Supporting the African Medicines Agency

European Medicines Agency's contribution to the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa

Background & context

The African continent is today home to 1.3 billion people.

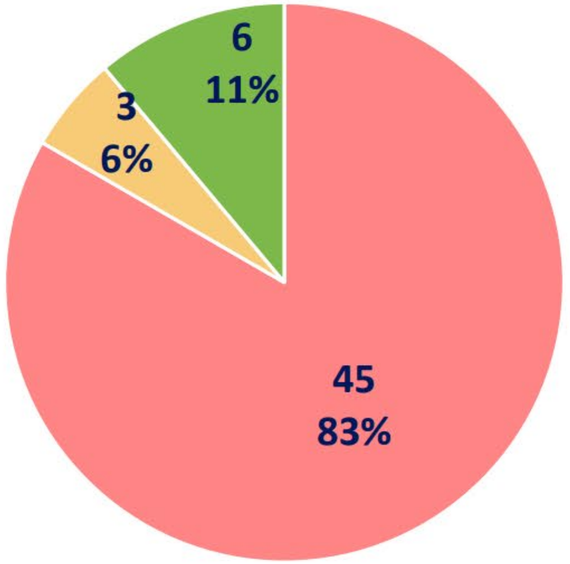
It accounts currently for 25% of the global disease burden but much of its population has limited access to the safe and effective medical products they need.

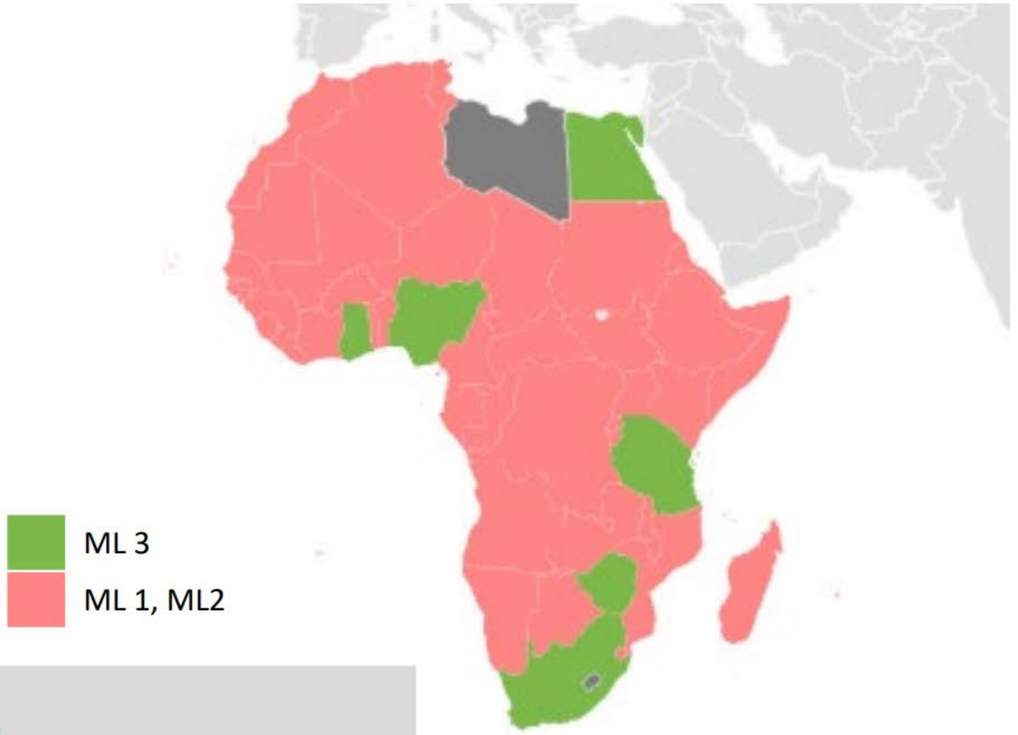
Health systems in Africa are over-dependent on international markets, importing 90% of medicines and 99% of their vaccines.

Sparked by the inequalities experienced during the COVID-19 pandemic, there is a wave of global momentum and political will to support an **African manufacturing ecosystem.**

Current status of national regulatory systems in Africa …1

Six (6) countries have NRAs at maturity level (ML) 3 according to WHO GBT





Results are based on NRA self-benchmarking and formal-benchmarking activities

Notes:

- *Egypt and South Africa are ML3 for regulation of vaccines (producing countries)*
- *Ghana, Nigeria, Tanzania and Zimbabwe are ML 3 for regulation of medicines and vaccines (non-producing)*

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization (WHO) concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on map represent approximate border lines for which there may be not yet be full agreement.

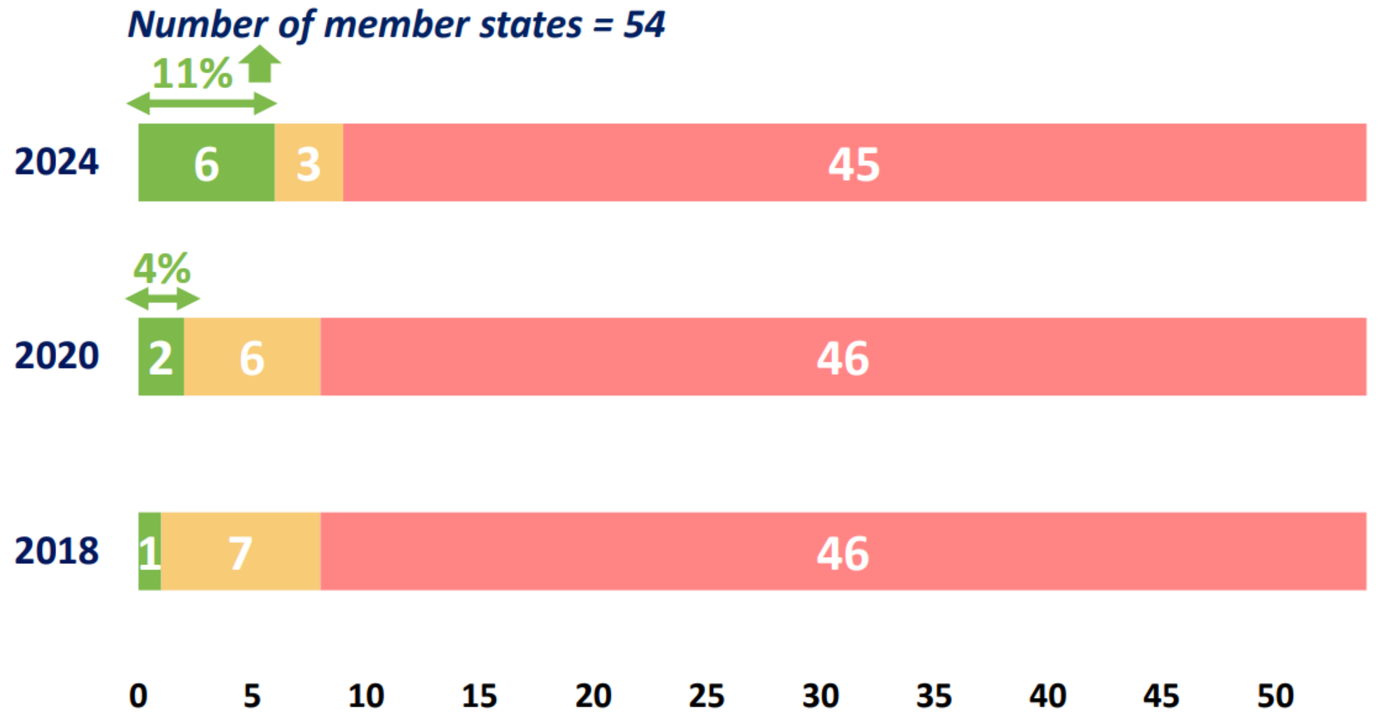
World Health Organization

NRAs = National Regulatory Authorities

Source: WHO RSS database, June 2024

Current status of national regulatory systems in Africa …2

(medicines and vaccines regulation)



ML1	*With some elements of regulatory system*
ML2	*Evolving national regulatory system*
ML3	*Stable, well functioning and integrated*

ML : *(regulatory system) maturity level*

Countries with NRAs at ML 3

Country	Year
Egypt	2022
Ghana	2020
Nigeria	2022
South Africa	2022
United Republic of Tanzania	2018
Zimbabwe	**2024**

Countries with NRAs at ML 2

Country	Year
Ethiopia	2023
Rwanda	2024
Senegal	2024

Project overview

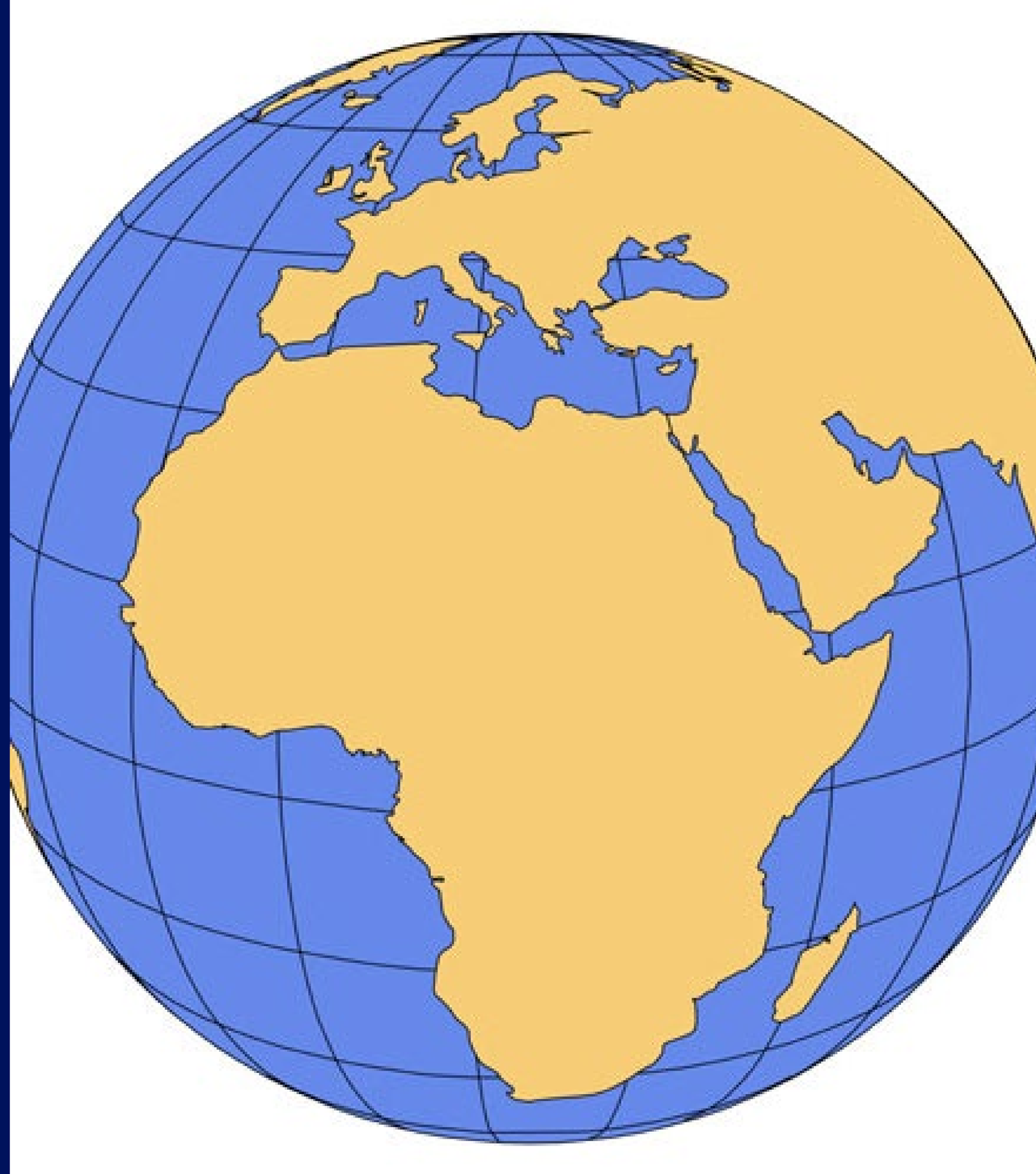
Commission decision 16 December 2022

- 10m EUR envelope
- support establishment of the African Medicines Agency (AMA)

EMA and DG INTPA negotiated contribution agreement

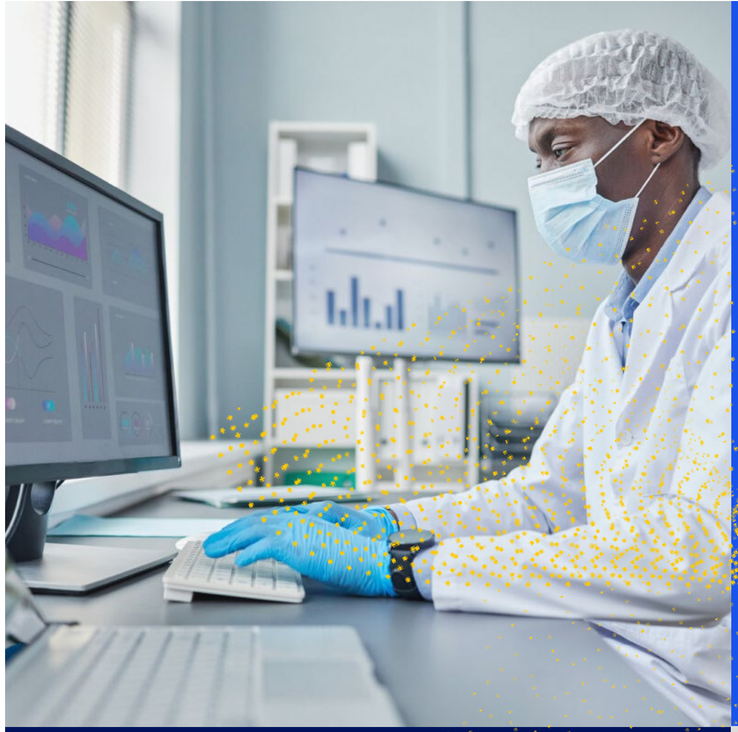
- EMA identified three priorities
- Aiming to deploy scientific and technical expertise
- Encompassing continental, regional and national level

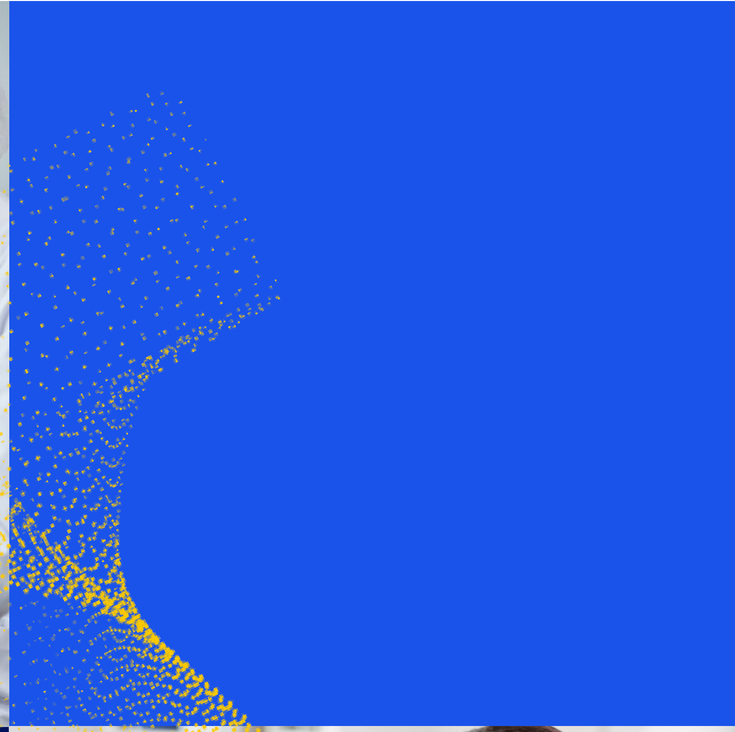
Collaboration with EEA member states a corner stone

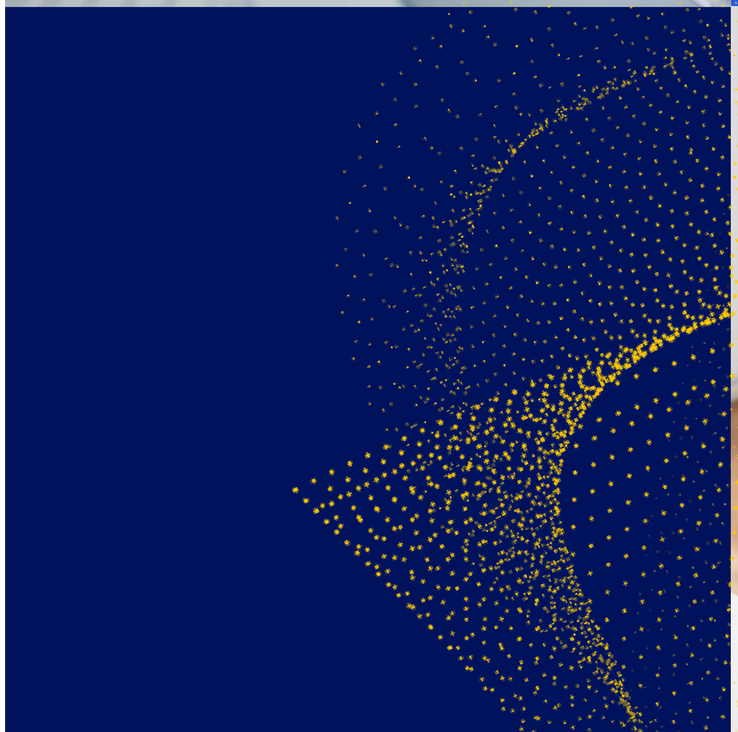


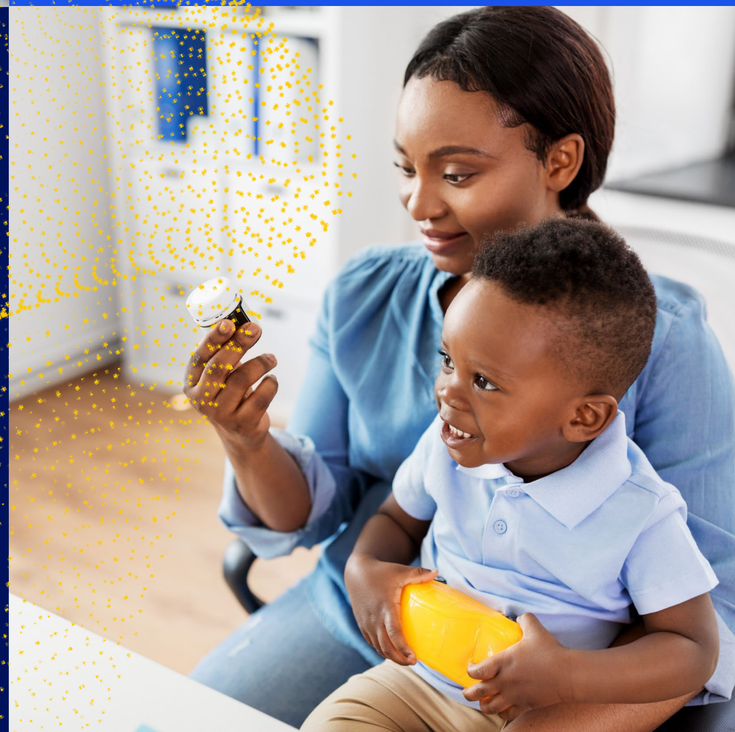
Description of Action

- Support regulatory strengthening at continental, regional and local levels
- Partner with African actors to address Africa's challenges
- Improve equitable access to safe, effective, quality-assured, and affordable essential vaccines, medicines, and health technologies in Africa
- Guided by discussions with African counterparts, the World Health Organization, and members of the CIP (WHO Coalition of interested parties).









What can EMA offer AMA?

1. Support the operationalisation of AMA

- Governance and foundations of AMA and its Technical Committees (TCs)
- Operationalisation and sustainability of AMA

2. Strengthen African scientific & regulatory expertise

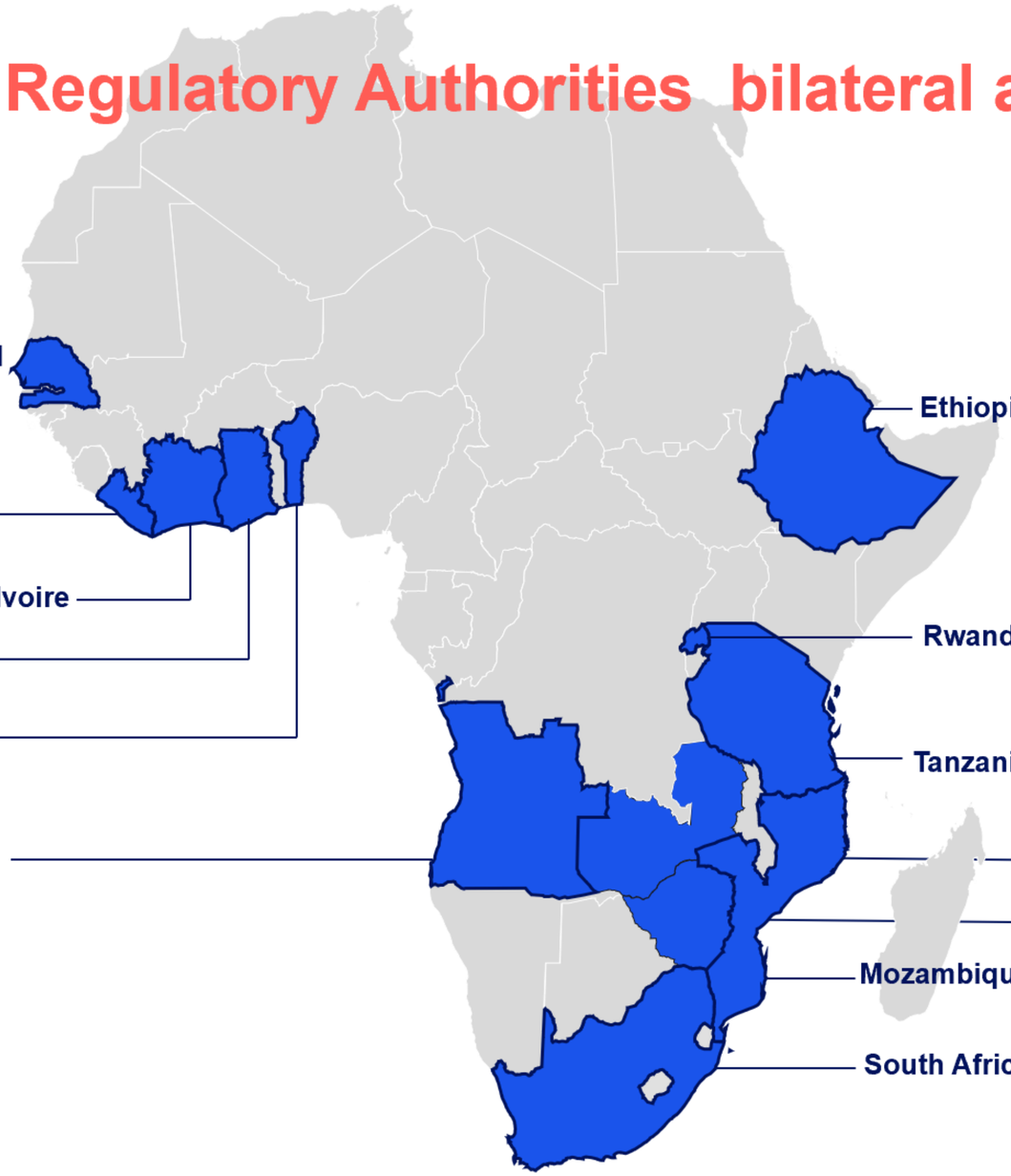
- Reinforce scientific and regulatory expertise for evaluation and supervision of medicines
- Reinforce the framework for working together as an African regulatory network

3. Coordinate and align European efforts

- Leverage Team Europe (MAV+) efforts
- Consider goals and activities of other international partners

OVERVIEW

Current National Regulatory Authorities bilateral actions in Africa.



France (ANSM) | Germany (PEI) | Belgium (FAMHP) ↔ **Senegal**

Germany (PEI) ↔ **Liberia**

Portugal (INFARMED) ↔ **Côte D'Ivoire**

Germany (PEI) ↔ **Ghana**

France (ANSM) ↔ **Benin**

Portugal (INFARMED) ↔ **Angola**

Ethiopia ↔ Denmark (DKMA)

Rwanda ↔ Austria (AGES) | France (ANSM) | Germany (PEI) | Lithuania (VVKT) | Sweden (MPA)

Tanzania ↔ Italy (AIFA) | Germany (PEI)

Zambia ↔ Germany (PEI)

Zimbabwe ↔ Germany (PEI)

Mozambique ↔ Portugal (INFARMED)

South Africa ↔ Germany (PEI)

EMA and NCAs can provide technical assistance to support regulatory authorities develop complementary regulatory functions

African Medicines Agency (AMA)

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.

A pilot for continental procedure for the evaluation of medicinal products will be launched in 2024 with EMA support.

Organs of the AMA

1. The Conference of the States Parties
2. Governing Board
3. The Secretariat
4. Technical Committees

AMA will serve six main functions

1. Marketing authorization
2. Inspection
3. Marketing surveillance
4. Safety monitoring
5. Oversight of clinical trials
6. Quality control

Any questions?

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