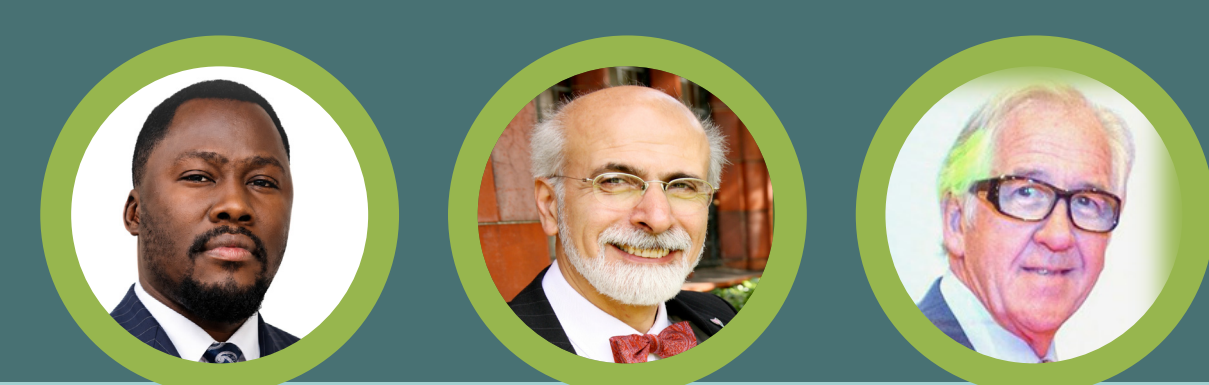




The African Medicines Agency (AMA)

Historical Perspective of its Origins, Evolution, Institutional Structure and Future Prospects

DIA 2026 — Philadelphia | Alex Juma Ismail
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Disclaimer: AMA is not a central approvals agency — it is a coordination, harmonisation, and capacity-building body designed to multiply the impact of Africa's regulatory ecosystem through shared science and collective action.

REGULATORY SCIENCE PUBLIC HEALTH AFRICA CONTINENTAL HARMONISATION

Towards Regulatory Harmonization



The Problem: A Fragmented Continental Landscape

- Fragmented Systems**
Divergent national standards and regulatory frameworks hinder cross-border collaboration and mutual recognition
- Delayed Access**
Quality-assured medicines reach African patients years after approval in high-income markets.
- Duplicated Assessments**
Multiple NRAs independently evaluate the same dossiers, wasting limited technical capacity.
- Variable Maturity**
NRA capabilities range from WHO Level 1 (basic) to Level 4 (advanced), creating significant disparities.

Objectives in Research Paper

- Historical Evolution**
Review AMA's development from the AMRH Programme through Treaty adoption and early operationalisation.
- Legal & Institutional Framework**
Analyse the AMA Treaty, governance structures, and the continental coordination architecture it establishes.
- Operational Pilots**
Examine the Continental Listing of Human Medicinal Products pilot to assess feasibility of reliance mechanisms.
- Future Prospects**
Assess the long-term potential of AMA and the structural challenges that remain for full operationalisation.

AMRH Origins: The Foundation of Continental Harmonisation

The Starting Point

The African Medicines Regulatory Harmonisation (AMRH) Programme was launched in 2009 by the African Union Development Agency (AUDA-NEPAD) as the continent's first structured response to regulatory fragmentation. It was designed to reduce duplication, build technical capacity, and establish shared regulatory standards across AU Member States.

Regional Pilots That Informed AMA

- EAC (East African Community) — pioneered joint technical assessments and work-sharing models
- SADC (Southern African Development Community) — developed harmonised registration guidelines
- ECOWAS (West Africa) — built assessor pools and shared procedural frameworks

Ratification Status: Growing Political Commitment

Progress as of December 2025

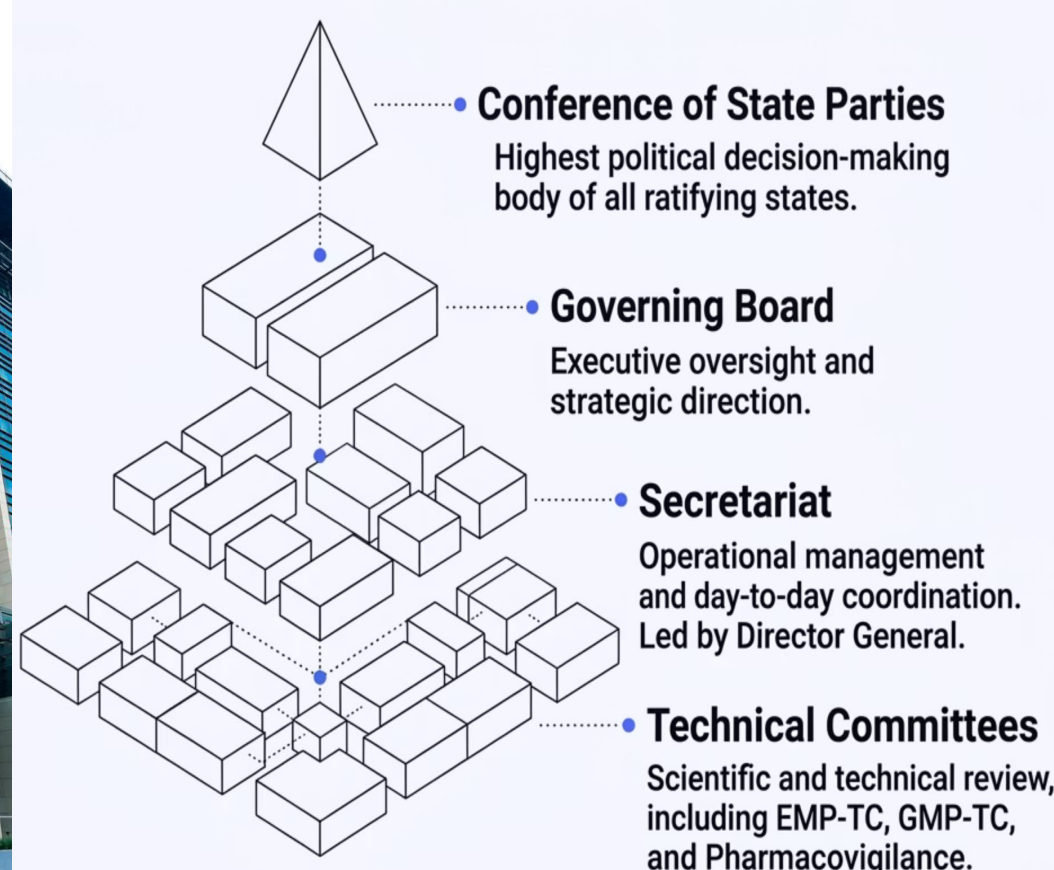
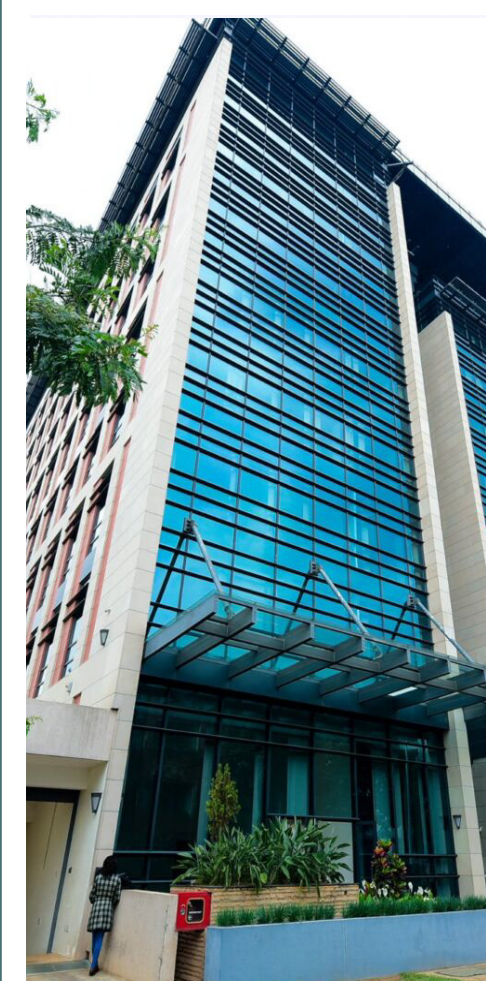
As of May 2026, 32 AU Member States had ratified the AMA Treaty — well above the 15-member threshold required for entry into force. This expansion reflects growing continental political will to invest in shared regulatory infrastructure and accelerate access to quality-assured medicines.



Crucially, non-ratifying countries are not excluded from the process. They continued to participate technically in AMRH pilot activities and working groups, maintaining engagement pending formal ratification.

32 States Ratified 55 AU Member States

AMA Governance Architecture



Each governance tier operates with defined mandates, ensuring accountability flows upward from the technical committees to the Conference of State Parties — Africa's collective regulatory voice.

Guiding Principles of the African Medicines Agency (AMA)



Functions of the AMA



Regulatory Model Comparison: AMA vs. EMA vs. FDA

AMA's model emphasizes reliance and convergence while respecting national sovereignty across diverse regulatory systems.

AMA Reliance & Sovereignty	EMA Centralised & Harmonised	FDA Federal & Centralised
Legal Basis: AU Treaty	Legal Basis: EU Regulation	Legal Basis: Federal law
Approval Authority: No direct approval	Approval Authority: EU-wide approvals	Approval Authority: Binding federal approvals
Key Mechanism: Reliance and work-sharing	Key Mechanism: Centralised review	Key Mechanism: Centralised oversight

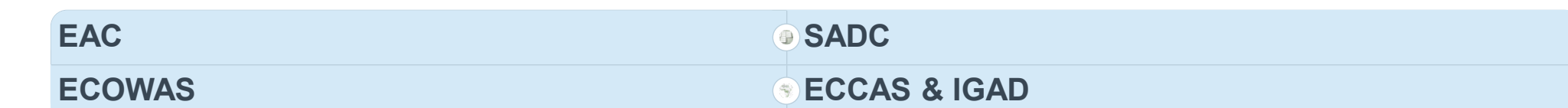
AMA's reliance-based model preserves national sovereignty while building toward continental convergence — making it uniquely suited to Africa's regulatory diversity.

Phased Implementation Strategy

AMA's operationalisation follows a structured three-phase roadmap designed to build regulatory capacity incrementally — from foundational institution-building through full continental lifecycle regulation. Each phase has clear milestones, deliverables, and governance checkpoints.



Role of Regional Economic Communities (RECs)



- RECs Pilot The Foundation**
 - Joint assessments
 - Harmonised SOPs
 - Shared assessor pools
- AMA Scales The Mechanism**
 - Adopts proven REC models
 - Continental deployment
 - Unified frameworks
- Africa Benefits The Outcome**
 - Unified regulation
 - Efficient approvals
 - Trusted health system

Together, RECs provide the foundation, experience, and partnerships that make AMA's vision of a unified, efficient, and trusted regulatory system for Africa possible.

Role of National Regulatory Authorities (NRAs)



The AMA Treaty: Legal Architecture



Legally Binding Instrument

The Treaty creates binding obligations for ratifying states to align their national regulatory frameworks with continental standards, participate in joint activities, and contribute to AMA's governance.

Continental Coordination Framework

Rather than replacing national authorities, the Treaty establishes a coordination and reliance model — enabling NRAs to leverage AMA assessments while preserving national legal sovereignty.

Hosted in Rwanda

Rwanda was selected as the host country for AMA's Secretariat, based in Kigali — recognizing the country's strong regulatory infrastructure and political commitment to the AU agenda.

Key Challenges to Full Operationalisation



While AMA's foundations are strong, significant structural and political challenges must be addressed to realise its full potential. These are not insurmountable — but they require sustained, coordinated action across the AU system.



Addressing these challenges with **political will, resources, and collaboration** will be critical to ensuring AMA delivers on its mandate and **transforms medicines regulation for the people of Africa**.

Conclusions



The African Medicines Agency represents the most significant continental advance in medicines regulation in Africa's history — the product of over 15 years of deliberate policy, technical groundwork, and political commitment across 55 AU Member States.

