African Medicines Agency

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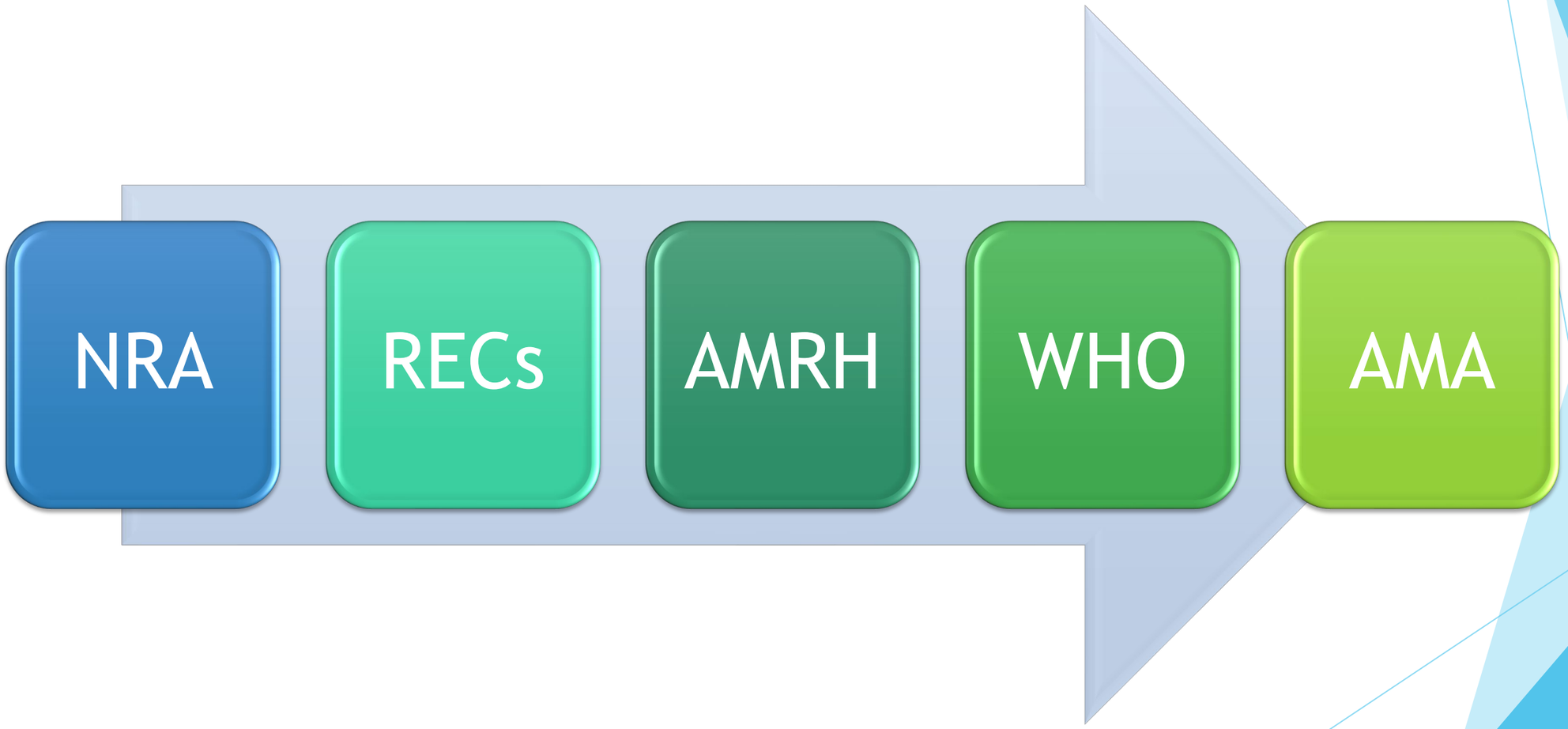
Loice Kikwai, Ph.D.

LCK Pharmaceutical Consulting

Hierarchy Of Drug Registration In Africa



National Regulatory Agencies (NRAs)

- RSS incl. development of **national well-functioning reliance pathways** (completed or under development)

55 countries

6 regions

Regional Economic Communities (REC)

- **Regional Joint Assessment Procedures (JAPs)**

African Medicines Agency (AMA)

- Foreseen to **coordinate joint assessments**, e.g. "highly complex" product dossiers (*tbc*)

1 continent

Beyond Africa

- **WHO Collaborative Registration Procedures** (PQ, 'SRA'- approved)
- **Swissmedic MAGHP and MAGHP 'light'** procedure
- **EU-M4All**

https://www.frontiersin.org/files/Articles/1207954/fmed-10-1207954-HTML-r2/image_m/fmed-10-1207954-g001.jpg

The African National Regulatory Authorities (NRA's)

The Product Registration Process in NRAs

Submission of Dossier

- Pharmaceutical companies submit a dossier containing the necessary information and data to support the registration of a medicine

Evaluation and Assessment

- The NRA evaluates the dossier and conducts assessments to ensure the medicine meets the required standards.

Approval and Registration

- If the medicine meets the required standards, the NRA grants approval and registers the medicine for use in the country.

Cont. the NRAs

National Medicines Regulatory Authorities (NRAs) in Africa:

- Ensure quality, safety, and efficacy of medicines

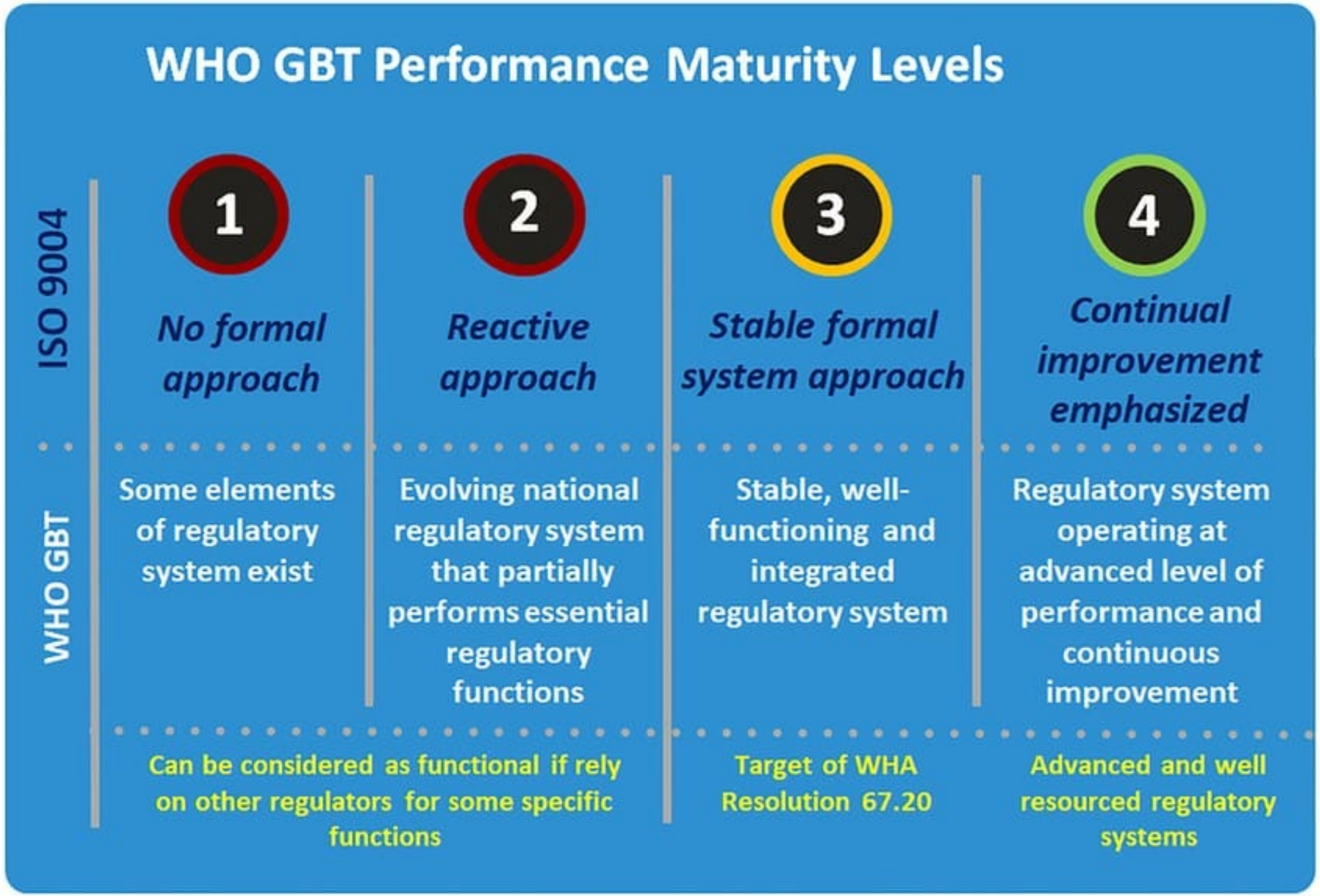
Each country has its own NRA. Responsible for:

- Evaluating and approving medicines for registration
- Ensuring compliance with national and international standards

World Health Organization (WHO) assessment: Developed Global Benchmarking Tool (GBT)

- Adapted from ISO 9004
- Used to evaluate regulatory capabilities of NRAs
- Categorizes NRAs into four distinct maturity levels

Cont. the NRAs



https://www.researchgate.net/publication/343739134/figure/fig2/AS:1143128118752970 6@1694276648230/WHO-global-benchmarking-tool-performance-maturity-levels-Source-World-health.tif

African NRAs Landscape

Limited High-Performing NRAs

All African countries (except Sahrawi Republic) have an NMRA or equivalent unit	No NMRA in Africa operates at maturity level 4	Four regulators at ML3 for medicines	Two regulators at ML3 for vaccines Majority at Lower Levels:	~95% of African NRAs at ML2 or below Significant portion at basic level (ML1)

Opportunities for Improvement

Substantial room for regulatory enhancement	Need for capacity strengthening	Need for harmonization across the continent

Efficiency Metrics

Average time for product registration: 6-18 months	Number of products registered annually varies by country (e.g., Nigeria's NAFDAC registers ~2,000 products/year)	Annual Inspections: 85%	Regulatory Actions Taken:500 recalls, 300 fines

https://pubmed.ncbi.nlm.nih.gov/33685518/

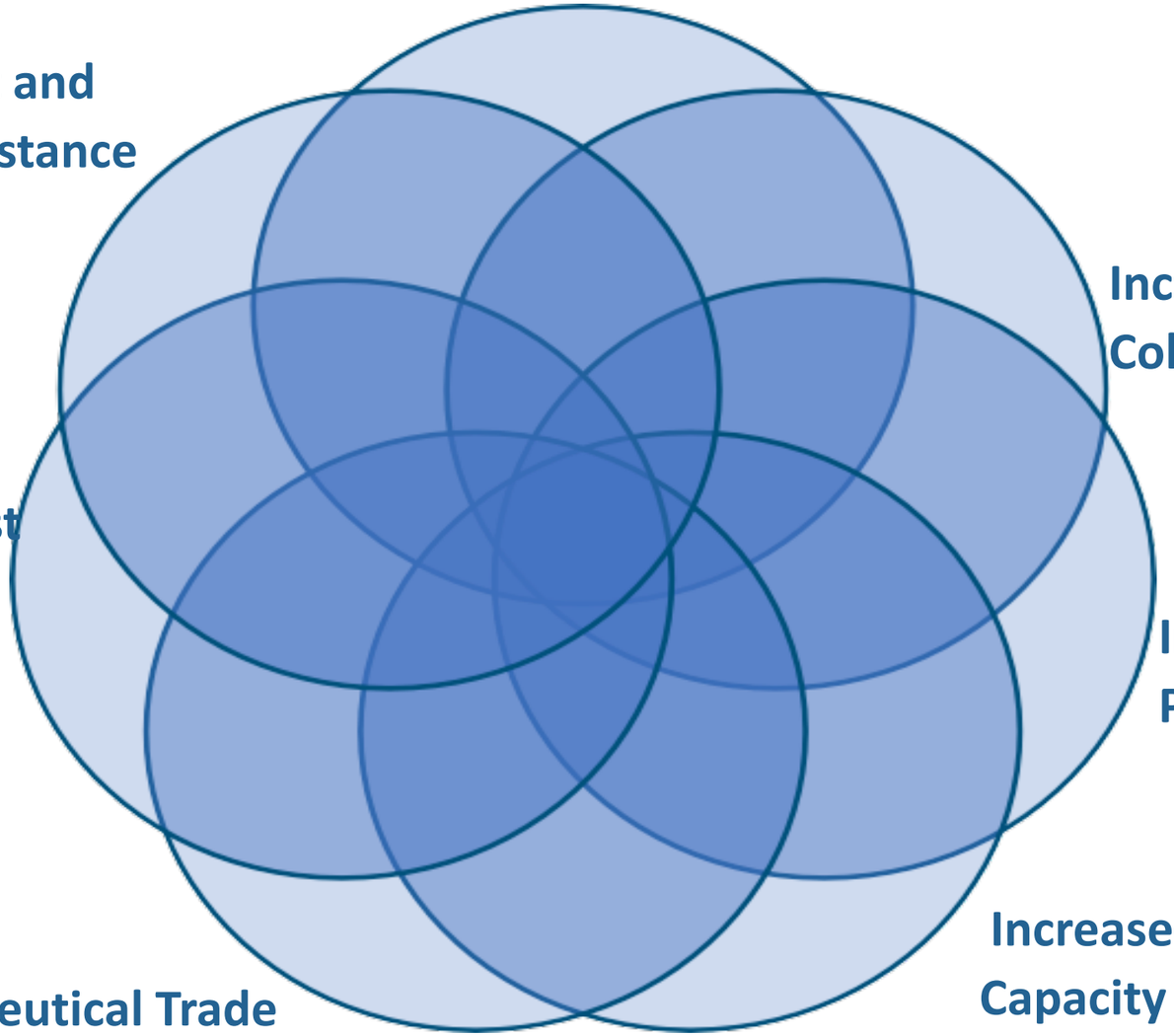
African NRAs Landscape

NRA Capacity	Regulatory Framework	Scope of Regulation	Quality Control & Surveillance in SSA	Challenges
• 7% moderately to developed • >90% minimal to no capacity	• 40/46 countries have legislation • 15% of NRAs have full legal mandate	• 65% control veterinary medicines • 69% regulate traditional/herbal medicines • 65% regulate broad range of products	• 72% have quality control labs • 63% engaged in market surveillance	• 4-7 year approval delays • >70% of products imported • Varied corporate profiles • High importation fuels illegal trade and substandard products

Landscapehttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC7938385/

https://pubmed.ncbi.nlm.nih.gov/33685518/

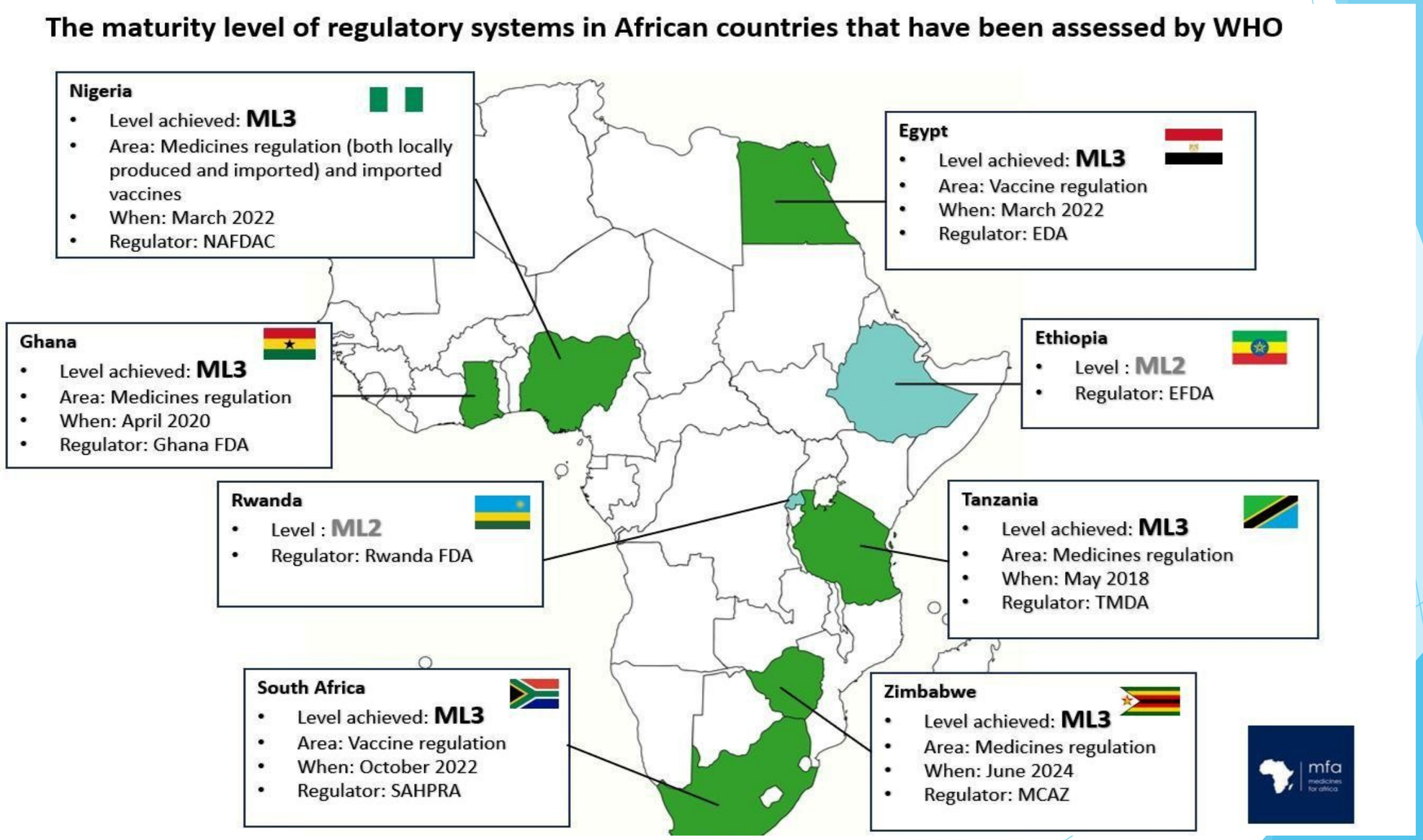
Significance of Regulatory Maturity Levels



Challenges in Reaching Maturity Level 3

- Critical Bottlenecks
- Resource Gaps
- Legislative and Governance Structures
- Capacity Strengthening
- Regulatory Harmonization
- WHO Prequalification

Current maturity levels of NRAs in African countries



https://www.linkedin.com/posts/medicines-for-africa_africa-health-healthcare-activity-7207607045261293568-EIWD?utm_source=social_share_video_v2&utm_medium=android_app&utm_campaign=copy_link

CHALLENGES FACED BY NRAs AND ITS IMPLICATIONS

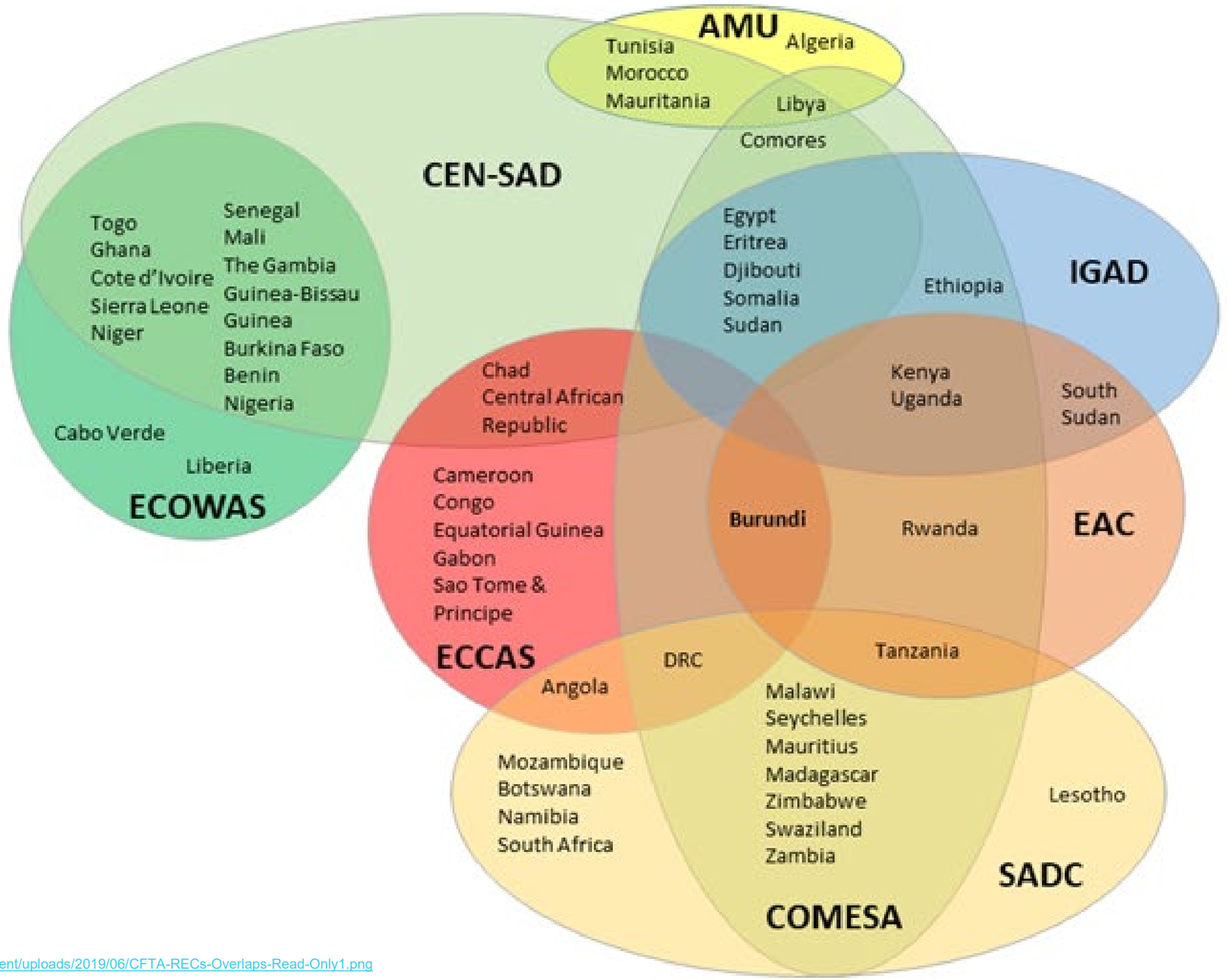
Challenges

- Weak or non-coherent legislative frameworks
- Sluggish medicine registration processes Delayed approval decisions
- Inefficiency in regulatory operations Limited technical capacity
- Inadequate resources (financial, human, and technological)
- Lack of harmonization with regional and international standards
- Insufficient coordination among different NMRAs
- Vulnerability to political pressures and corruption
- Difficulty in retaining skilled personnel

Implications

- Poor access to priority essential medicines for patients
- Overpriced medicines due to inefficient regulatory processes
- Increased risk of substandard and falsified medicines entering the market
- Delayed introduction of new and potentially life-saving drugs
- Hindrance to local pharmaceutical industry growth and competitiveness
- Reduced investor confidence in the pharmaceutical sector
- Inconsistent quality standards across different African countries
- Inefficient use of limited regulatory resources
- Increased healthcare costs due to regulatory inefficiencies
- Potential public health risks due to inadequate

Regional Economic Communities (RECs)

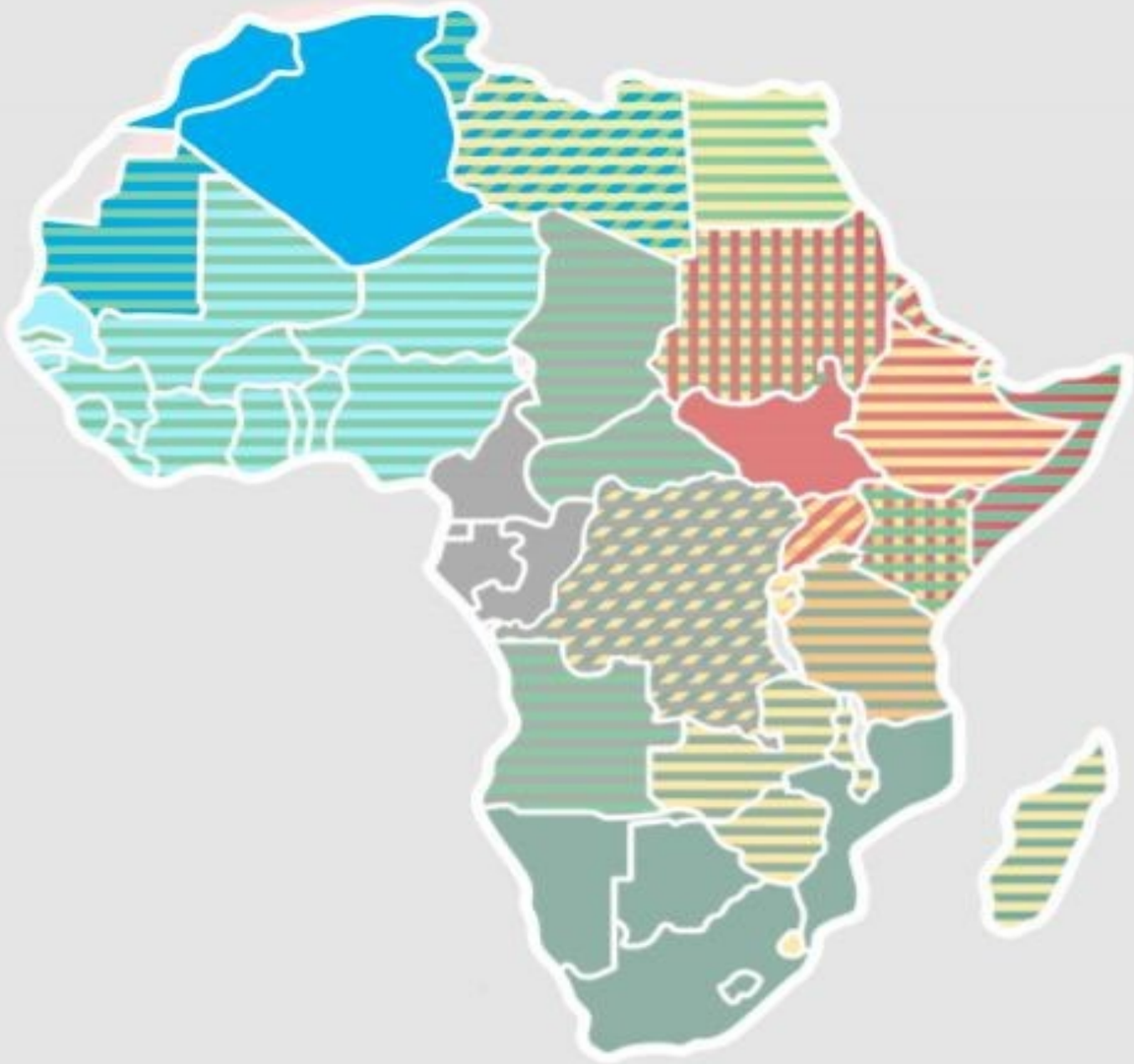


https://imanidevelopment.com/wp-content/uploads/2019/06/CFTA-RECs-Overlaps-Read-Only1.png

Regional Economic Communities

The African Union recognises eight different RECs under its administration:

- Arab Maghreb Union (UMA)
- Common Market for Eastern and Southern Africa (COMESA)
- Community of Sahel–Saharan States (CEN–SAD)
- East African Community (EAC)
- Economic Community of West African States (ECOWAS)
- Intergovernmental Authority on Development (IGAD)
- Southern African Development Community (SADC)
- Economic Community of Central African States (ECCAS)



AMRH Regional Economic Communities | AUDA-NEPAD- AMRH

https://thelawyer.africa/wp-content/uploads/2024/01/RECs.png

REC	Key Features	Governance/Approach
EAC (East African Community)	Harmonized product registration process	Steering Committee Technical Working Groups
ECOWAS (Economic Community of West African States)	Similar product registration process to EAC	Steering Committee Expert Working Groups
SADC (Southern African Development Community)	Harmonized product registration process 16 countries in Southern Africa Key members: South Africa, Botswana, Mozambique, Tanzania	ZAZIBONA Collaborative Procedure for joint assessments
IGAD (Intergovernmental Authority on Development)	Harmonized process and joint assessments Product registration processes priorities: Streamlined for public health 7 countries in the Horn of Africa Members: Ethiopia, Kenya, Uganda, Djibouti, Somalia, South Sudan, Eritrea	Collaborates with WHO and EAC
SACU (Southern African Customs Union)	Common external tariff Regulates imports of controlled goods Utilizes COMESA Certificates of Origin Product registration processes priorities: Free movement of goods	Revenue sharing system Uses permit system Focuses on duty-free trade
COMESA (Common Market for Eastern and Southern Africa)	Operates a free trade area 21 countries from North to Southern Africa Key members: Egypt, Kenya, Ethiopia, Uganda, Zimbabwe Supports private sector Preferential access to EU market	Balances free movement with revenue sharing Trade and Development Bank for Eastern and Southern Africa Economic Partnership Agreements
ECCAS (Economic Community of Central African States)	Promotes trade liberalization 11 countries in Central Africa Key members: Cameroon, Angola, Democratic Republic of Congo	Developing customs union Planned customs union for further integration

Cont. RECs

Regional Guidelines and Standards:

- Developed and implemented by RECs
- Ensure common standards for medicines registration

Aim to:

- Meet quality standards & Improve medicine accessibility

Harmonization Through RECs:

- Drive AMRH program
- Establish regional regulatory frameworks
- Harmonize NMR systems
- Streamline process for essential medicines
- Registration time reduced by 20%

Regional Harmonization Initiatives:

- Launched by RECs
- Focus on harmonizing product registration
- Ensure consistency across member states

Objectives:

- Reduce duplication of efforts
- Improve coordination
- Enhance registration efficiency
- Mutual Recognition Agreements (MRAs): 10 MRAs in place
- Capacity Building: 50 training sessions conducted annually1,000 professionals trained annually

The Role of RECs in AMRH

In Intergovernmental organizations across Africa

- Promote economic and social development
- Work towards harmonizing policies and regulations
- Foster trade and facilitate regional integration

In Healthcare:

- Play critical role in supporting AMA
- Help ensure access to safe, effective, and quality medical products

In NRAs:

- Bring together countries with shared economic and political interests
- Promote regional integration
- Foster economic development

RECs collaborate with the AMA to enhance regulatory capacity through several key areas:

Harmonization of Regulatory Requirements:

- RECs work with the AMA to align technical requirements for medical products across member states, essential for the effective functioning of the AMA.

Capacity Building:

- RECs provide technical support and capacity building for National Medicines Regulatory Authorities (NMRAs) to enhance their regulatory capacity. The AMA complements these efforts by providing guidance and resources.

Information Sharing:

- RECs facilitate information sharing among member states and with the AMA to ensure stakeholders are aware of the latest developments and best practices in medicines regulation.

Joint Inspections:

- RECs coordinate joint inspections of Active Pharmaceutical Ingredients (API) manufacturing sites with the AMA to ensure they meet required standards, optimizing resource use and avoiding duplication.

Advocacy:

- RECs advocate for the ratification of the AMA Treaty among member states, building political goodwill and support for the treaty. The AMA provides technical assistance to support the implementation.

Coordination:

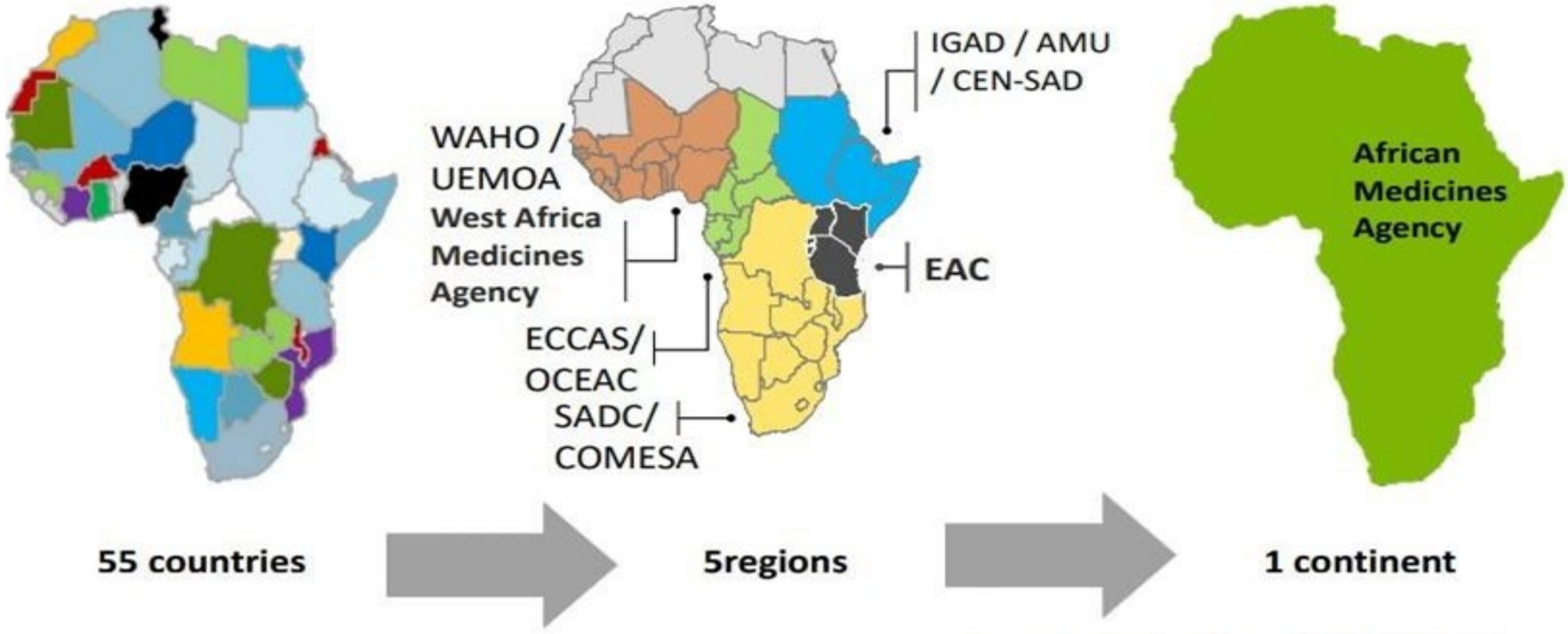
- RECs work closely with the AMA to align policies, strategies, and activities, ensuring member states collaborate effectively to achieve the goals of the AMA Treaty.

Support for Local Pharmaceutical Production:

- RECs collaborate with the AMA to create a conducive environment for the growth of the pharmaceutical industry, including harmonizing regulatory requirements, facilitating trade, and building capacity.

The African Medicines Regulatory Harmonization (AMRH)

African Union Vision



Source: adapted from AMRH/NEPAD

https://healthpolicy-watch.news/wp-content/uploads/2021/03/DPTuQf-XcAAxM2t-768x295.jpg

The AMRH

The Establishment

In 2009 to strengthen national, regional, and continental regulatory systems.

The Aims

To establish the AMA for:

1. Efficient resource utilization.
2. Minimizing administrative hurdles.
3. Improved work sharing & collaboration.

The Goal

To optimize the healthcare system and ensure timely access to effective, safe, and quality medicines for patients across Africa.

AMRH's Guiding Framework

Based on AU Pharmaceutical Manufacturing Plan for Africa (PMPA)

Leadership and Collaboration

Led by: African Union Development Agency-NEPAD (AUDA-NEPAD)

MAIN FOCUS AREAS OF AMRH PROGRAM

- Enhancing Capacity:
  - Improve human and institutional regulation capacity for medical products and technologies
- Harmonizing Frameworks:
  - Align policies and regulatory frameworks across member states Facilitating Research: Coordinate research and knowledge management on medicines regulation at country, regional, and continental levels
- Aligning Activities:
  - Ensure regulatory activities align with the AMRH Framework and African Medicines Agency (AMA)
- Contribution to AU Strategic Documents:
  - Pharmaceutical Manufacturing Plan for Africa (PMPA)
  - Road Map on Shared Responsibility for HIV/AIDS, Tuberculosis, and Malaria Response
  - Health Research Strategy for Africa
  - Africa Health Strategy (under review)

Major Achievements / Results of the AMRH Program

Programme/Initiative	Year	Key Achievements
AU Model Law	2016 2024	Developed by NEPAD Agency through AMRH programme Endorsed by AU Heads of State and Government Aims to harmonize medicines regulatory systems Target: 20 countries and 5 RECs to adopt by end of 2018
ECOWAS MRH Programme	2015	Launched in Accra, Ghana Established joint MRH Project Steering Committee, Formed seven Technical Working Groups (TWGs), Agreed on collaboration between WAHO and WAEMU
SADC MRH Programme and ZAZIBONA Initiative	2015	SADC joined MRH project Developed SARPAM ZAZIBONA scheme: 103 products reviewed, 28 recommended for registration Part of SADC Framework for Regulatory Harmonization
IGAD MRH Programme	2015	Member States signed Call for Action Committed to establishing MRH programme Supports development of regional pharmaceutical policy
ECCAS/OCEAC MRH Programme	2015	Collaboration framework under discussion Builds on CEMAC regional pharmaceutical policy Regulatory systems assessment planned for 2016
RCoREs and Regulatory Pool of Experts Database	2014	11 Regional Centres of Regulatory Excellence designated Comprehensive database of regulatory experts developed
Strengthening Pharmaceutical Innovation in Africa	N/A	Report developed with COHRED and George Institute
EAC MRH Programme	2012	First to develop harmonized technical guidelines (adopted 2014) Published compendium for EAC Partner States Piloted AMRH M&E Framework
Expanded ToRs of PMPA Technical Committee	2011	Facilitated by NEPAD Agency Endorsed by AU Conference of Ministers of Health Led to development of PMPA Business Plan with UNIDO support

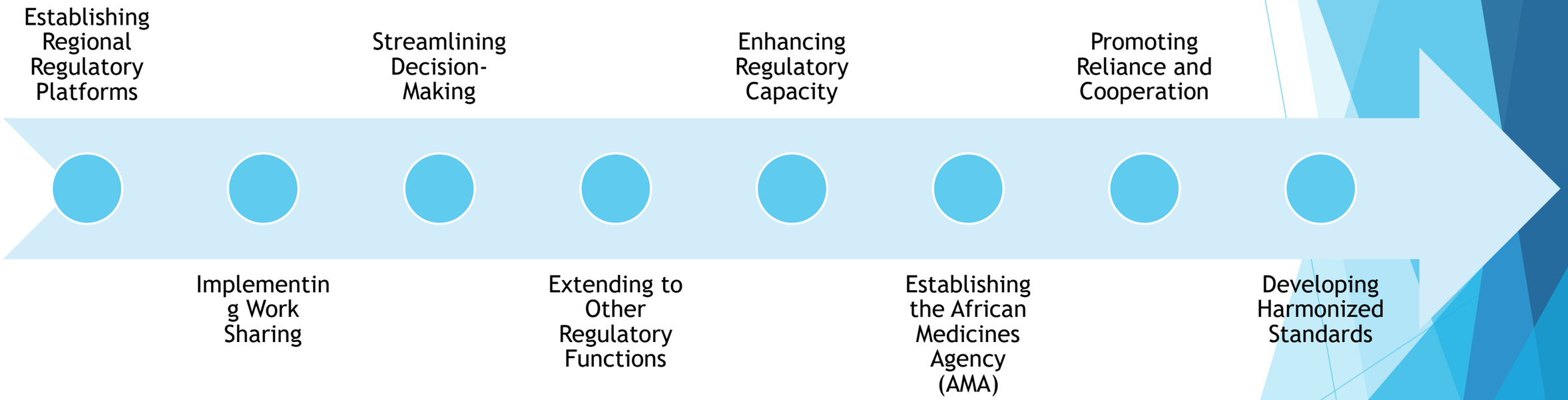
The Stakeholders

- NRAs
- African Union Commission (AUC)
- WHO
- World Bank
- RECs
- Pan African Parliament (PAP)
- Bill and Melinda Gates Foundation (BMGF)

Components of the AMRH governance

Component	Description
Steering Committee	Provides strategic direction and oversight
Technical Committees	Focus on specific areas (e.g., quality assurance) and offer technical guidance
Regional Regulatory Platforms	Conduct joint assessments and inspections to streamline decision-making
Information Management System	Facilitates information sharing between members and stakeholders
Partnership Platform	Promotes collaboration and information exchange among various stakeholders
African Medicines Agency (AMA)	Continental regulatory agency overseeing AMRH implementation
Model Law	Framework for member states to domesticate and implement AMRH principles
Regional Centers of Regulatory Excellence	Provide training and capacity building
Good Manufacturing Practice (GMP)	Ensures medical products meet quality, safety, and efficacy standards
Clinical Trials Oversight	Ensures safety and efficacy of medical products during trials

AMRH Strategies for Harmonization



Benefits of AMRH

Improved access to quality, safe, and effective medicines

Reduced duplication of efforts and costs

Enhanced regulatory capacity and collaboration

Streamlined regulatory processes

Increased efficiency and effectiveness

Challenges and Obstacles facing AMRH

Varying regulatory frameworks and capacities across countries

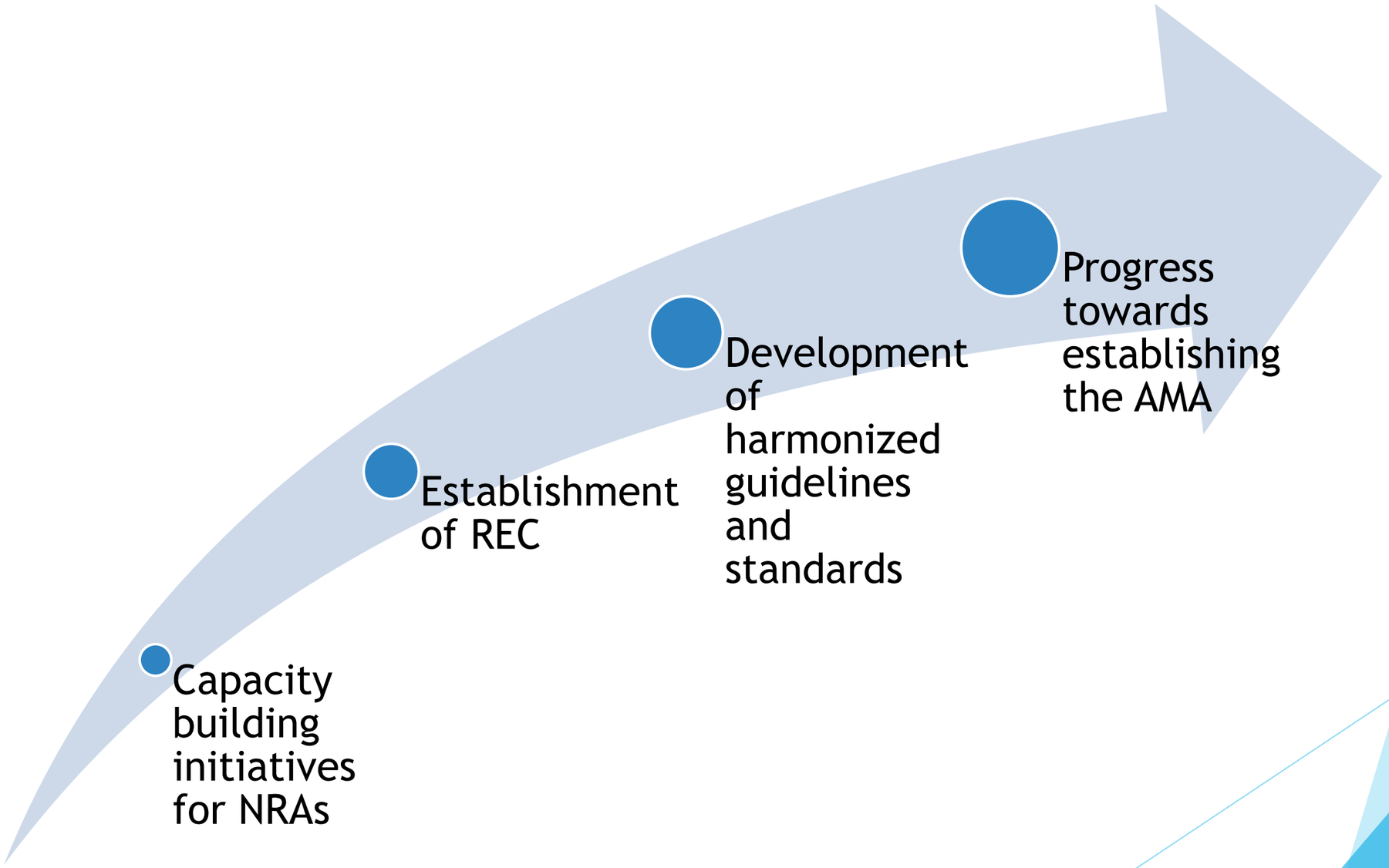
Limited resources (financial, human, infrastructure)

Lack of harmonization in legal frameworks

Resistance to change and lack of political will

Complexity of coordinating multiple stakeholders

AMRH Milestones and Achievements



Future Perspectives

- Expansion to other medical products (e.g., vaccines, diagnostics)
- Continuous capacity building and resource mobilization
- Strengthening of regulatory systems across Africa
- Full operationalization of the African Medicines Agency (AMA)

https://africanpharmaceuticalreview.com/wp-content/uploads/2024/01/AMA-1024x576.jpg

WHAT IS AFRICAN MEDICINES AGENCY (AMA)?

AMA | African Medicines Agency

AMA will be established as a Specialized Agency of the African Union (AU) to improve access to quality, safe and efficacious medical products in Africa.

01 Coordination and strengthening of ongoing initiatives to harmonize medicines regulation, promote cooperation and mutual recognition of regulatory decisions.

02 Carrying out regulatory oversight of selected medical products and providing technical guidance to State Parties and RECs.

03 Pooling expertise and capacities and strenthening networking for optimal use of the limited resources available.

ORGANS OF THE AMA

- **A** The Conference of parties
- **B** Governing Board
- **C** The Secretariat
- **D** Technical Committees

https://www.tmda.go.tz/uploads/1667487794-AMA%20Pamphlet_0-1-2-1.png

Establishment

The AMA has been established by AU to contribute to the improvement of access to medicines within the African continent 11 February 2019

Objectives

The AMA aims to ensure the availability of quality, safe, and effective medical products by coordinating regional harmonization systems and implementing the AU Model Law on Medical Products Regulation.

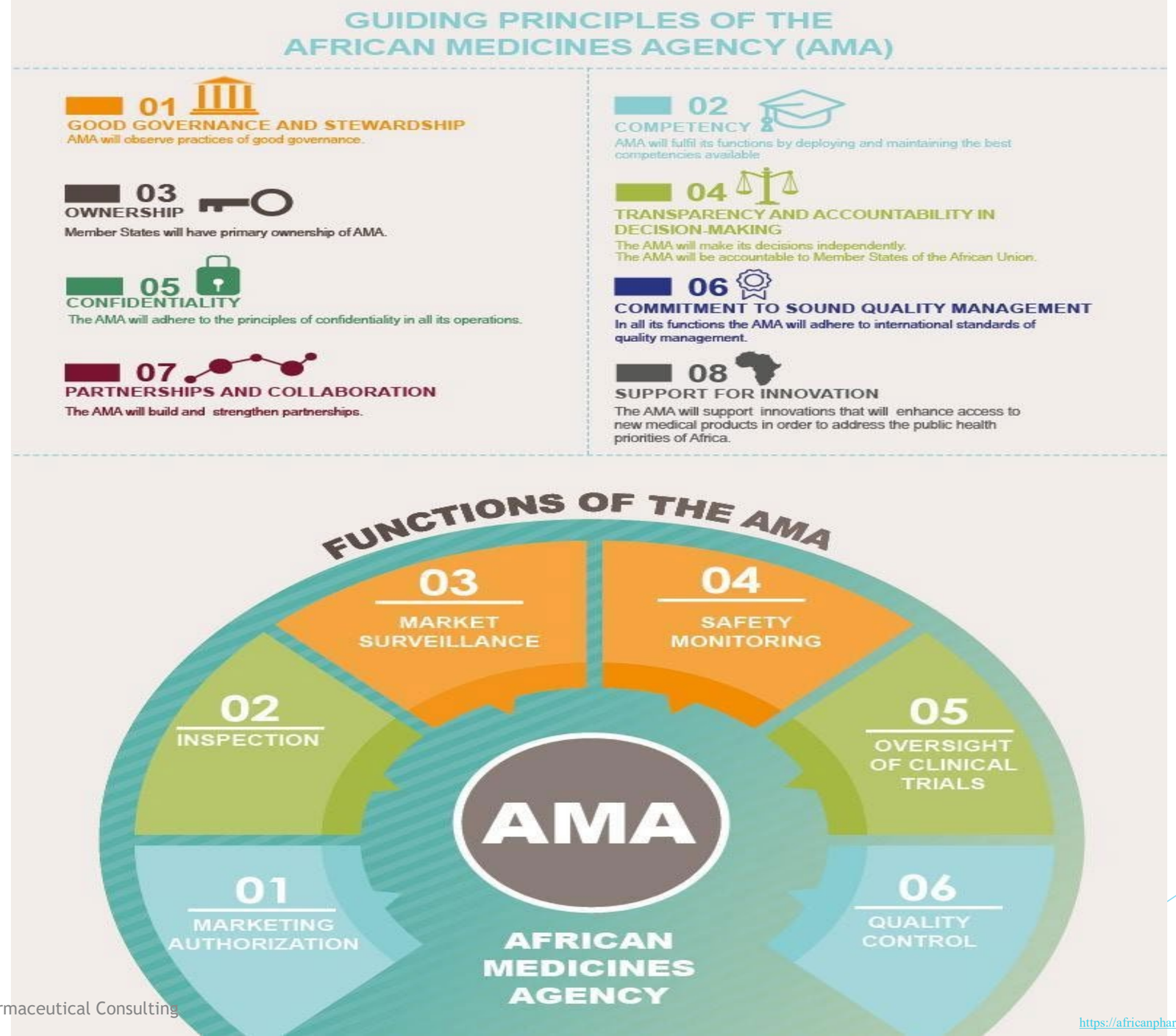
Mission and Vision

Mission; Provide Leadership in creating an enabling regulatory environment for Pharmaceutical Sector Development in Africa

Vision; African People have Access to essential Medical Products and Technologies

The Governing Board

- 5 Heads of National Medicines Regulatory Authority (NMRAs) from each region,
- One (1) Regional Economic Community (REC) representative,
- One (1) representative of Regional Health Organization (RHOs),
- 1 representative of National Committees Responsible for bioethics on rotational basis and
- The Commissioner for Health, Humanitarian Affairs and Social Development (HHS) at the African Union Commission (AUC).



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Key Roles of the AMA

- Technical support to RECs
- Capacity building for NMRAs
- Guidelines and standards development
- Joint assessments and inspections
- Coordination mechanism
- Funding
- Partnerships
- Training and capacity building
- Information sharing
- Leadership

African Medicines Agency Countdown
status of support

37 countries have supported the AMA treaty

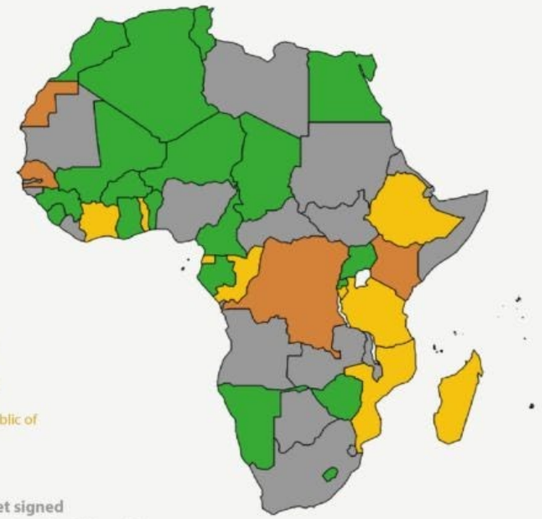
21 countries have ratified and deposited the treaty

21 **Member States ratified and deposited**
Algeria, Benin, Burkina Faso, Cameroon, Chad, Egypt, Gabon, Ghana, Guinea, Lesotho, Mali, Mauritius, Morocco, Namibia, Niger, Rwanda, Seychelles, Sierra Leone, Tunisia, Uganda, Zimbabwe

5 **Member States ratified but NOT deposited**
Cape Verde, Kenya, Democratic Republic of Congo, Saharawi Arab Democratic Republic, Senegal

11 **Member States signed but NOT ratified**
Burundi, Comoros, Cote d'Ivoire, Equatorial Guinea, Ethiopia, Madagascar, Mozambique, Republic of Congo, Sao Tome and Principe, Tanzania, Togo

18 **Member States have NOT yet signed**
Angola, Botswana, Central African Republic, Djibouti, Eritrea, Eswatini, Gambia, Guinea-Bissau, Liberia, Libya, Malawi, Mauritania, Nigeria, South Sudan, Somalia, South Africa, Sudan, Zambia



Health Policy Watch

The AMA Treaty entered into force on 5 November 2021 - after the 15th instrument of ratification was received by the African Union.

Sources: African Union infographics - https://au.int/en/documents/20211105/infographics-treaty-establishment-african-medicines-agency, updated by AU Comms - https://twitter.com/Dottienjagi/status/1468217802439995396. States "supporting" refers to countries that have signed treaty and/or ratified the treaty. (Two states, Burkina Faso and Namibia ratified and deposited the treaty without ever signing it formally).

https://healthpolicy-watch.news/wp-content/uploads/2023/08/Copy-of-map_v11-724x1024.png

African Union

African Medicines Agency (AMA)

The Treaty for the establishment of the African Medicines Agency (AMA) was adopted in February 2019, by the 32nd Session of the Assembly of Head of State and Government. The Assembly further called on its Member States to sign and ratify the Treaty in order for the Treaty to enter into force as soon as possible (Assembly/AU/Dec.735 (XXXII).

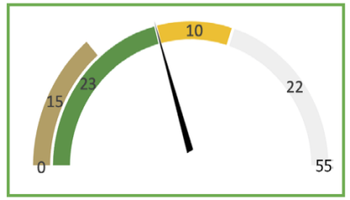
AMA will be the second continental health agency after the Africa Centres for Disease Control and Prevention (Africa CDC), that will enhance the capacity of States Parties and Regional Economic Communities (RECs) to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent. AMA will also promote the adoption and harmonization of medical products regulatory policies and standards, as well as provide scientific guidelines and coordinate existing regulatory harmonization efforts in the African Union recognized RECs and Regional Health Organizations (RHOs).

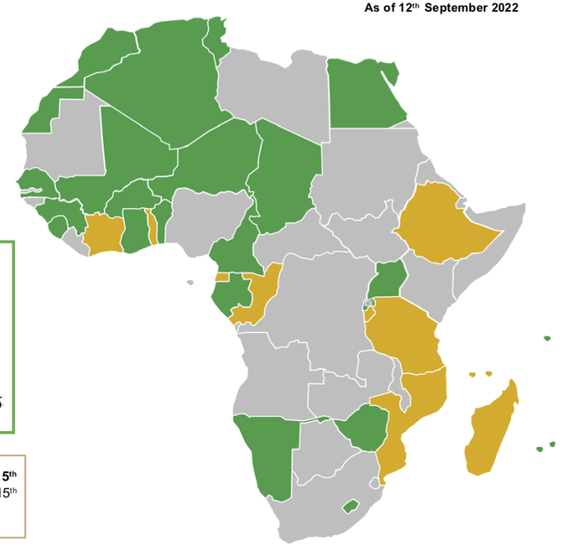
As of 12th September 2022

23 Number of Member States that have ratified the Treaty and deposited the instrument at the Commission

30 Number of Member States that have signed the AMA Treaty

22 Number of Member States that have neither signed nor ratified





The AMA Treaty entered into force on **5th November 2021** upon the deposit of the 15th instrument of ratification at the African Union Commission

The HeadQuarters of AMA will be in Rwanda

Member States that have only signed the AMA Treaty
1. Burundi
2. Comoros
3. Cote d'Ivoire
4. Ethiopia
5. Republic of Congo
6. Equatorial Guinea
7. Madagascar
8. Mozambique
9. Tanzania
10. Togo

Member States that have signed, ratified and deposited the instrument of ratification at the Commission
1. Algeria
2. Benin
3. Burkina Faso*
4. Cameroon
5. Chad
6. Egypt
7. Gabon
8. Ghana
9. Guinea
10. Lesotho
11. Mali
12. Mauritius
13. Morocco
14. Namibia*
15. Niger
16. Rwanda
17. Saharawi
18. Senegal
19. Seychelles
20. Sierra Leone
21. Tunisia
22. Uganda
23. Zimbabwe

Ratification without signing

For further enquiries, please contact:
- Office of the Legal Counsel of the African Union Commission
- Prof. Julio RAKOTONIRINA | The Director of Health and Humanitarian Affairs Directorate | Department of Health ,Humanitarian Affairs and Social Development, African Union Commission | Tel: +251903384845 | Email: julioR@africa-union.org

For media enquiries, please contact:
- Ms. Dorothy Njagi | Strategic Communication Expert, Directorate of Health and Humanitarian Affairs, African Union Commission | Tel: +251940559950 | E-mail: njagid@africa-union.org

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Obstacles to Ratification

Ratification

- Lack of adequate resources
- Limited financial resources
- Perceived disadvantages
- Unclear ratification process
- Ambiguity on the role of AMA
- Political environment
- Lack of information

Benefits of AMA

Support for local pharmaceutical production	Harmonized regulatory requirements	Capacity building	Increased confidence
Access to databases	Collaboration with regulators	Partnership opportunities	Catalyzing trade (AfCFTA)
Identification of substandard and falsified medical products	Expanded access to quality medicines	Joint reviews and assessments	Access to API database and optimized healyhcare

Challenges and recommendations for improving the product registration process in Africa

Challenges	Recommendations
Lack of Harmonization: Inconsistent regulatory requirements across member states.	Enhance Harmonization: Align technical requirements and processes across member states.
Absence of Enforcement Mechanisms: Lack of effective means to ensure adherence to harmonization initiatives.	Establish Enforcement Mechanisms: Develop robust enforcement measures, including sanctions for non-compliance.
Resource Constraints: Limited financial, human, and technical resources for coordination efforts.	Mobilize Resources: Secure additional resources from member states and international partners.
Lack of Stakeholder Involvement: Insufficient engagement of private sector and civil society.	Engage Stakeholders: Actively involve pharmaceutical companies, healthcare providers, and patient groups.
Competing Priorities: Balancing medicines registration with other regional integration priorities.	Prioritize Harmonization: Elevate medicines registration harmonization as a key priority with adequate resources.
Lack of Transparency and Accountability: Insufficient transparency in decision-making processes.	Enhance Transparency and Accountability: Publish information on plans, progress, and establish feedback channels.

Areas for Improvement in Regulatory Capacity

Areas for Improvement in Regulatory Capacity	Description
Performance Auditing	Accountability, transparency, efficiency
Capacity Building	HR, institutions, policy making, project management, global dialogue
Regional Integration	Harmonize requirements, facilitate trade, promote joint economic development
Governance	Transparent, accountable, effective structures/process
Institutional Capacity	Robust regulatory framework, enhanced coordination and communication
Technical Assistance	Trade facilitation, customs, standards, regulations
Information Sharing	Among members states, with AU
Coordination	Align initiatives, achieve regional integration goals
Accountability	Clear roles & responsibilities, transparency in decision making, public participation & feedback
Transparency	Open and accessible process, Publish activities, decisions, finances

Q&A

Open floor for DISCUSSION