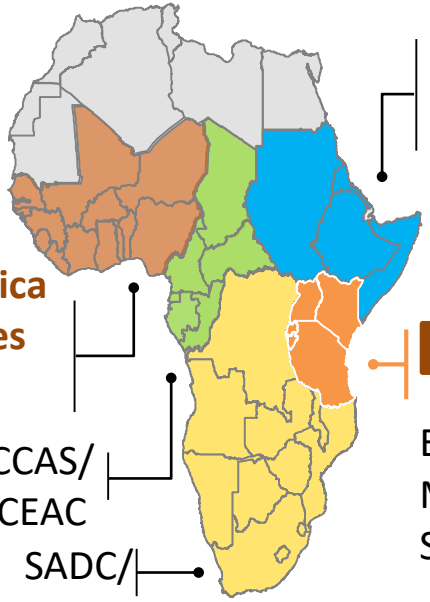
As part of its mandate to strengthen regulatory capacity development in Africa, the NEPAD Agency through its AMRH programme has designated **11 Regional Centres of Regulatory Excellence (RCOREs)** in **eight diff erent regulatory funct ons**



African Union Vision

AMA Milestones:

- January 2015 AU Executive Council Decision on AMRH as a foundation for AMA
- AMA Task Team established since Nov 2014
- Legal, institutional framework and business plan drafted
- AUC, WHO & NEPAD Agency Joint Secretariat
- AMA Launch



IGAD / AMU / CEN-SAD

WAHO / UEMOA **West Africa Medicines Agency**

EAC

East African Community Medicines and Food Safety Commission

ECCAS/ OCEAC

SADC/ COMESA

55 countries → **5regions** → **1 continent**

Key Lessons Learnt

1. Alignment of National, Regional, AU and Global Policy Frameworks
2. Regional Integration, Harmonization
3. Sustainable Institutional Capacity Development Programmes
4. Effective Knowledge Management
5. Effective Governance and Coordination Mechanism
   – structures, M&E framework, accountability

The Future
we want for Africa
AGENDA 2063
Unity, Prosperity & Peace
2013, Year of Pan Africanism
and African Renaissance
50
OAU - AU

Thank you!