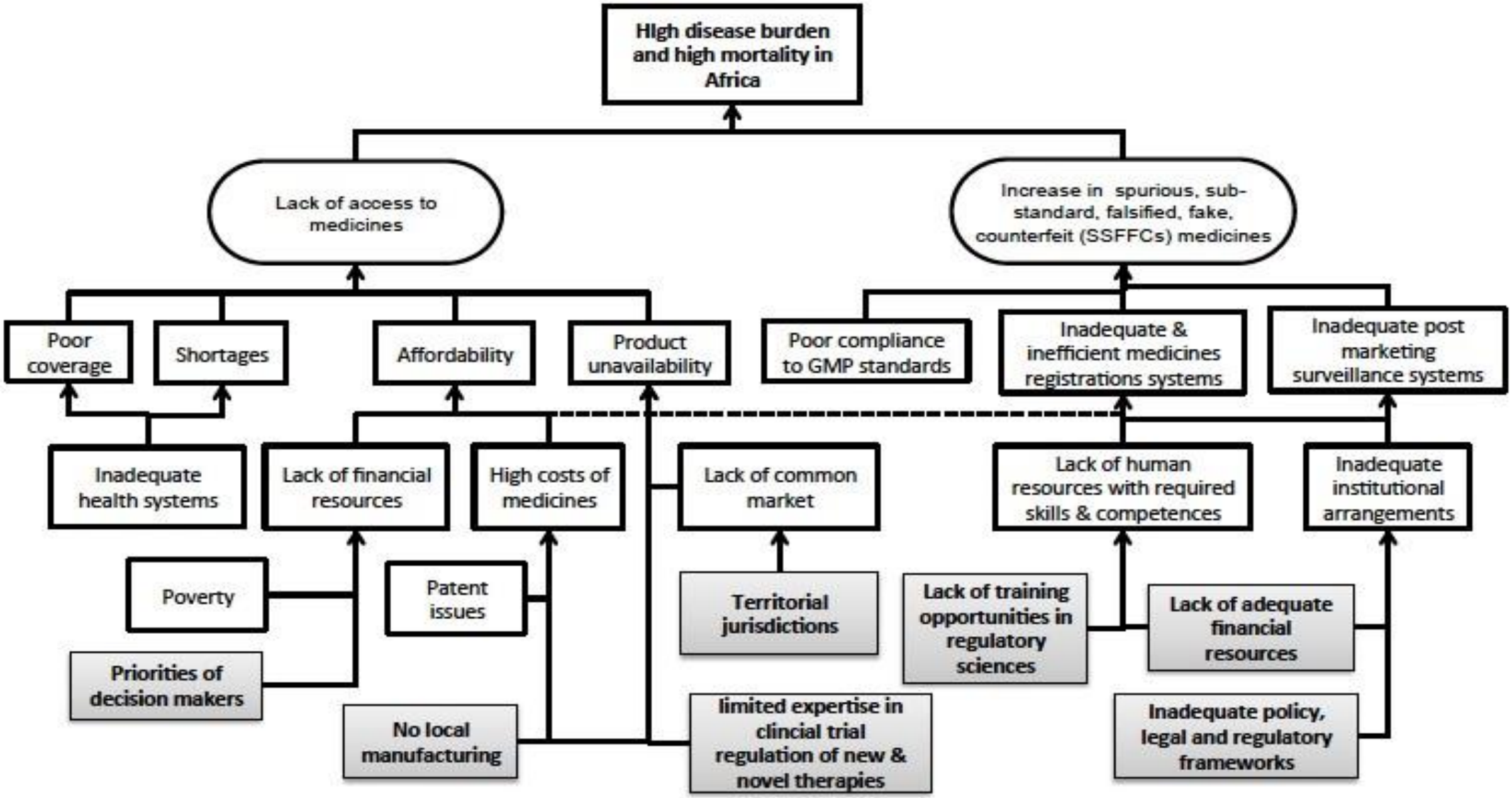

HIgh disease burden and high mortality in Africa
Lack of access to medicines
Increase in spurious, sub-standard, falsified, fake, counterfeit (SSFFCs) medicines
Poor coverage
Shortages
Affordability
Product unavailability
Poor compliance to GMP standards
Inadequate & inefficient medicines registrations systems
Inadequate post marketing surveillance systems
Inadequate health systems
Lack of financial resources
High costs of medicines
Lack of common market
Lack of human resources with required skills & competences
Inadequate institutional arrangements
Poverty
Patent issues
Territorial jurisdictions
Lack of training opportunities in regulatory sciences
Lack of adequate financial resources
Priorities of decision makers
No local manufacturing
limited expertise in clincial trial regulation of new & novel therapies
Inadequate policy, legal and regulatory frameworks

An estimated 39% of AU Member States have limited regulatory capacity to implement all the regulatory functions.

- The analysis further reveals that most NMRAs have inappropriate organizational structures to implement medical products regulatory functions.
- In some countries, the entities responsible for coordinating and overseeing the implementation of medical products regulation are units under departments of the ministry of health.
- Although these entities are expected to be autonomous, full-fledged departments with statutory authority (boards or commissions) to ensure their independence, transparency and accountability in decision-making, the reality is differed

The analysis of studies shows that the Regional Economic Communities (RECs), namely East African Community (EAC), Southern African Development Community (SADC), Economic Community of West African States (ECOWAS), West African Economic and Monetary Union (UEMOA) and Central African Economic and Monetary Union (CEMAC) are at various stages of economic integration and have policies, laws, regulatory tools and standards for harmonization of medical products regulation.

Some of the RECs are also working towards joint dossier reviews and inspection of pharmaceutical manufacturing plants, which is a key factor for building regulatory capacity among participating countries in regional harmonization schemes.

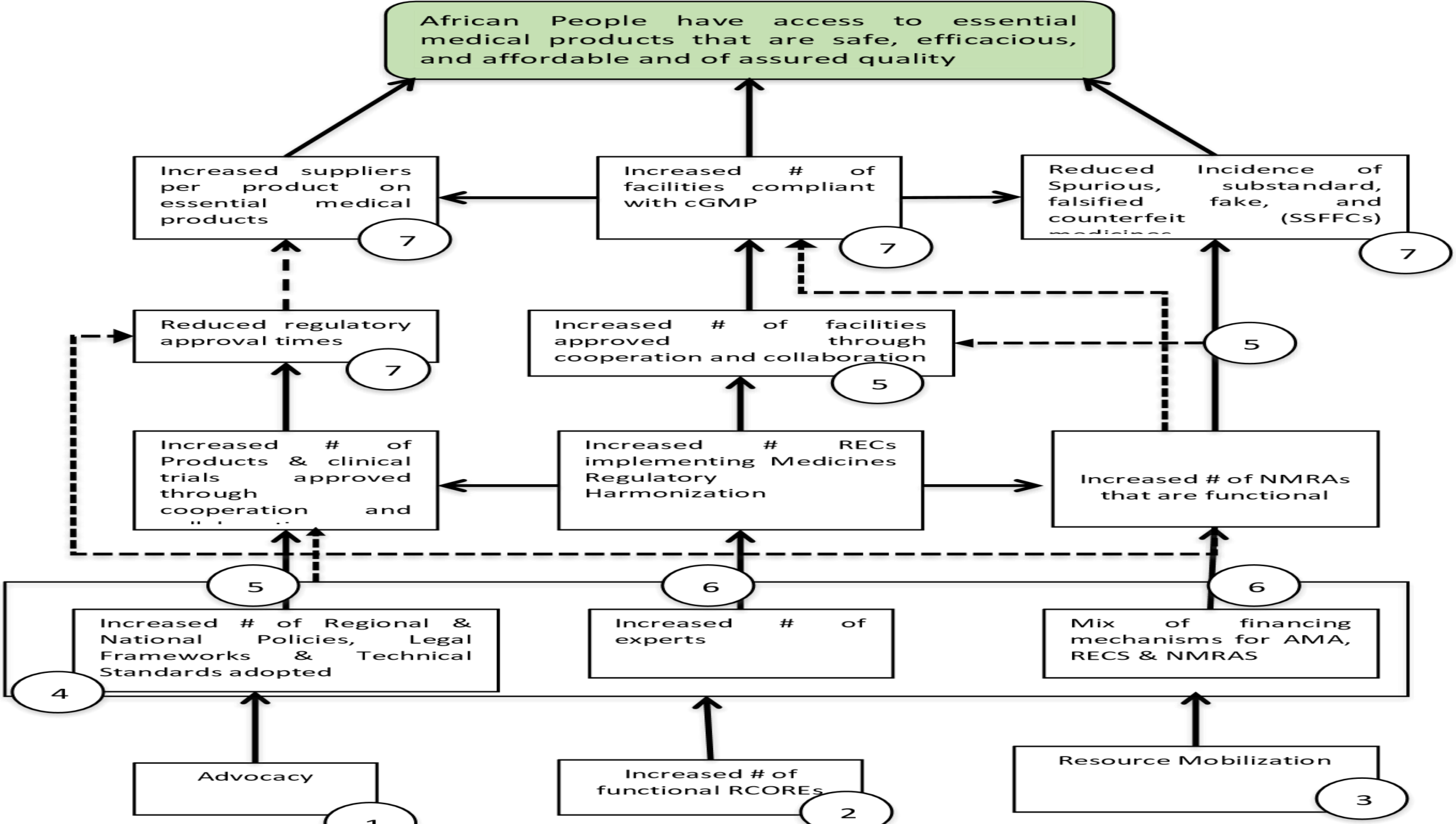
TOWARDS REGULATORY HARMONIZATION

- Country regulatory agency
- 5 regional Regulatory agencies: ECOWAS, ECCAS, IGAD/AMU, EAC, SADC

Tomorrow : One regulatory agency

ISSUES AND CHALLENGES

- Despite the capacity building efforts of partners to strengthen national and subregional regulatory systems and promote harmonization, evidence shows that the capacity of countries to regulate medical products is still inadequate in Africa.
- However, some of the countries have better regulatory systems than others. This disparity in regulatory capacity provides further justification for establishing a continental regulatory system.
- Moreover, implementation of agreed procedures and processes, coordination of regulatory practices across subregions, priority-setting for products against target diseases, promotion of manufacturing and optimal use of the limited resources available to the NMRAs remain significant challenges.


African People have access to essential medical products that are safe, efficacious, and affordable and of assured quality
Increased suppliers per product on essential medical products
7
Increased # of facilities compliant with cGMP
7
Reduced Incidence of Spurious, substandard, falsified fake, and counterfeit (SSFFCs)
7
Reduced regulatory approval times
7
Increased # of facilities approved through cooperation and collaboration
5
5
Increased # of Products & clinical trials approved through cooperation and
Increased # RECs implementing Medicines Regulatory Harmonization
Increased # of NMRAs that are functional
5
6
6
Increased # of Regional & National Policies, Legal Frameworks & Technical Standards adopted
4
Increased # of experts
Mix of financing mechanisms for AMA, RECS & NMRAS
Advocacy
1
Increased # of functional RCOREs
2
Resource Mobilization
3

The African Union Heads of State and Government adopted the treaty for the establishment of the African Medicine Agency (AMA) during their 32nd Ordinary Session of the Assembly on 11 February 2019 in Addis Ababa, Ethiopia

Vision

The vision for establishment of the AMA is to ensure that all Africans have access to affordable medical products for priority diseases/conditions that meet internationally recognized standards of quality, safety and efficacy.

Mission

The mission of the AMA at the continental level is to coordinate national and subregional medicines regulatory systems, carry out regulatory oversight of selected medical products and promote cooperation, harmonization and mutual recognition of regulatory decisions.

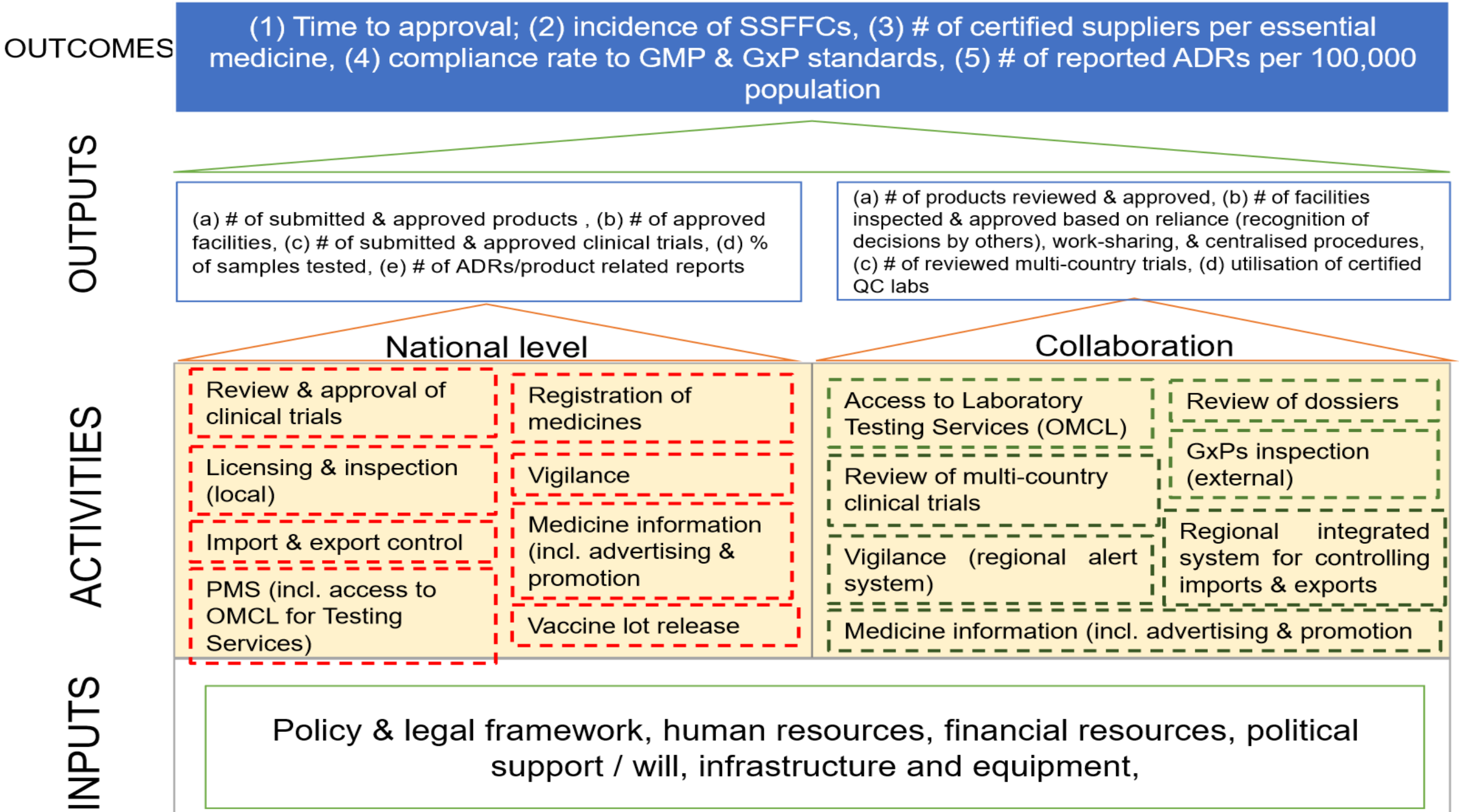
Functions of the AMA (1/2)

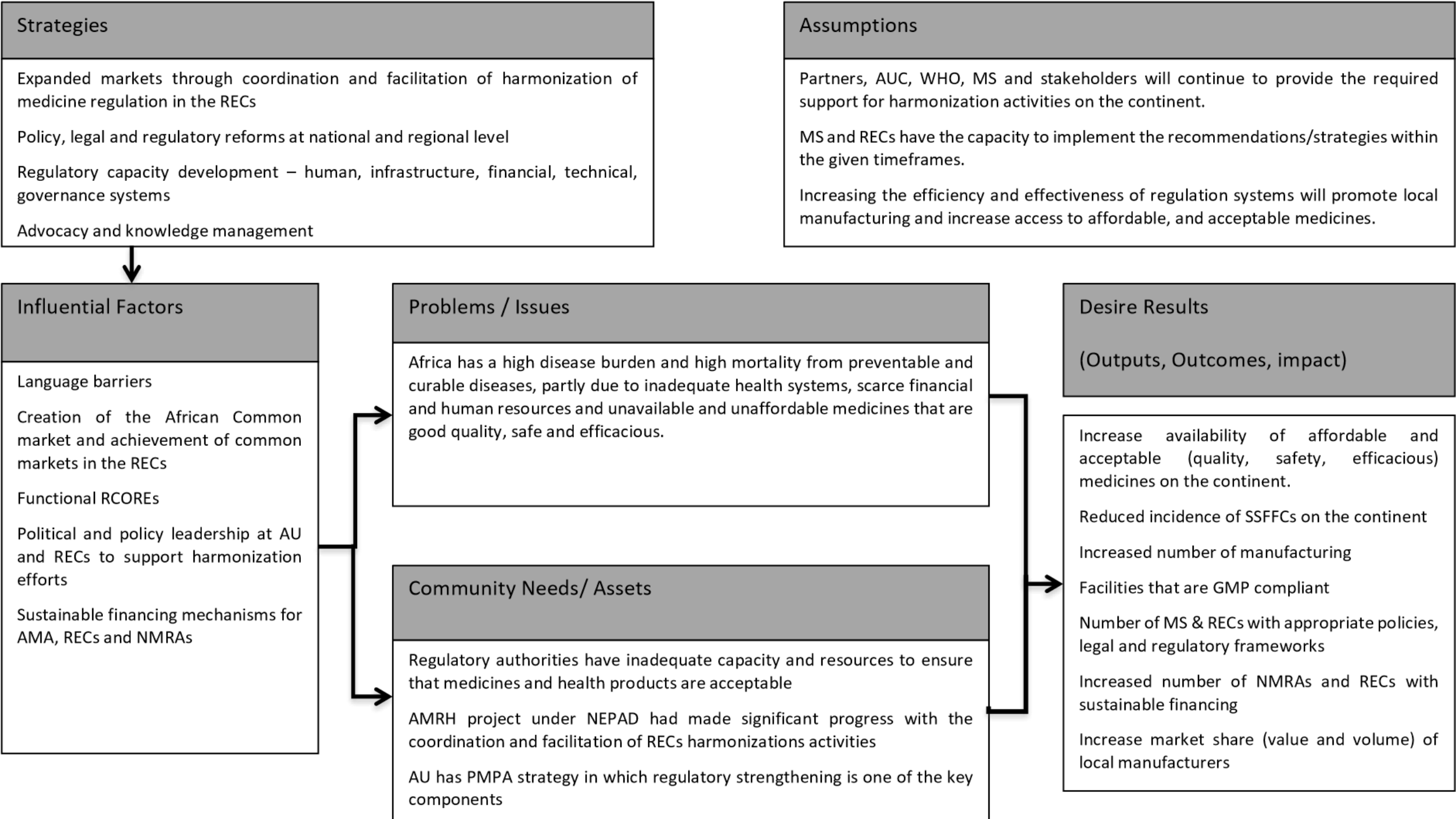
The AMA will have a coordination and stewardship function for the regulatory activities of the Member States. Among the core regulatory functions, the AMA will perform the following:

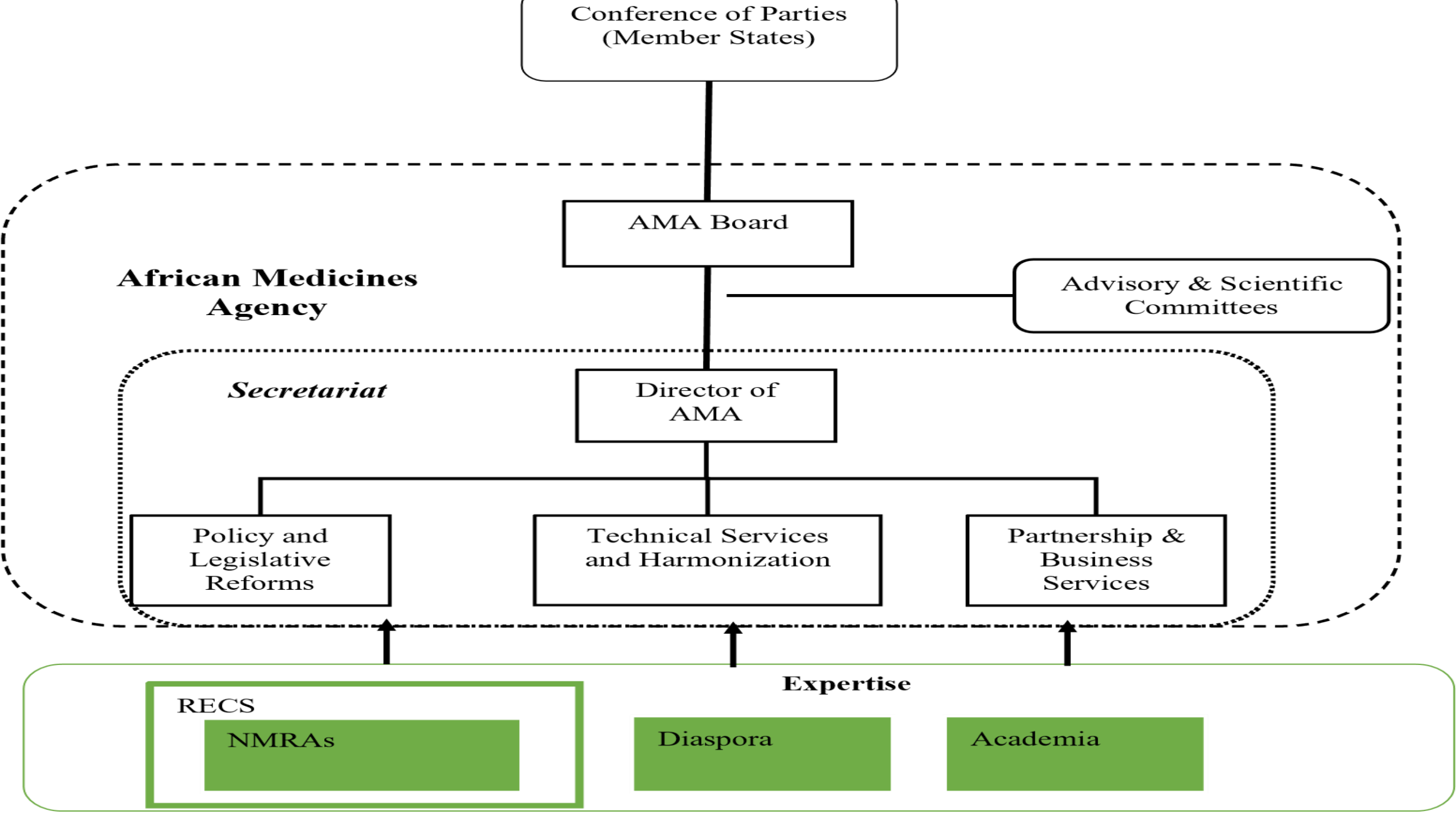
- (a) Marketing authorization: The AMA will be responsible for evaluation and decision making with regard to selected medical products for treatment of priority diseases/conditions as determined by the African Union.
- (b) Inspection: The AMA will undertake coordination and share information on a regular basis in regard to all products that it has authorized for marketing.
- (c) Market surveillance: The AMA will coordinate the collection and sharing of information on all medical products including SSFFC medical products.

Functions of the AMA (2/2)

- (d) Safety monitoring: The AMA will be responsible for making regulatory decisions concerning products selected for treatment of priority diseases/conditions as determined by Member States, based on available safety information. In addition, the AMA will collect and store information on the quality and safety of medical products and share them with all its Member States and even globally. It will also establish collaboration with global and regional centres in the area of safety monitoring.
- (e) Oversight of clinical trials: The AMA will coordinate joint reviews of applications for conduct of clinical trials.
- (f) Quality control: The AMA will coordinate and network quality control laboratory services for national and subregional regulatory authorities.


OUTCOMES
(1) Time to approval; (2) incidence of SSFFCs, (3) # of certified suppliers per essential medicine, (4) compliance rate to GMP & GxP standards, (5) # of reported ADRs per 100,000 population
OUTPUTS
(a) # of submitted & approved products , (b) # of approved facilities, (c) # of submitted & approved clinical trials, (d) % of samples tested, (e) # of ADRs/product related reports
(a) # of products reviewed & approved, (b) # of facilities inspected & approved based on reliance (recognition of decisions by others), work-sharing, & centralised procedures, (c) # of reviewed multi-country trials, (d) utilisation of certified QC labs
ACTIVITIES
National level
Review & approval of clinical trials
Licensing & inspection (local)
Import & export control
PMS (incl. access to OMCL for Testing Services)
Registration of medicines
Vigilance
Medicine information (incl. advertising & promotion
Vaccine lot release
Collaboration
Access to Laboratory Testing Services (OMCL)
Review of multi-country clinical trials
Vigilance (regional alert system)
Review of dossiers
GxPs inspection (external)
Regional integrated system for controlling imports & exports
Medicine information (incl. advertising & promotion
INPUTS
Policy & legal framework, human resources, financial resources, political support / will, infrastructure and equipment,


Strategies
Expanded markets through coordination and facilitation of harmonization of medicine regulation in the RECs
Policy, legal and regulatory reforms at national and regional level
Regulatory capacity development – human, infrastructure, financial, technical, governance systems
Advocacy and knowledge management
Assumptions
Partners, AUC, WHO, MS and stakeholders will continue to provide the required support for harmonization activities on the continent.
MS and RECs have the capacity to implement the recommendations/strategies within the given timeframes.
Increasing the efficiency and effectiveness of regulation systems will promote local manufacturing and increase access to affordable, and acceptable medicines.
Influential Factors
Language barriers
Creation of the African Common market and achievement of common markets in the RECs
Functional RCOREs
Political and policy leadership at AU and RECs to support harmonization efforts
Sustainable financing mechanisms for AMA, RECs and NMRAs
Problems / Issues
Africa has a high disease burden and high mortality from preventable and curable diseases, partly due to inadequate health systems, scarce financial and human resources and unavailable and unaffordable medicines that are good quality, safe and efficacious.
Community Needs/ Assets
Regulatory authorities have inadequate capacity and resources to ensure that medicines and health products are acceptable
AMRH project under NEPAD had made significant progress with the coordination and facilitation of RECs harmonizations activities
AU has PMPA strategy in which regulatory strengthening is one of the key components
Desire Results
(Outputs, Outcomes, impact)
Increase availability of affordable and acceptable (quality, safety, efficacious) medicines on the continent.
Reduced incidence of SSFFCs on the continent
Increased number of manufacturing
Facilities that are GMP compliant
Number of MS & RECs with appropriate policies, legal and regulatory frameworks
Increased number of NMRAs and RECs with sustainable financing
Increase market share (value and volume) of local manufacturers


Conference of Parties
(Member States)
AMA Board
African Medicines
Agency
Advisory & Scientific
Committees
Secretariat
Director of
AMA
Policy and
Legislative
Reforms
Technical Services
and Harmonization
Partnership &
Business
Services
Expertise
RECS
NMRAs
Diaspora
Academia