NEPAD
TRANSFORMING AFRICA

AMRH
African Medicines Regulatory Harmonisation Programme

Strategic Framework 2016 – 2020

Table of CONTENTS

About NEPAD 3

About AMRH 4

Strategic Direction I: Policy Alignment and Regulatory Reforms 5

Strategic Direction II: Regional Integration and Harmonization 6

Strategic Direction III: Human and Institutional Capacity Development 6

Strategic Direction IV: Enabling Environment: Coordination, Partnership and Resource Mobilization 7

Monitoring and Evaluation Framework 8

Regional Economic Communities (RECs) and Regional Organizations (ROs) 11

AMRH Regional Presence in Africa 12

Regional Centres of Regulatory Excellence (RCOREs) 13

About NEPAD

The New Partnership for Africa's Development (NEPAD) is a socio-economic flagship programme of the African Union (AU). The NEPAD Planning and Coordinating Agency (NPCA) was established in 2010 as an outcome of the integration of NEPAD in to the African (AU) structures and processes. The NEPAD Agency is the implementing agency of the AU that advocates for NEPAD, facilitates and coordinates the development of NEPAD continent-wide programmes and projects, mobilizes resources and engages the global community, Regional Economic Communities (RECs) and member states in the implementation of these programmes and projects. The NEPAD Agency replaced the NEPAD Secretariat which had coordinated the implementation of NEPAD programmes and projects since 2001.

With mandate from the AU, the NEPAD Agency implements four (4) Investment Programmes that address new and emerging development trends in Africa as follows:

- Skills and Employment for Youths
- Industrialization, Science, Technology and Innovation
- Regional Integration, Infrastructure and Trade
- Natural Resources Governance and Food Security

NEPAD Vision

Build an integrated, prosperous and peaceful Africa driven by its own citizens and representing a dynamic force in the global arena

NEPAD Mission

Work with African countries, both individually and collectively towards sustainable growth and development

About AMRH

The African Medicines Regulatory Harmonization (AMRH) initiative is a programme of the African Union (AU) implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Under the theme "Strengthening of Health Systems for Equity and Development in Africa", the AU Conference of Health Ministers (AUCHM) in April 2007 responded to the AU Assembly Decision 55 (Assembly/AU/Dec.55 (IV) taken during the Abuja Summit in January 2005 which mandated the African Union Commission (AUC) to develop the PMPA within the framework of the NEPAD. The programme started in 2009 as a response to addressing challenges faced by National Medicine Regulatory Authorities (NMRAs) in Africa. These challenges include; weak or non-coherent legislative frameworks, redundant/duplicative processes, sluggish medicine registration processes and subsequent delayed decision, inefficiency and limited technical capacity, among others. The work of AMRH is guided by three focus areas: policy alignment, regional integration and harmonization, and human and institutional capacity development.

The programme works in collaboration with the AUC, Pan-African Parliament (PAP), World Health Organization (WHO), Bill and Melinda Gates Foundation, World Bank (WB), UK Department for International Development (DFID) and US Government-PEPFAR and Global Alliance for Vaccines and Immunization (GAVI). The AMRH Strategic Plan defines the strategic direction for the medicines harmonization agenda in Africa and provides direction to advance the development of the pharmaceutical sector and provides guidance in monitoring and evaluation.

AMRH Vision

African people have access to essential medical products and technologies

AMRH Mission

Provide leadership in creating an enabling regulatory environment for pharmaceutical sector development in Africa

Strategic Direction I: Policy Alignment and Regulatory Reforms

Specific Objective
Enhanced Policy Coherence in Regional Economic Communities (RECs) and AU member states for public health and pharmaceutical industry development

Targets

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

Strategic Direction II: Regional Integration and Harmonization

Specific Objective

Increased use of harmonized policies and regulatory frameworks by member states

Targets

- At least 5 regions and 25 countries have adopted regionally agreed regulatory technical guidelines and standards by 2020
- AMRH project scope expanded to cover clinical trials oversight, post-marketing surveillance and pharmacovigilance, medical devices and diagnostics in 5 regions by 2020
- AMRH M&E framework implemented in 3 regions by 2020

Strategic Direction III: Human and Institutional Capacity Development

Specific Objective

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

Targets

- 15 regional centres of regulatory excellence operational by 2020
- Curricula on Regulatory Science in alignment with WHO Global Curricula Framework by 2018
- 10% increase in the number of regulatory experts in Africa by 2020
- 50% of experts in the “Pool of Regulatory Experts” utilized by 2020
- African Regulatory Professional Fellowship Programme developed and administered by 2020
- Align regulatory systems strengthening programmes with AMRH and AMA

Strategic Direction IV: Enabling Environment: Coordination, Partnership and Resource Mobilization

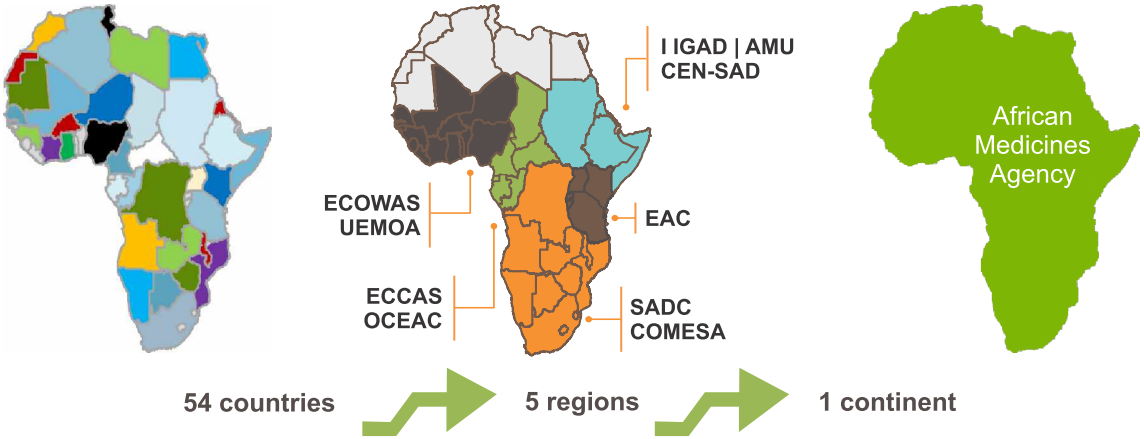
Specific Objective

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

Targets

- 50% of NMRA resources mobilized locally or through broadened bilateral and multilateral sponsors by 2019
- 50% of funding for AMRH initiative mobilized from other sources by 2020
- Partnership Platform Accountability Framework developed and implemented by 2020
- Scientific and regulators conferences convened bi-annually
- AMRH Advocacy and Communication strategy implemented from 2016
- Scientific & Regulators conferences convened biennially
- At least 4 functional Technical working Groups (TWGs) by 2018
- AMRH transitioned into AMA by 2018

The African Union Vision



Monitoring and Evaluation Framework

CATEGORY 1: Policy and Legal Framework

- Indicator 1: Availability of a current and comprehensiveness of the National Medicines Policy
- Indicator 2: Availability and comprehensiveness of the legal framework
- Indicator 3: Date of last review or amendment of the medicines law

CATEGORY 2: NMRA Governance

- Indicator 4: The level of autonomy of the NMRA
- Indicator 5: Availability of structures to support NMRA decision making process

CATEGORY 3: NMRA Financing

- Indicator 6: Level of NMRA funding
- Indicator 7 (a): Reliability of NMRA Funding
- Indicator 7 (b): Reliability of NMRA Funding

CATEGORY 4: Medicines Evaluation and Registration, and GMP Inspection Systems

- Indicator 8: Availability of a system for registration of medicines
- Indicator 9: Availability of a GMP Inspection system
- Indicator 10: Ability of NMRA to track registration applications
- Indicator 11: Percentage of products applications whose registration decision has been made within the standard time

Monitoring and Evaluation Framework

- Indicator 12: Percentage of product applications jointly assessed whose decision are made within standard time.
- Indicator 13: Average timelines attained for regulatory decisions to be made on applications for product registration
- Indicator 14: Percentage of NMRAs using regionally agreed guidelines
- Indicator 15: Proportion of NMRAs participating in joint assessments
- Indicator 16: Proportion of NMRAs participating in joint GMP inspections

CATEGORY 5: Functional Quality Management System (QMS)

- Indicator 17: Attainment of Quality Management System (QMS) requirements by NMRA
- Indicator 18: Percentage of NMRAs ISO 9001 Certified in Registration and GMP Inspection
- Indicator 19: Availability of mechanism for addressing customer concern

CATEGORY 6: Information Management System (IMS)

- Indicator 20: Attainment of requirements for an integrated Information Management System (IMS)

CATEGORY 7: Level of Transparency

- Indicator 21: Availability of key regulatory information to the general public
- Indicator 22: Availability of stakeholders' engagement platform(s)

Monitoring and Evaluation Framework

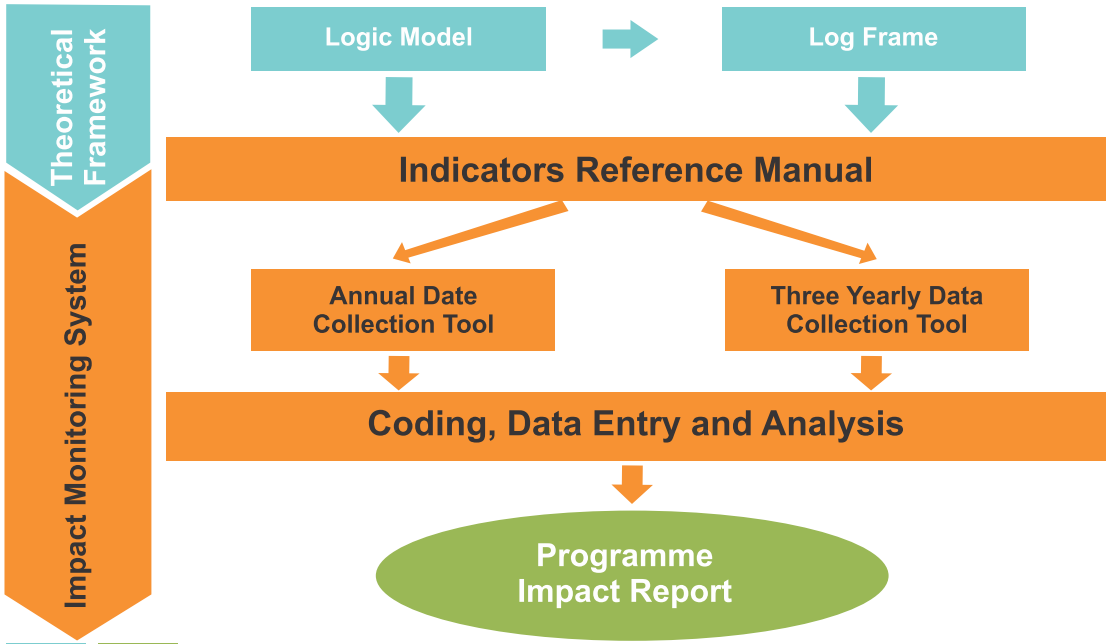
CATEGORY 8: NMRA Human Resources Capacity

- Indicator 23: Medical products regulatory experts' density
- Indicator 24: Internal NMRA capacity

Category 9: Partnerships and Coordination

- Indicator 25: Partnership coordination towards collective impact on regulatory systems strengthening
- Indicator 26: Proportion of partners that are aligning to the AMRH framework

Impact Oriented Monitoring Methodology for AMRH



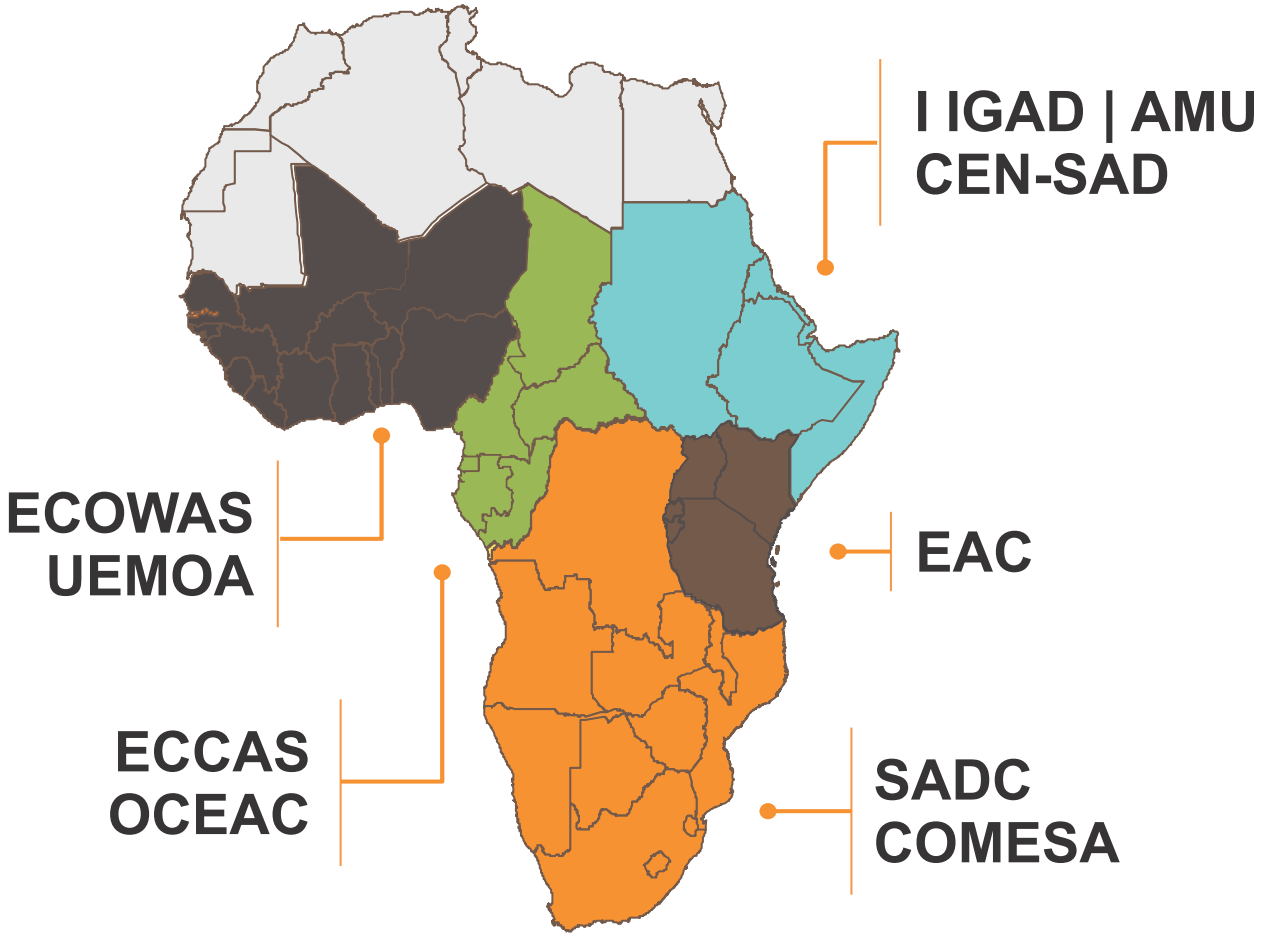
Regional Economic Communities (RECs) and Regional Organizations (ROs)

The AMRH programme works with Regional Economic Communities (RECs) and Regional Organizations (ROs) to improve public health by increasing access to good quality, safe and effective medicines through harmonizing medicines regulations, and expediting registration of essential medicines. The following RECs and ROs are currently part of the programme:

- East African Community (EAC)
- Economic Community of West African States (ECOWAS)
- West African Economic and Monetary Union (WAEMU)
- Southern Africa Development Community (SADC)
- Economic Community for Central African States (ECCAS)
- Organization for Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC)
- Intergovernmental Authority on Development (IGAD)
- Community of Sahel-Saharan States/Arab Maghreb Union (CEN-SAD/AMU)
- Common Market for Eastern and Southern Africa (COMESA)

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

AMRH Regional Presence in Africa



Regional Centres of Regulatory Excellence (RCOREs)

RECORES are centres of research and development, as well as practical hands on professional learning that concentrate existing skills and resources to enable participants to work collaboratively across national borders and across disciplinary areas on major long term projects to meet Africa's needs and enhance its human potential. As of 2016, the African Union (AU) through the Nepad Agency and the AMRH Programme has designated a total of 11 RCORES specialized in different regulatory functions as follows:

1. **RCORE in Pharmacovigilance**

   - University of Ghana Medical School - WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance
   - Pharmacy and Poisons Board (PPB), Kenya

2. **RCORE in training in core regulatory functions**

   - St. Luke's Foundation, Tanzania - Kilimanjaro School of Pharmacy
   - University of Ibadan, Nigeria - Centre for Drug Discovery, Development and Production

3. **RCORE in quality assurance and quality control of medicines**

   - North West University (NWU) - Potchefstroom Campus, South Africa - WHO Collaborating Centre for the Quality Assurance of Medicines
   - National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

4. **RCORE in medicine registration and evaluation, quality assurance/quality control and clinical trials oversight**

   - Medicines Control Authority of Zimbabwe (MCAZ)

5. **RCORE in licensing of the manufacture, import, export, distribution and; inspection and surveillance of manufacturers, importers, wholesalers and dispensers of medicines**

   - National Drug Authority (NDA), Uganda

6. **RCORE in clinical trials oversight**

   - University of Ouagadougou, Burkina Faso - Direction General de la Pharmacie du Medicament et des Laboratoires

7. **RCORE in medicines registration and evaluation and clinical trials oversight**

   - Foods and Drugs Authority (FDA), Ghana

8. **RCORE in medicine evaluation and registration**

   - School of Pharmacy, Muhimbili University of Health and Allied Sciences (MUHAS) - Tanzania Drugs and Food Authority (TDFA)

More RCORES will be established and operationalized during the project implementation period from 2016 - 2020 to continue consolidating regulatory functions at regional level.

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