ESTABLISHING AFRICAN MEDICINES AGENCY (AMA)

'Luanda Commitment by Ministers of Health on African Medicines Agency: Setting Milestones towards its Establishment'

APR 2014

1st Meeting of African Ministers of Health

ADOPTED

Establish AMA Task Team

DEC 2015

Executive Council Decision

ENCAPSULATED

Define Scope of AMA

1. ESTABLISH A TASK TEAM

2. DEFINE THE SCOPE

AMA TASK TEAM

ESTABLISHED NOVEMBER 2014

Key Documents

- Legal Framework
- Institutional Framework
- Business plan for AMA

VISION

All Africans have access to affordable medical products

MISSION

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.

AMRH

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GUIDING PRINCIPLES OF THE AFRICAN MEDICINES AGENCY (AMA)

01 GOOD GOVERNANCE AND STEWARDSHIP

AMA will observe practices of good governance.

02 COMPETENCY

AMA will fulfil its functions by deploying and maintaining the best competencies available

03 OWNERSHIP

Member States will have primary ownership of AMA.

04 TRANSPARENCY AND ACCOUNTABILITY IN DECISION-MAKING

The AMA will make its decisions independently.
The AMA will be accountable to Member States of the African Union.

05 CONFIDENTIALITY

The AMA will adhere to the principles of confidentiality in all its operations.

06 COMMITMENT TO SOUND QUALITY MANAGEMENT

In all its functions the AMA will adhere to international standards of quality management.

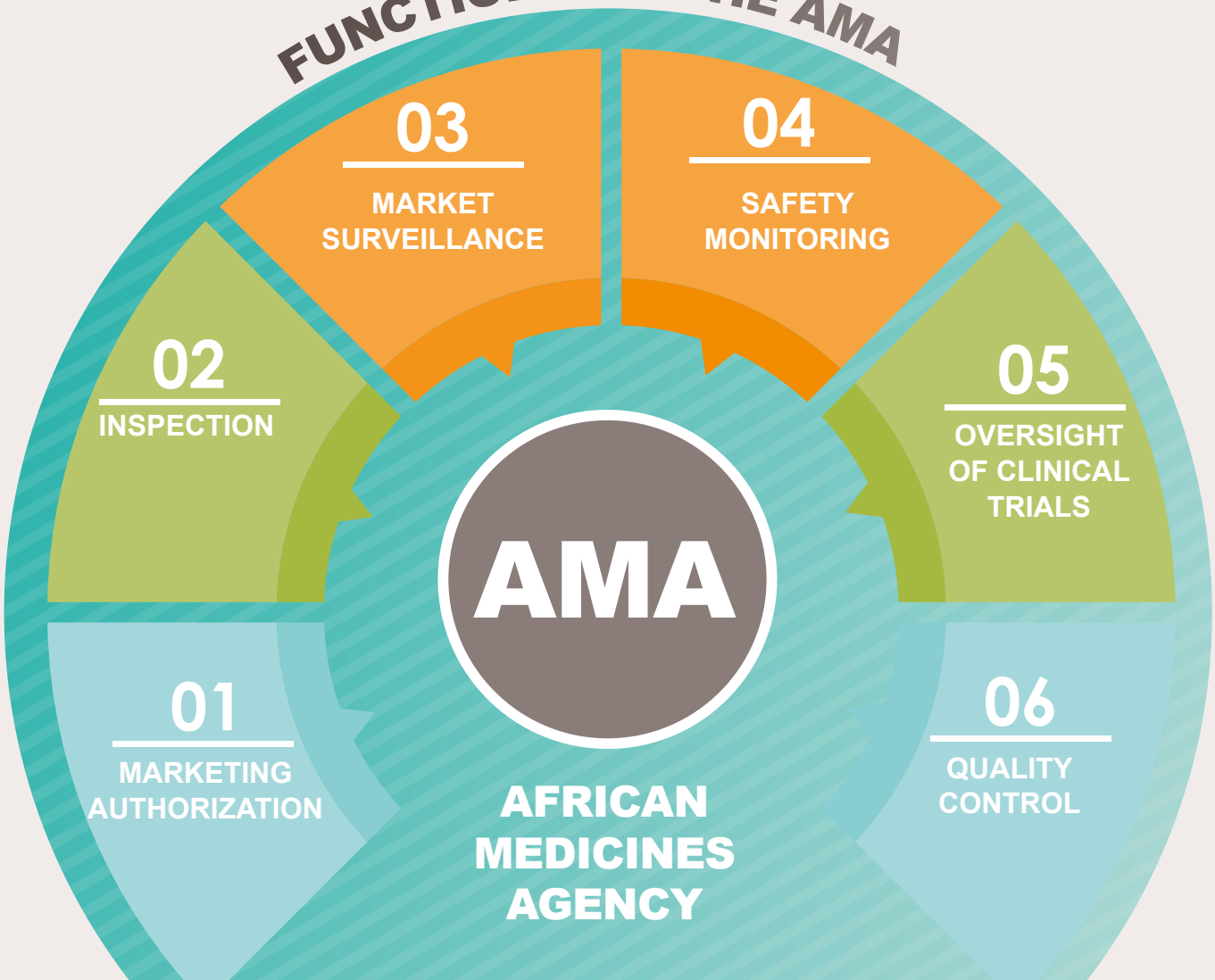
07 PARTNERSHIPS AND COLLABORATION

The AMA will build and strengthen partnerships.

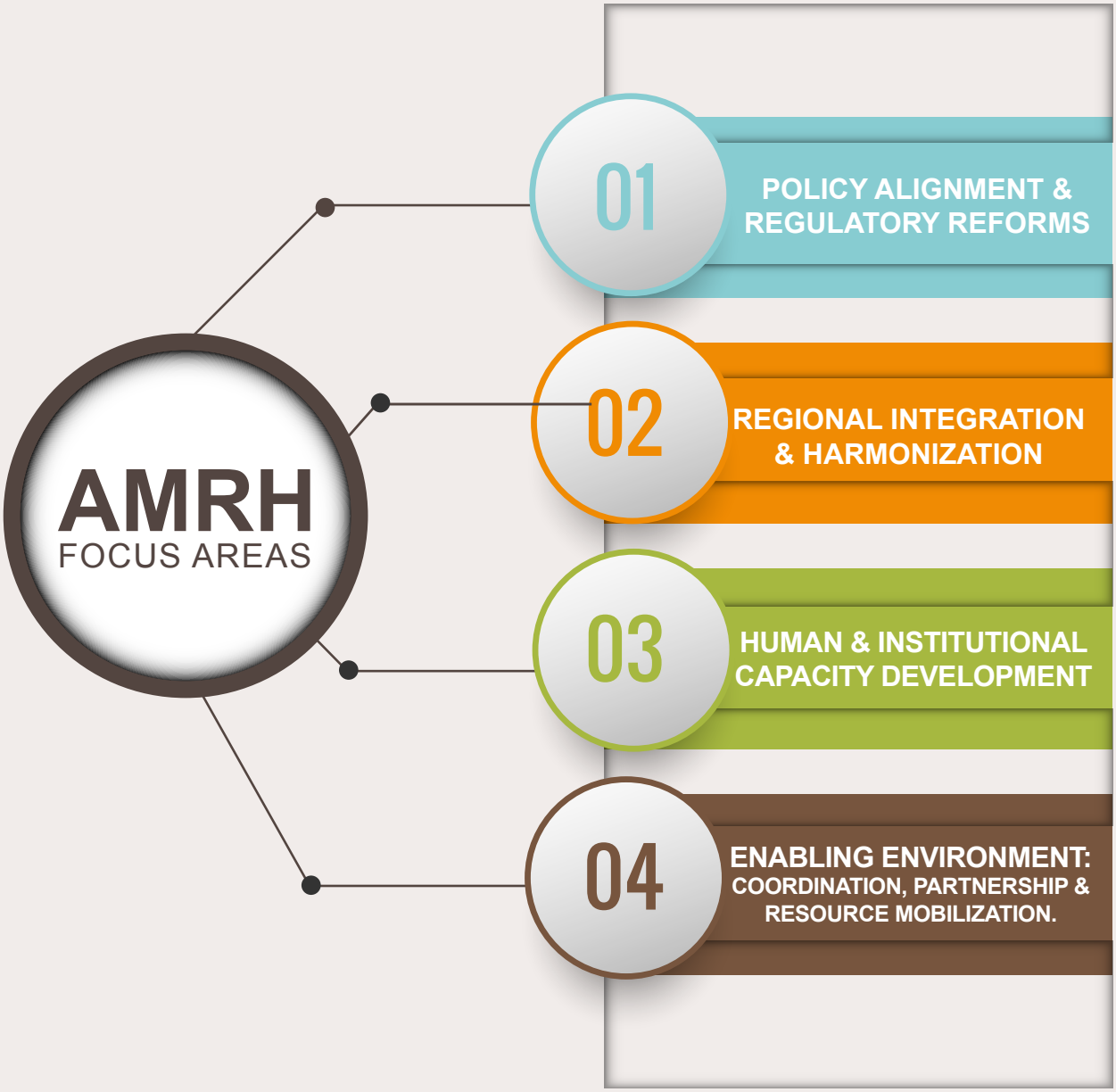
08 SUPPORT FOR INNOVATION

The AMA will support innovations that will enhance access to new medical products in order to address the public health priorities of Africa.

FUNCTIONS OF THE AMA



ABOUT THE AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH)



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AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH)
FOUR FOCUS AREAS

1 POLICY ALIGNMENT & REGULATORY REFORMS

Enhanced policy coherence in Regional Economic Communities (RECs) and AU member states for public health and pharmaceutical industry development

- Policy, legal and institutional framework for the establishment of African Medicine Agency (AMA) endorsed by AU — 2018
- **3 REGIONS** have adopted regional policies and legal frameworks for regulation of medicines — 2020
- **25 COUNTRIES** have domesticated the Model Law on Medical Products regulation
- **10 COUNTRIES** implementing pharmaceutical innovation framework and PMPA
- **3 REGIONS** have implemented Innovative GMP Certification Schemes

2 REGIONAL INTEGRATION & HARMONIZATION

Increased use of harmonized policies and regulatory frameworks by member states

- **5 REGIONS AND 25 COUNTRIES** have adopted regionally agreed regulatory technical guidelines and standards — 2020
- AMRH project scope expanded to cover clinical trials oversight, post-marketing surveillance and pharmacovigilance, medical devices and diagnostics in **5 REGIONS**
- AMRH M&E framework implemented in **3 REGIONS**

3 HUMAN AND INSTITUTIONAL CAPACITY DEVELOPMENT

Increased human and institutional capacity for regulation of medical products and technologies

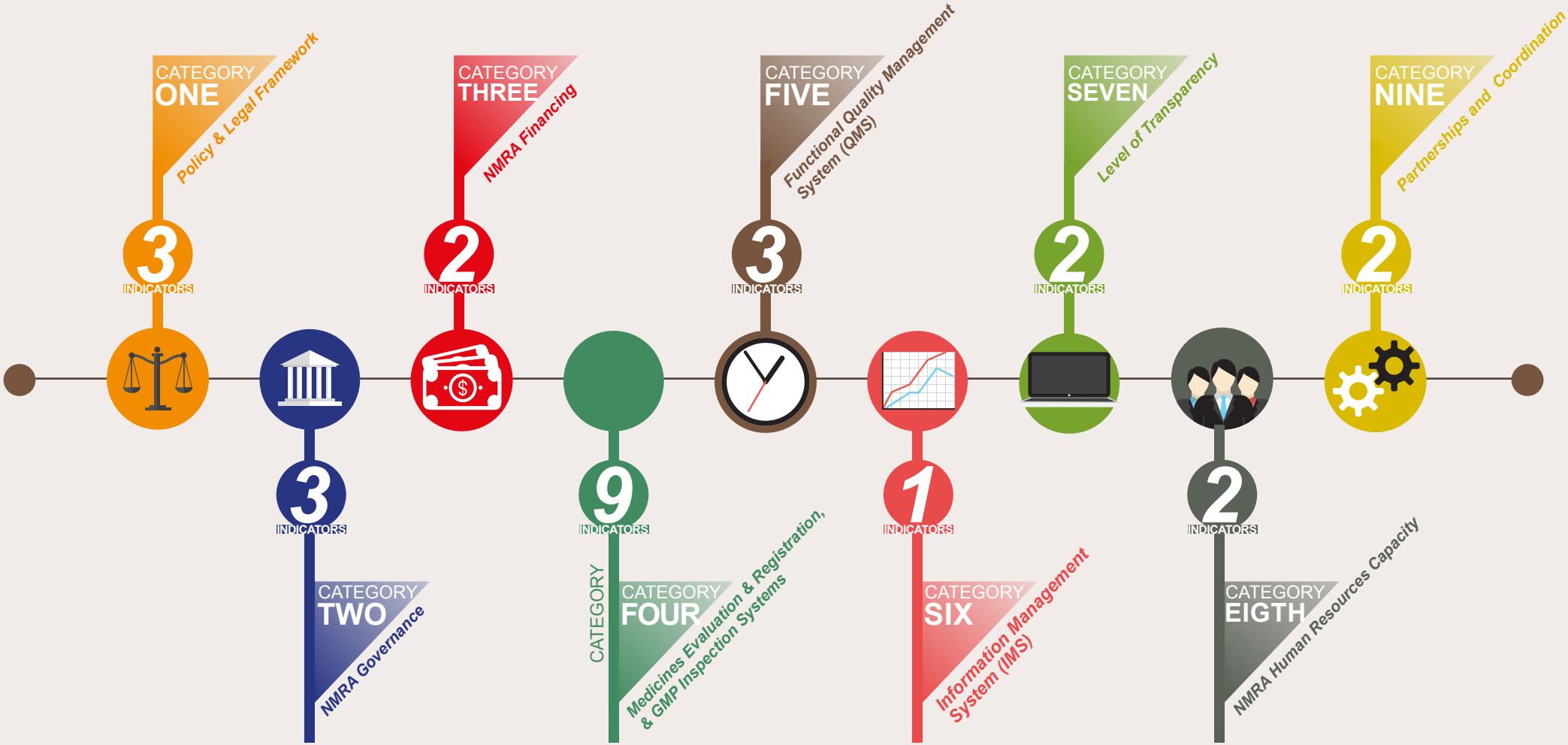
- Curricula on Regulatory Science in **alignment** with WHO Global Curricula Framework — 2018
- **15 REGIONAL CENTRES** of regulatory excellence operational — 2020
- **10% INCREASE** in the number of regulatory experts in Africa
- **50%** of experts in the "Pool of Regulatory Experts" utilized
- African Regulatory Professional Fellowship Programme **DEVELOPED AND ADMINISTERED**
- Align regulatory systems strengthening programmes with AMRH and AMA

4 ENABLING ENVIRONMENT: COORDINATION, PARTNERSHIP AND RESOURCE MOBILIZATION

Effective coordination and alignment of regulatory interventions with AMRH Framework and African Medicines Agency (AMA)

- Scientific and regulators conferences convened bi-annually
- Scientific & Regulators conferences convened biennially
- AMRH Advocacy and Communication strategy implemented from 2016
- At least **4 FUNCTIONAL TECHNICAL WORKING GROUPS** (TWGs) — 2018
- **AMRH TRANSITIONED INTO AMA**
- **50% OF NMRA RESOURCES MOBILIZED** locally or through broadened bilateral and multilateral sponsors — 2019
- **50% OF FUNDING** for AMRH initiative mobilized from other sources — 2020
- **PARTNERSHIP PLATFORM** Accountability Framework developed and implemented

AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH)
MONITORING AND EVALUATION FRAMEWORK



MONITORING AND EVALUATION FRAMEWORK
9 CATAGORIES | 27 IINDICATORS

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AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH)
MONITORING AND EVALUATION FRAMEWORK

INDICATORS

CATEGORY ONE

- **AVAILABILITY** of a current and comprehensiveness of the **NATIONAL MEDICINES POLICY**
- **AVAILABILITY** and comprehensiveness of the **LEGAL FRAMEWORK**
- **DATE OF LAST REVIEW** or amendment of the **MEDICINES LAW**

CATEGORY TWO

- The **LEVEL OF AUTONOMY** of the NMRA
- **AVAILABILITY OF STRUCTURES** to support NMRA decision making process
- **PREDICTABILITY** of NMRA decision making process

CATEGORY THREE

LEVEL OF NMRA FUNDING

(a): **RELIABILITY OF NMRA FUNDING**
(B): **RELIABILITY OF NMRA FUNDING**

CATEGORY FOUR

- **AVAILABILITY** of a system for **REGISTRATION OF MEDICINES**
- **AVAILABILITY** of a GMP Inspection system
- **ABILITY** of NMRA to **TRACK REGISTRATION APPLICATIONS**
- **PERCENTAGE** of products applications whose registration decision has been made within the standard time
- **PERCENTAGE** of product applications jointly assessed whose decision are made within standard time
- **AVERAGE TIMELINES** attained for regulatory decisions to be made on applications for product registration
- **PERCENTAGE** of NMRAs using regionally agreed guidelines
- **PROPORTION OF NMRAS** participating in joint GMP inspections
- **PROPORTION OF NMRAS** participating in joint assessments

CATEGORY FIVE

- **ATTAINMENT of Quality Management System (QMS)** requirements by NMRA
- **PERCENTAGE OF NMRAS** ISO 9001 Certified in Registration and GMP Inspection
- **AVAILABILITY** of mechanism for addressing customer concern

CATEGORY SIX

- **ATTAINMENT** of requirements for an integrated Information Management System (IMS)

CATEGORY SEVEN

- **AVAILABILITY** of key regulatory information to the general public
- **AVAILABILITY** of stakeholders' engagement platform(s)

CATEGORY EIGHT

- **MEDICAL PRODUCTS REGULATORY** experts' density
- **INTERNAL NMRA Capacity**

CATEGORY NINE

- **TOWARDS** collective impact on regulatory systems strengthening.
- **PROPORTION OF PARTNERS** that are aligning to the AMRH framework

MONITORING AND EVALUATION FRAMEWORK
9 CATAGORIES | 27 IINDICATORS

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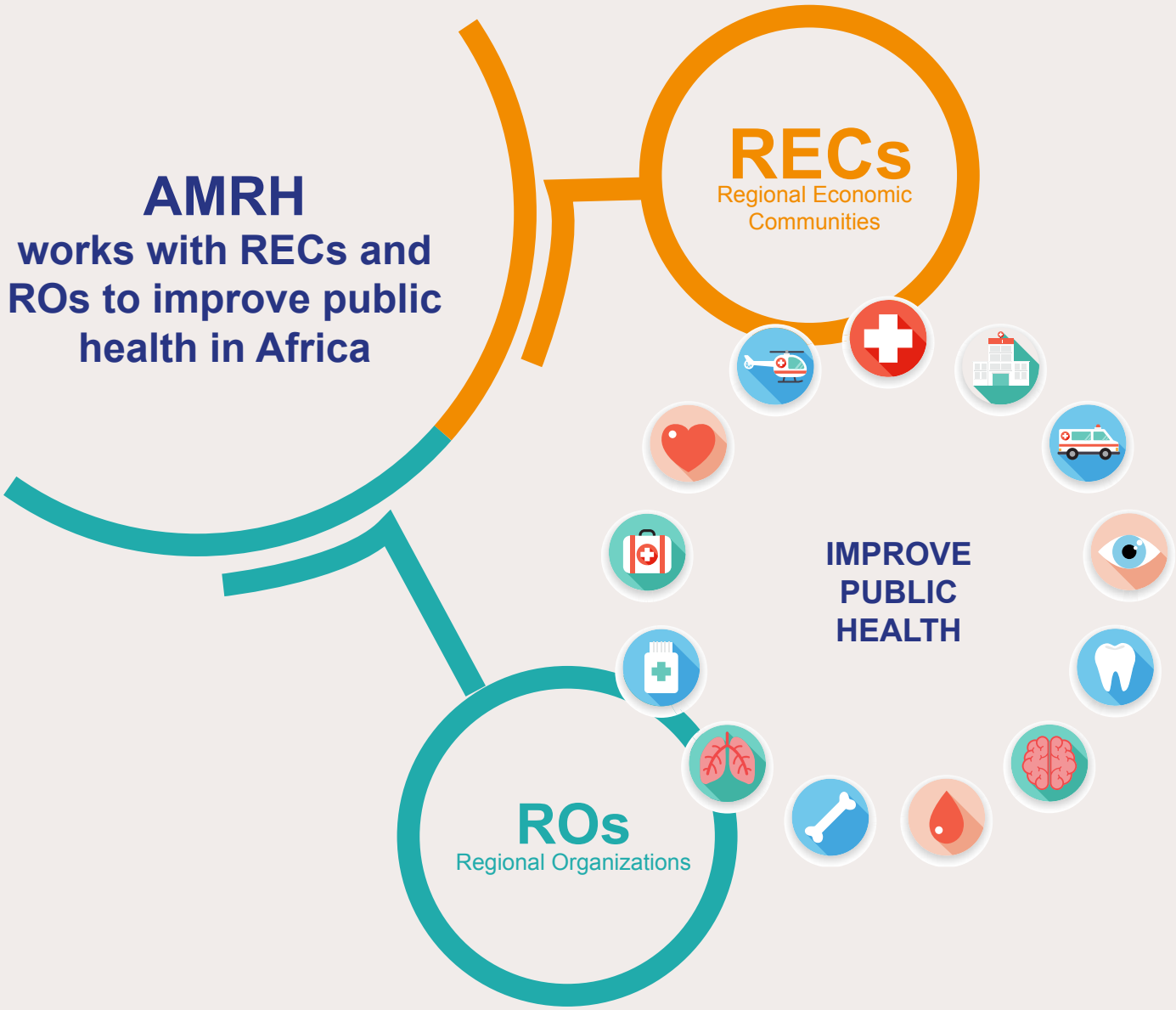
AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH) FRAMEWORK FOR WORKING WITH RECs AND ROs



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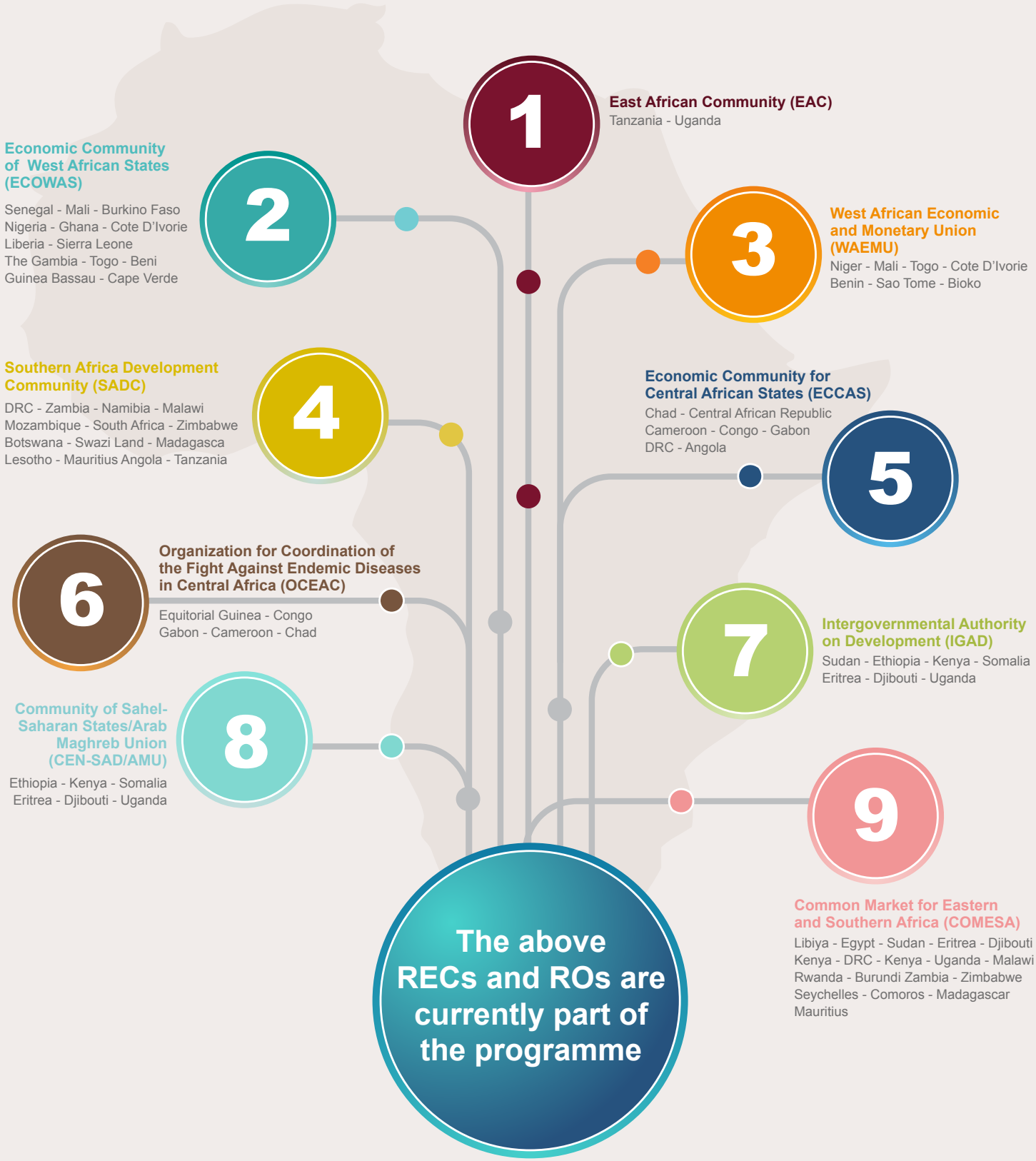
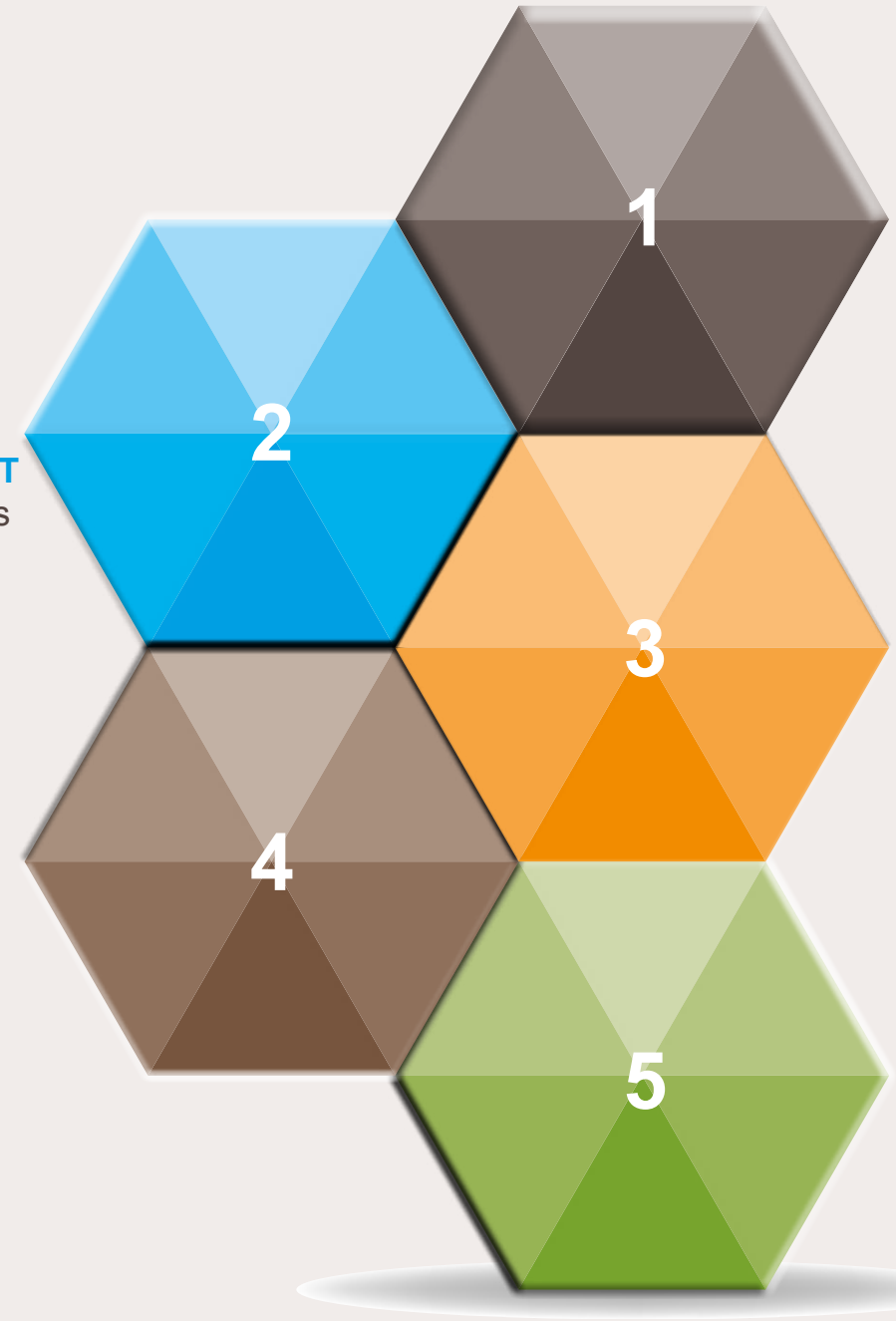
REGIONAL ECONOMIC COMMUNITIES (RECs) & REGIONAL ORGANIZATIONS (ROs)



The programme is expanding and networking to include other RECs and ROs on the continent.

AFRICAN MEDICINES REGULATORY HARMONIZATION (**AMRH**) **WAS DESIGNED TO ACHIEVE THE FOLLOWING**



ADOPTION of standardised technical guideline requirements

Joint **REGIONAL ASSESSMENT** of applications

Joint regional Good Manufacturing Practice (GMP) **INSPECTIONS**

Regulatory **CAPACITY BUILDING**

Adoption of **LEGAL FRAMEWORKS** to support regulation and harmonisation.

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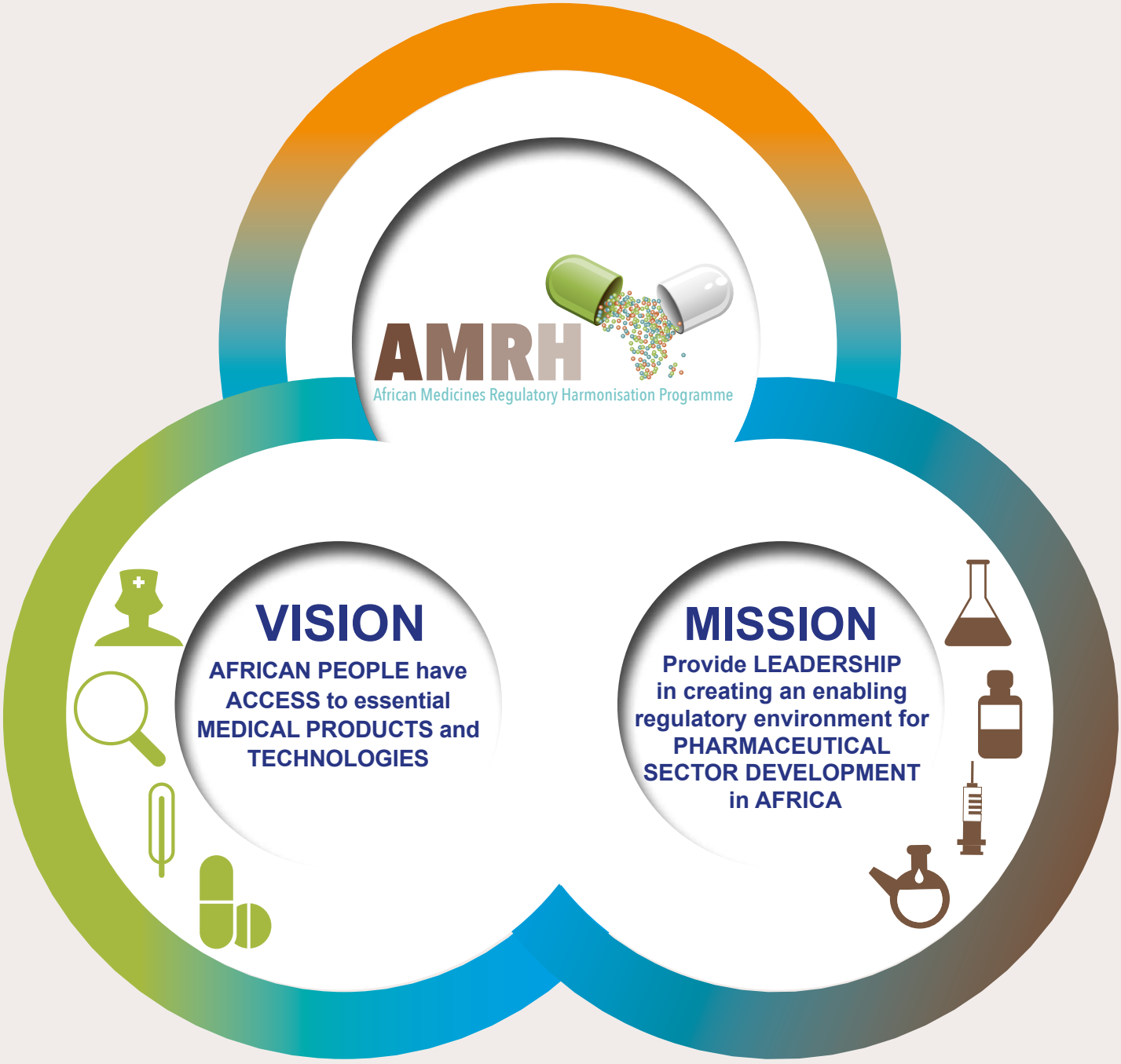
AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH) **VISION & MISSION**



AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH)
PARTNERSHIP PLATFORM

1. AFRICAN UNION COMMISSION (AUC)
2. PAN-AFRICAN PARLIAMENT (PAP)
3. WORLD HEALTH ORGANIZATION (WHO)
4. BILL AND MELINDA GATES FOUNDATION
5. WORLD BANK (WB)
6. UK DEPARTMENT FOR INTERNATIONAL DEVELOPMENT (DFID)
7. US GOVERNMENT-PEPFAR
8. GLOBAL ALLIANCE FOR VACCINES & IMMUNIZATION (GAVI)
9. CIVIL SOCIETY ORGANIZATIONS (CSO'S), INDUSTRY AND PRIVATE SECTOR

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AFRICAN MEDICINES REGULATORY HARMONIZATION (AMRH)
GOAL