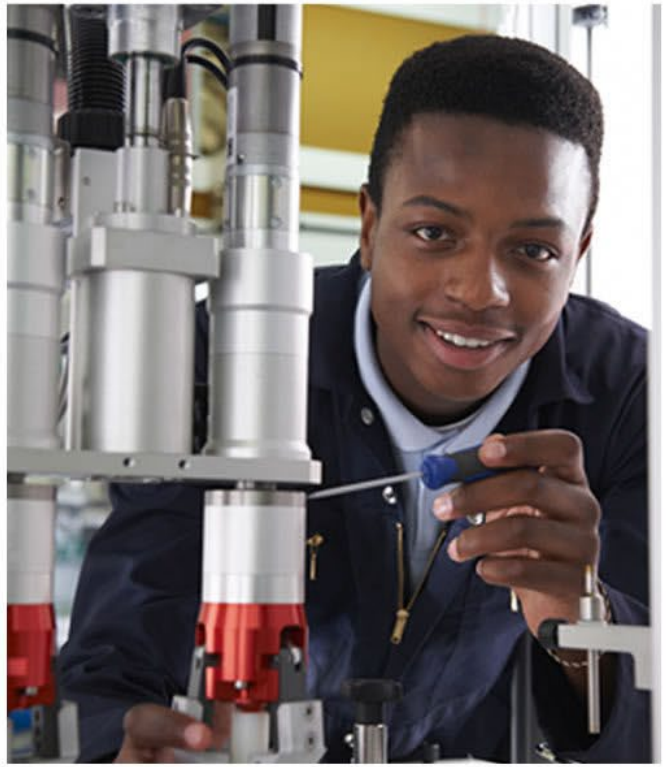
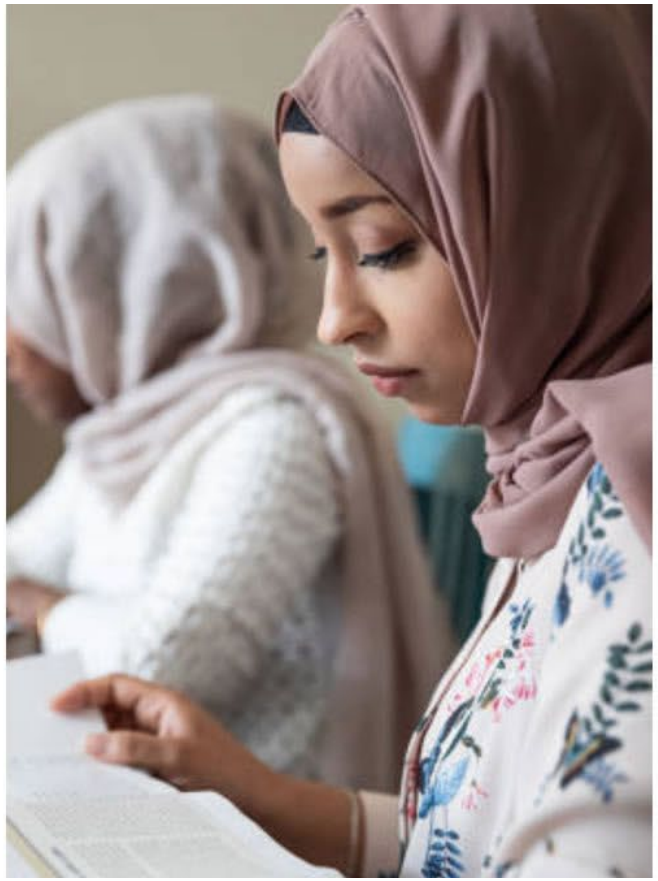
AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

JOINT UNICEF – UNFPA – WHO MEETING WITH MANUFACTURERS AND SUPPLIERS

Theme: Regional Procurement and Enabling Regulatory environment

28 November 2022





The African Medicines Regulatory Harmonization Initiative & African Medicines Agency
Margareth Ndomondo-Sigonda, Head – Heath Programme & AMRH

Presentation Outline

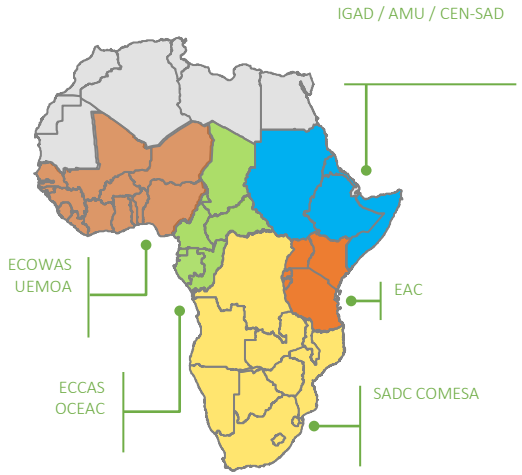
The African Medicines Regulatory Harmonization (AMRH) Initiative

The African Medicines Agency (AMA)

What regulatory and quality assurance mechanisms would enable regional procurement of health products

The African Medicines Regulatory Harmonization (AMRH) Initiative Overview

- Is a partnership birthed by the PMPA and formalized in 2009
- 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
- *Aim of AMRH to improve access to medical products and technologies in Africa through harmonisation of medicines regulation in five regions in Africa (SADC, EAC, IGAD, ECCAS and ECOWAS).*

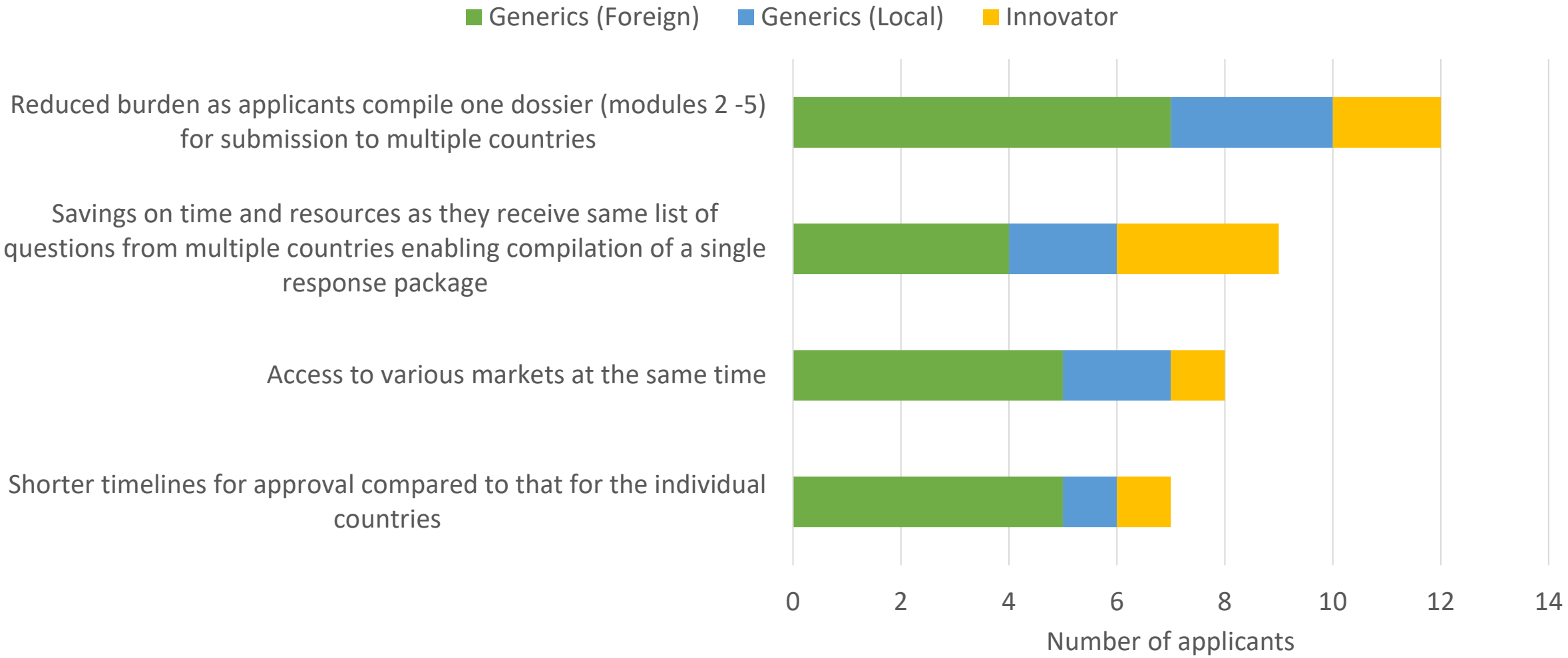


The Pathway

Regional regulatory platforms
- Harmonized standards (technical requirements / guidelines)
- Joint 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*

Benefits of the MRH initiatives to applicants: The EAC Case



Improved quality of dossier review process

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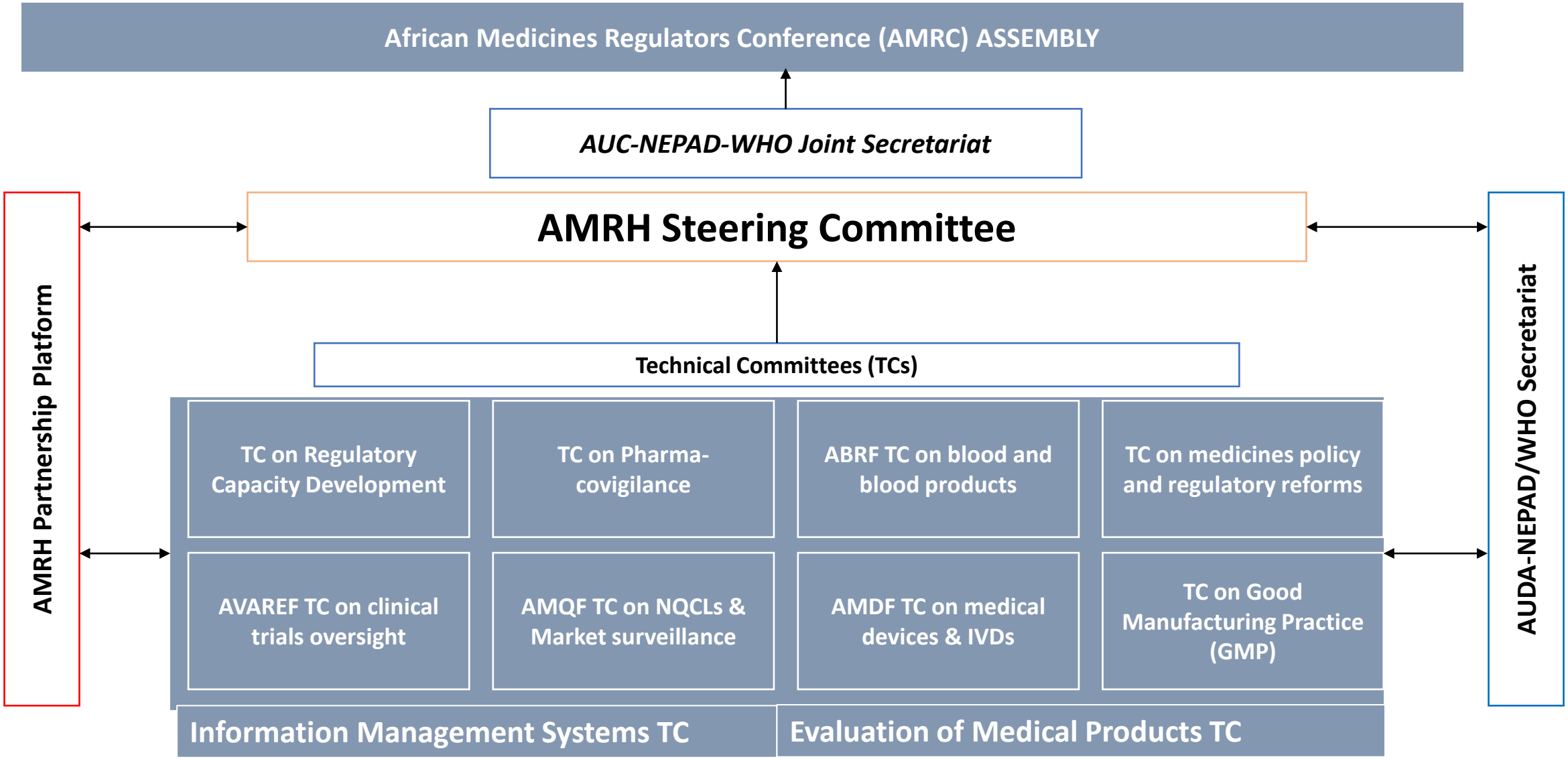
The African Medicines Regulatory Harmonization Governance Framework



5 Year Plan to support the AU Vision on Vaccines production and AMA Operationalization

The African Medicines Agency (AMA)

- AMA Goal
- Status of AMA Treaty Ratification and Hosting of HQ

The Africa Medicines Agency Goal

To strengthen regulatory systems continent wide through:

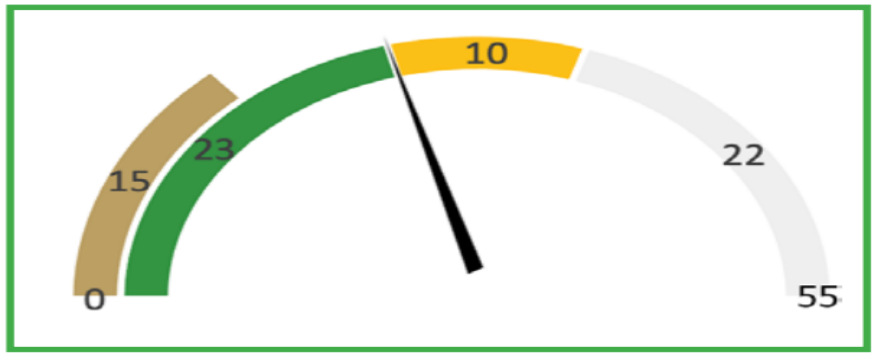
- Continental-wide harmonization of technical standards and processes in alignment with international standards
- Coordinating ongoing regulatory harmonization initiatives including joint assessments of medical products, joint inspections of manufacturing sites, clinical trial oversight, safety monitoring of medical products, AU Model Law domestication, RCOREs.
- Supporting countries to assess complex molecules e.g. Vaccines; facilitate authorization of products during emergencies.
- Providing scientific and regulatory advice in support of local pharma industry development including the Partnerships for African Vaccine Manufacturing (PAVM) & PMPA Frameworks.
- Removing unnecessary technical barriers to trade in support of African Continental Free Trade Area (AfCFTA).

Status of Ratification of AMA Treaty

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

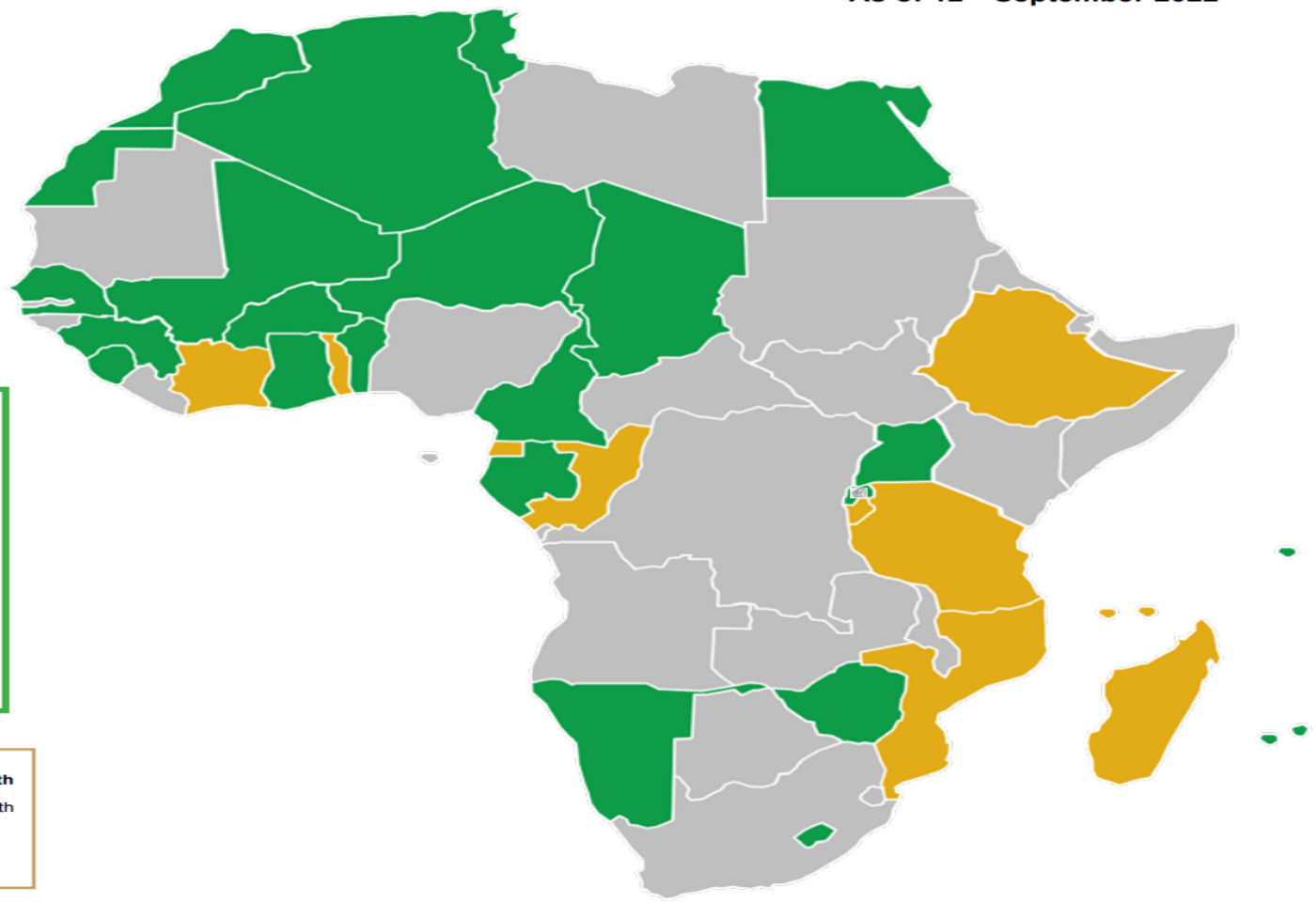
22 Member States that have neither signed nor ratified



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

As of 12th September 2022



AMA to take on the ongoing regulatory systems strengthening & harmonization Initiatives

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What regulatory and quality assurance mechanisms would enable regional procurement of health products

- Harmonization of technical requirements for medical products registration and GMP requirements
- Joint reviews of dossier applications
- Joint inspections of manufacturing sites
- Strengthened network of national medicines quality control laboratories to assist in laboratory analysis and post marketing surveillance activities

Thank you!