AFRICAN MEDICINES REGULATORY HARMONISATION PROGRAMME PLAN FOR IMPLEMENTATION OF PMPA

STRATEGIC PLAN

2016-2020

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ABBREVIATIONS

AMRH	African Medicines Regulatory Harmonization
AMU	Arab Maghreb Union
AU	African Union
AUC	African Union Commission
BMGF	The Bill and Melinda Gates Foundation
CHAI	Clinton Health Access Initiative
CENSAD	Community of Sahel-Saharan States
COMESA	Common Market for Eastern and Southern Africa
DFID	United Kingdom Department of International Development
EAC	East African Community
ECCAS	Economic Community of Central African States
ECOWAS	Economic Community of West African States
EDCTP	European and Developing Countries Clinical Trials Partnerships
IGAD	Inter-Governmental Organization for Development
OCEAC	Organization for the fight Against Endemic diseases in Central Africa
MoU	Memorandum of Understanding
MRH	Medicines Registration Harmonization
NEPAD	New Partnership for Africa's Development
NGO	Non-Governmental Organization
NMRA	National Medicines Regulatory Authority
NPCA	NEPAD Planning and Coordinating Agency
PDPs	Product Development Partnerships
PAP	Pan African Parliament
PMPA	Pharmaceutical Manufacturing Plan for Africa
RECs	Regional Economic Communities
SADC	Southern African Development Community

SARPAM	Southern Africa Regional Programme on Access to Medicines
UNAIDS	Joint United Nations Programme on HIV/AIDS
UEMOA	The West African Economic and Monetary Union
WB	The Wold Bank
WHO	World Health Organization

EXECUTIVE SUMMARY

Since 2009, NEPAD Agency in collaboration with the African Medicines Regulatory (AMRH) Initiative Partners, has been coordinating the programme through the African Union (AU) regional economic communities (RECs) and Member States. Based on consensus reached in February 2009 among the AU RECs, Member States and partners, significant progress has been recorded in the development and subsequent implementation of the AMRH programme in the continent. We are now witnessing implementation of harmonized guidelines for registration of generic medicines, good manufacturing practice (GMP), quality management systems (QMS) and information management system (IMS) in the East African Community (EAC) and the Southern African Development Community (SADC). Replication of the East African Community Model in the Southern, Western, Central and North-Eastern African regions is key for cross-REC consistency and also serves as a foundation for establishment of the African Medicines Agency (AMA).

The AMRH Implementation Tool Kit and Monitoring and Evaluation Framework will assist in standardizing and shaping implementation approaches and ensure consistencies across RECs and countries. The AU Model Law on Medical products Regulation will further complement and facilitate programme implementation and serve as a guide for countries to review their national laws and subsequent establishment of semi-autonomous national medicines regulatory agencies (NMRAs), to ensure effective regulation of medical products and technologies. All these efforts are aimed to ensure effective, efficient and transparent regulatory processes and services that will ultimately contribute to availability of quality, safe and effective medical products and technologies and improve the health outcomes of the African populations.

NEPAD Agency will continue to exercise its mandate by improving and strengthening coordination of regional programmes, partners and stakeholders while facilitating policy and political advocacy through a robust monitoring, evaluation and knowledge management framework. The coordination of partners working in the medicines regulatory space is aimed to ensure streamlined efforts; reduce overlapping work programs; instil accountability; and sustain gains achieved thus far. This includes advocacy for alignment of the African Vaccines Regulatory Forum (AVAREF) with AMRH; domestication of the African Union (AU) Model Law for Medical products regulation; and utilization of the Regional Centers of Regulatory Excellence as a framework for standardized regulatory sciences training in Africa. The established governance structures will be transitioned into the African Medicines Agency based on the AU Executive Council Decision **EX.CL/Dec.857(XXVI).**

The challenges faced during the first phase of implementation of the AMRH Programme; lessons learnt; continental and global policy frameworks, instruments and decisions will provide direction for the second phase of the programme. This includes Agenda 2063; Science, Technology, and Innovation Strategy for Africa (STISA) 2024; Africa Health Strategy (AHS) 2016-2030; and its corresponding Africa Research for Health Strategy; which set the socio-economic development vision for Africa. This will be done in alignment with Sustainable Development Goals (SDGs) and other global developmental frameworks. In undertaking its role, the Agency will continue to work with WHO as a lead technical agency and the World Bank, responsible for management of the Global Medicines Regulatory Harmonization Multi Donor Trust Fund (GMRH-MDTF).

1. INTRODUCTION

Strengthening regulatory capacity, governance and accountability in the pharmaceutical sector is in every nation's interest; it provides an opportunity to drive economic development and growth in the pharmaceutical sector. Even more importantly from a public health perspective, a functional regulatory environment is a prerequisite to increasing access to new medicines and to improving the quality of drugs in circulation, which ultimately should save lives and improve health outcomes. In realization of challenges posed by lack of good quality, safe and affordable medicines to the majority of African population, the African Union (AU) Assembly in January 2005 through decision 55 (Assembly/AU/Dec.55(IV)) mandated the African Union Commission (AUC) to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of New Partnership for Africa's Development (NEPAD). One of the critical components to advance the PMPA agenda is the provision of an enabling environment for development of the pharmaceutical industry hence the inception of the African Medicines Regulatory Harmonization Initiative. In addition, the AU approved the Roadmap for Shared Responsibility and Global Solidarity on HIV, TB and Malaria response in Africa which emphasizes the need for access to medicines and regulatory harmonization.

In 2009, a consortium of partners including the NEPAD Agency, Pan African Parliament (PAP), the World Health Organization (WHO), Bill & Melinda Gates Foundation (BMGF), UK Department for International Development (DFID), and the Clinton Health Access Initiative (CHAI) came together to establish the African Medicines Regulatory Harmonization (AMRH) Initiative. In addition, the AMRH initiative received endorsement by the Pan African Parliament (PAP) committees on Health and S&T in 2007 & 2008; the African Ministerial Conference on Science and Technology decision in 2008, the NEPAD Agency and PAP joint consensus meeting with RECs and National Medicines Regulatory Authorities (NMRAs) in February, 2009.

In 2011, NEPAD Agency developed a comprehensive five year strategic plan (2011-2015) that provided direction for the implementation of the AMRH Programme during this period.
In addition, the funding from the Bill & Melinda Gates Foundation (BMGF) in 2011 enabled the World Bank to set up a Global Medicines Regulatory Harmonization (GMRH) multi-donor trust fund to implement AMRH and scale up activities elsewhere in the world.

Using the NEPAD Agency model of intervention in the African continent, the AMRH Programme works with Regional Economic Communities (RECs) 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 aim is to ensure that regulatory requirements and practice in Africa meet the internationally accepted standards by strengthening pharmaceutical sector governance and regulatory systems. The East African Community (EAC) successfully launched the Medicines Regulatory Harmonization (MRH) Programme in March 2012, in Arusha, Tanzania while the Economic Community of West African States/West African Economic and Monetary Union (ECOWAS/UEMOA) and the Southern Africa Development Community (SADC) launched their reginal MRH Projects in 2015. The Economic Community for Central African States (ECCAS) in collaboration with the Organization for Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC); and the Intergovernmental Authority on Development (IGAD) are at different levels of implementation.

Considering that the regulatory landscape in Africa is dynamic and has undergone considerable changes since the launch of implementation of the AMRH Strategic Plan 2011-2015, and its expiry in 2015, the need arises to develop a new AMRH Strategic Plan (2016-2020). The AMRH Strategic Plan (2016-2010) defines the key strategic directions for the harmonization agenda in Africa, building on the achievements of the last five years and taking into account the prevailing global and continental regulatory environment, opportunities, challenges and lessons learned. A key development is the African Union (AU) decision to establish the African Medicines Agency (AMA), through its Executive Council Decision **EX.CL/Dec.857(XXVI),** that recognized the need to strengthen the capacity for regulation of medical products in Africa, and the harmonization of medicines regulatory systems as a foundation for the establishment of regional and continental medicines agencies. This is within the context of the AMRH and as part of the PMPA Framework.The AU Executive Council further endorsed the milestones for AMA's creation and tasked NEPAD Agency, AUC and WHO with defining the scope of the medical products to be covered.

Looking forward, implementation of the AMRH Initiative and its expanded scope in alignment to the PMPA Framework, needs to take into account the AU decision, policy instruments and declarations and also various developments at continental and global levels. These include the ongoing review of the Africa Health Strategy and Research for Health Strategy, African Sustainable Development Goals and AU Agenda 2063 which set the socio-economic development vision for Africa.

This Strategic Plan, apart from providing direction for the overall implementation of the AMRH Programme, it will also provide guidance on expansion of scope of regulatory functions and products to be covered in the REC harmonization schemes. In addition, the Strategic Plan 2016-2020, will provide a framework for facilitating operationalization of the PMPA Business Plan.

The present document aims to detail the rationale and content of the AMRH Strategic Plan 2016-2020. It consists of several parts and sections; the first addressing achievements, challenges and lessons learned in the implementation of the AMRH Strategic Plan 2011-2015. The second part covers strategic issues, themes, directions and objectives as well as the strategic framework. The third part outlines the results framework as well as monitoring, evaluation and impact assessment. And the last part covers the AMRH Strategic Plan 2016-2020 Budget.

2. ACHIEVEMENTS

The NEPAD Agency and African Union Commission (AUC) have continued to coordinate and harmonise follow-up actions on the PMPA including the preparation of concrete plan of actions in collaboration with regional economic communities (RECs), the World Health organization (WHO) and other partners. Some of the progress made include the "Strengthening pharmaceutical innovation in Africa" report, produced by COHRED and NEPAD, with the George Institute and the tools designed to support countries in moving forward on Pharmaceutical Innovation.

Furthermore, the NEPAD Agency undertook to compose a Consortium[1] which has been spearheading the African Medicines Regulatory Harmonization initiative since 2009 as part of implementation of PMPA. To date, the AMRH Programme has made significant progress in its engagements with the AU RECs and countries. Some of these achievements include:

Launch and subsequent implementation of RECs Medicines Regulatory Harmonization (MRH) Programmes: Through the AMRH Initiative, the East African Community (EAC) successfully launched the Medicines Regulatory Harmonization (MRH) Programme in March 2012, in Arusha, Tanzania. Notable achievements include the development of harmonized technical guidelines with subsequent adoption by the EAC Council of Ministers in September 20, 2014 and publication of compendia for use by all the EAC Partner States. In addition, two pilot projects between WHO Medicines Prequalification Program (WHO-PQP) and EAC on joint assessments and inspections in 2011 and 2013 have led to subsequent approval of 5 and 7 products respectively. The EAC now has expanded the scope of the programme to add drug safety (pharmacovigilance) strengthening; clinical trials oversight; regulation and quality assurance of medical devices including diagnostics; and harmonization of regulation of vaccines; with other partners joining in to provide both technical and financial support. As the EAC MRH Programme enters its second phase, the question on most minds is the sustainability after external funding declines or phases out. In this regard, the EAC Secretariat in collaboration with NMRAs has instituted the Regulators Forum as a platform for coordinating MRH activities after end of project. In addition, the framework for Mutual Recognition is being worked out to serve as a legal instrument for acceptance of decisions among the NMRAs in the region.

Following the development of the medicines regulatory harmonization (MRH) project proposal for the Southern African Development Community (SADC) in 2011, breakthrough activities were agreed and supported under the DFID Funded Project, the Southern Africa Regional Programme on Access to Medicines and Diagnostics (**SARPAM**). Among other things, with technical support from WHO, the ZAZIBONA Scheme was initiated in 2013 as a collaboration framework for registration of medicines between the four SADC countries namely Zambia, Zimbabwe, Botswana and Namibia. The ZAZIBONA Scheme was officially integrated as part of the broader SADC Framework for Regulatory Harmonization since 2014. The SADC Regulators Forum further endorsed the implementation of MRH Programme using the ZAZIBONA approach. To date, 105 products have been reviewed under ZAZIBONA Scheme, with subsequent registration of a total of 28 products in Botswana (25), Namibia (13), Zambia (11) and Zimbabwe (20). While fourteen (14) products were recommended for non-registration, sixty one (61) are pending responses from manufacturers. The SADC guidelines for registration of medicines and the common technical document format are aligned to the EAC Model while efforts are being made to adapt the GMP, QMS and IMS standards. This has been achieved through a collaborative framework between SADC Secretariat, NEPAD, World Bank, and WHO.

[1]The AMRH consortium consists of the African Union's New Partnership for Africa's Development (NEPAD Agency), the Pan African Parliament (PAP), the World Health Organization (WHO), the Bill & Melinda Gates Foundation, the UK Department for International Development (DFID), the Clinton Health Access Initiative (CHAI)

Together with AMRH Partners[2], NEPAD Agency facilitated the launch of the West Africa MRH Project in February 2015, which included the establishment of a joint MRH Programme Steering Committee and formation of seven Technical Working Groups (TWGs). Additionally, a framework of collaboration between WAHO and WAEMU and a joint three years plan of action (2014-2016) was agreed. Harmonization of WAHO and WAEMU CTDs has beed carried out with technical support from WHO. The region will now be moving into developing technical guidelines through its TWGs. A series of twinning activities between regional agencies have also been undertaken as part of capacity and confidence building among NMRAs. In order to initiate activities in the Central Africa region, NEPAD Agency in collaboration with ECCAS, OCEAC and WHO developed a collaborative framework to spell out activities with clear roles and responsibilities for partners involved in the implementation of the MRH Programme. A mapping exercise will be carried uot in Q2 2016 to establish the status or regulatory systems in Member States that will inform the MRH Project development process.

The 1st IGAD Member States NMRAs meeting held in August 2015 in Addis Ababa, Ethiopia agreed and signed the Call for Action to initiate implementation of a regional MRH Programme. The 2nd meeting convened from 26-26 April, 2016 and agreed on the establishment of the IGAD MRH Steering Committee, the TWGs and a Coordinating Unit as part of IGAD Health and Social Development Department. In addition, the NMRAs agreed to; i) establish a sustainable financing mechanism for the IGAD Regional program; ii) build the capacity of IGAD secretariat and its member states to ensure effective coordination and implementation of the program; iii) establish an integrated information management system that links all authorities and enables joint activities and develop a website for information sharing and exchange; iv) initiate a phased approach for harmonization of medicines regulation based on the priorities identified in the IGAD member states; and v) support the development of an overarching regional pharmaceutical policy and the adoption of modern legislative frameworks, based on the AU Model Law. Furthermore, it was agreed that the IGAD regional Medicines Regulatory Collaboration and Harmonization Program be hosted by the Government of the Sudan.

Initiation and implementation of continental Programmes: At the continental level, NEPAD Agency has facilitated the development of the AU Model Law on Medical products regulation with the view to address the prevailing legislative gaps at national level. In addition, in order to streamline the ad-hoc regulatory training programmes and address the human resource gap inherent in most African countries, the Agency has spearheaded the designation of eleven (11) Regional Centers of Regulatory Excellence (RCoREs) since 2014; using the existing academic, research and regulatory institutions. The RCOREs serve as a framework for standardized training on regulatory sciences and systematic regulatory capacity development platform for Africa which will ensure sustainability. Furthermore, a database of regulatory experts has been developed with the view to provide resource to RCoREs. In addition, The Agency facilitated the convening of the 1st Scientific Conference on Medicines Regulation in Africa from 1-2 December, 2013 followed by the 3rd African Medicines Regulators Conference (AMRC) from 3-5 December, 2013.

[2] NEPAD Agency, African Union Commission (AUC), Pan African Parliament (PAP), World Health Organization (WHO), World Bank (WB), Bill and Melinda Gates Foundation (BMGF), UK Department for International Development (DFID), US Government (PEPFAR) and GAVI

Furthermore, the Agency facilitated the review and expansion of scope of terms of reference for the PMPA Technical Committee with subsequent endorsement by the African Union Conference of Ministers of Health (CAMH-5) convened from 17-19 April, 2011 in Windhoek, Namibia. This has culminated in galvanizing the work of the PMPA Technical Committee with subsequent development of the PMPA Business Plan with support from United National Industrial Development Organization (UNIDO). Furthermore, the Specialised Technical Committee on Health, Population and Drug Control (STC-HPDC) in its meeting held from 13-17 April 2015, in Addis Ababa, Ethiopia, approved 2015 approved the implementation of GMP roadmap through national and regional certification schemes. The STC-HPDC further recommended that the biennial African Medicines Regulators Conference (AMRC) be institutionalised within the AU institutional framework, to be coordinated by NEPA Agency and AUC in collaboration with WHO.

3. CHALLENGES AND LESSONS LEARNED

Some of the important lessons coming out of the AMRH Programme implementation that are useful for increasing development impact and effectiveness include the need to allocate resources to institutionalize capacity, in addition to building technical skills. The most important message emerging from the regional harmonization process is the value of capacity-building, both human and institutional, to ensure sustainability. In addition, commitment to strategic sharing of information to improve effectiveness requires clarifying the roles of development partners in the medicines regulatory space. This is critical to avoid duplication of work programs. Furthermore, the regional harmonization process is shedding light on the uniqueness of each region in regards to medicines regulatory harmonization and convergence.

Some of the challenges encountered in the implementation of the AMRH Programme include: i) differences in the economic status of participating countries and the corresponding wide variation in regulatory capacity; ii) ownership and buy-in from national and regional key stakeholders requires more consultation and additional time to materialize than anticipated when a project is planned; and iii) donor partners working in the medicines regulatory space have overlapping work programs which require better coordination.

One of the key success factors of the AMRH Initiative, is clarity in roles and responsibilities among the implementing partners. Under this partnership, NEPAD Agency is responsible for coordination of regional programmes, partners and stakeholders while facilitating policy and political advocacy in Africa. The World Health Organization (WHO) on the other hand is responsible for providing technical guidance and the requisite international expertise to boost regional capacities. The World Bank is responsible for overall coordination and fiduciary oversight of the initiative.

4. PURPOSE OF THE STRATEGIC PLAN

The 2nd AMRH Strategic Plan covering the period 2016-2020, is aimed at taking stock of lessons learnt and challenges faced during the implementation of the 1st Strategic plan (2011-2015). This plan provides strategic direction in advancing pharmaceutical sector development programmes. It will further provide guidance in monitoring, evaluation and impact assessment for the next five years (2016-2020). The results framework has been elaborated which

provides the necessary input, outputs and expected outcomes at the end of the planning period. A budget estimate has been provided as a vehicle for mobilising the needed resources.

Oversight of this plan will be done through the established governance and management structures namely the AMRH Advisory Committee, the Technical Working Groups and the NEPAD Agency AMRH Secretariat. While the AMRH Advisory Committee shall be responsible for providing strategic and policy guidance on medicines regulatory issues in Africa, the technical work shall continue to be delegated to the established Technical Working Groups (TWGs) on Regulatory capacity Development and on Medicines Policy and Regulatory Reforms. Other TWG will be constituted based on identified needs.

The governance and management action plans shall be formulated in line with the strategic themes based on NPCA mandate namely, *coordination of implementation of continental and regional priority programmes and projects; mobilization of resources and partners; conducting and coordinating research and knowledge management; monitoring and evaluation of implementation of programmes; and advocacy on the AU and NEPAD vision, mission and core values.* These strategic themes will enable the AMRH programme to focus resources and efforts towards driving the NEPAD Agency vision and delivering on its mandate during the implementation period.

5. HIGH LEVEL STATEMENTS

The high level statements for the AMRH Programme are derived from, and support the NEPAD **Mission** and **Vision Statements.** New Partnership for Africa's Development (NEPAD) is an African Union strategic framework for Pan-African socio-economic development, adopted by African Heads of State and Government of the Organization of the African Union (OAU) in 2001. The NEPAD Framework was ratified by the African Union (AU) in 2002 to address Africa's development problems within a new paradigm with a view to reduce poverty, put Africa on a sustainable development path, halt the marginalization of Africa, and empower women. The NEPAD Secretariat was transformed and integrated into the structures and processes of the AU in 2010 as **NEPAD Planning and Coordinating Agency (NEPAD Agency).**

NEPAD Vision*:*

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

NEPAD Mission:

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

Core Values of NEPAD

The NEPAD core principles and values are based on four key elements – the facilitator, mobiliser, agent of change and learning organisation; as indicated in **Table 1** below:

Value Statement	Focus	Description
Pan-Africanism	Participatory	Commitment to actively take part in meetings, conferences, workshops and other fora convened to achieve the NEPAD vision
	Consultative	Commitment to promote the participation of all stakeholders, including the AU member states, the AU Commission, civil society, RECs, development partners, and the private sector
	Partnership	Commitment to working in partnership with RECs, AU member countries, civil society, the private sector, development partners as well as other stakeholders
	Integration	Commitment to align the NEPAD Agency with AU structures and processes
	Inclusive	Commitment to involve all relevant major groups
Accountability & Transparency	Accountability	Commitment to be accountable and accessible to African leaders, AU member states, all major groups, and staff commitment to taking responsibility for all actions in carrying out the mandate of the NEPAD Agency
	Responsibility	Commitment to taking responsibility for all actions in carrying out the mandate of the NEPAD Agency
	Transparency	Commitment to operate in an open manner
	Democracy	Commitment to operating the NEPAD Agency within a consultative and democratic framework
	Fairness	Commitment to treat all staff members justly and fairly, irrespective of their race, origin, gender, age, religion, language, culture, or ethnicity
Professionalism	Ethical	Commitment to observe the legal systems and ethical norms
	Honesty	Commitment to be honest with all stakeholders
	Ingenuity	Commitment to keep abreast of new developments in relevant fields of expertise and to be innovative in carrying out the mandate of the NEPAD Agency
	Integrity	Commitment to consistently observe the core values
	Mutual Respect	To value each other's contribution to the vision and goals of the NEPAD, and the strategic plan
	Peaceful	Commitment to adhere to peaceful settlement of all disputes as well as promote a peaceful environment
Effective Delivery & Results Orientated		The NEPAD Agency is committed to effectively facilitate the implementation of all NEPAD decisions, within the AU member countries and other structures of the AU. It will focus on obtaining results

The NEPAD Planning and Coordinating Agency (NPCA) Core Functions

The core functions of NPCA are derived from its mandate, and aims to:

a. Facilitate and coordinate the implementation of continental and regional programmes and projects;
b. Mobilize resources and partners in support of the implementation of Africa's priority programmes and projects;
c. Conduct and coordinate research and knowledge management;
d. Monitor and evaluate the implementation of programmes and projects; and
e. Advocate on the AU and NEPAD vision, mission, core principles and values.

6. STRATEGIC ISSUES, THEMES DIRECTIONS AND OBJECTIVES

Strategic themes are broad service areas in which AMRH needs to deliver, in order to drive the NPCA vision and mission. They are priority or focus areas that cluster related strategic objectives based on NEPAD Agency mandate. Strategic issues are challenges faced by the NPCA in managing the AMRH Programme resulting from its internal and external environment as listed here below:

Table 2: Strategic Themes and Issues

STRATEGIC THEMES	STRATEGIC ISSUES
❖ Facilitate and coordinate implementation of continental and regional programmes and projects	▪ Weak governance and management structures ▪ Inadequate coordination of programme and partners at national, regional and continental levels ▪ Weak medicines regulatory capacity
❖ Research and Knowledge Management	▪ Language barriers due to historical heritage ▪ Inadequate knowledge and skills for medicines regulation and pharmaceutical production
❖ Partnership with stakeholders & resource mobilization	▪ Weak partnerships ▪ Poor stakeholder relations ▪ Inadequate operational budget ▪ Dependence on donor funding ▪ Duplication of efforts by partners
❖ Monitoring, evaluation & impact assessment	▪ Low implementation rate of AU decisions ▪ Accountability for results ▪ Evidence-based decision making
❖ Policy & Advocacy	▪ Incoherent policies: public health, industrial development, trade and STI ▪ Inadequate medicines legislations ▪ Conflicting regulatory requirements ▪ Multi membership to RECs ▪ Lack/inadequate access to quality, safe, efficacious and affordable essential medicines by African patients

Strategic themes of AMRH are the key focus areas that drive its mission as derived from the NEPAD Agency core functions as provided in **Table 3** while strategic objectives are aligned to themes as summarised in **Table 4** below:

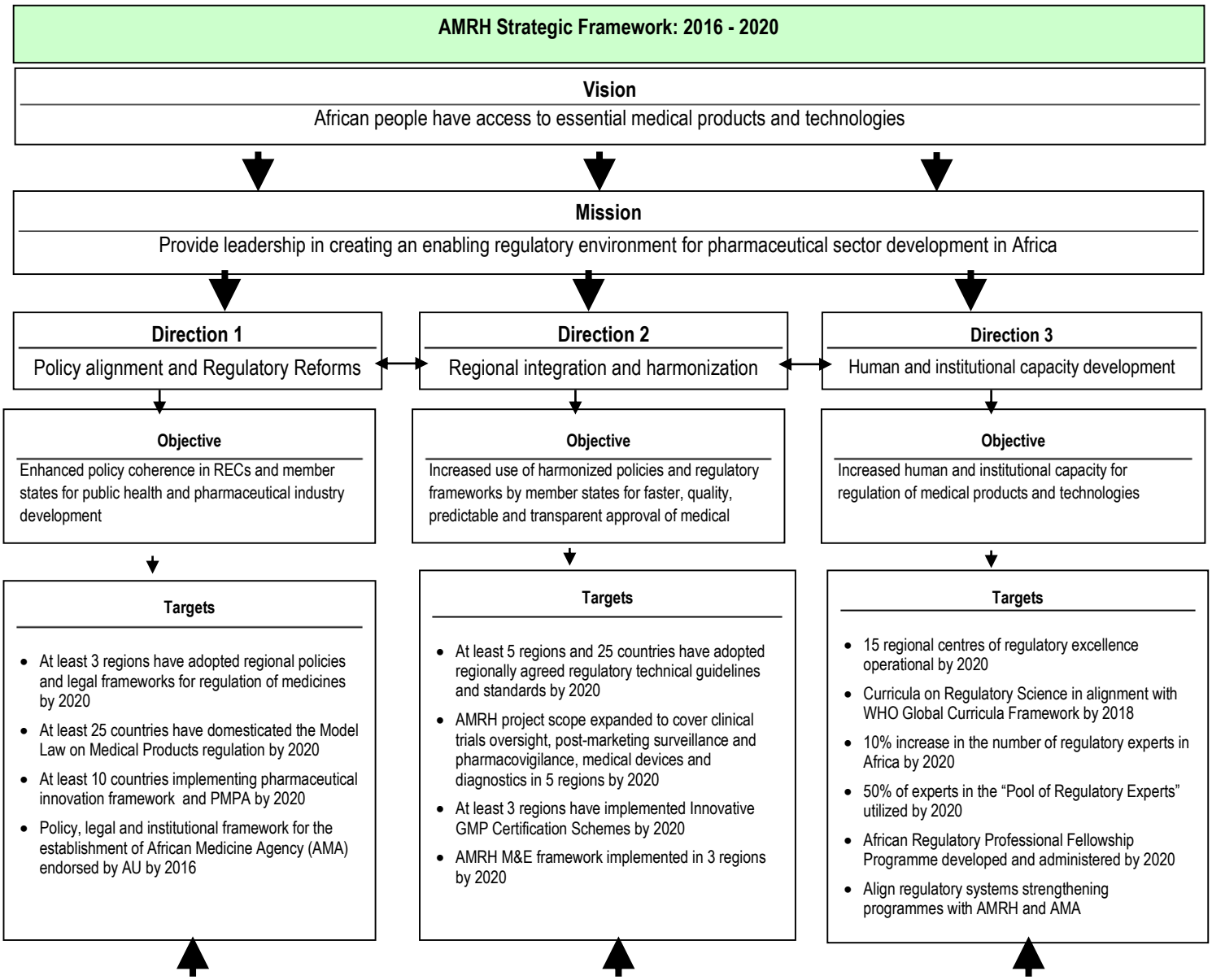
Table 3: Strategic Themes in Context

STRATEGIC THEME	AIM
Facilitate and coordinate implementation of continental and regional programmes and projects	To improve coordination of programmes and partners
Research and Knowledge Management	To provide a platform for knowledge generation, peer learning, research and information gathering and sharing, create knowledge and learning arenas that form the basis for long-term planning, development and implementation of programmes and project amongst member states, partners and other stakeholders
Partnership with Stakeholders and resource mobilisation	To establish, maintain and enhance stakeholder relations and mobilise resources
Monitoring, evaluation & impact assessment	To institute performance measurement tools based on NPCA indicators
Policy & Advocacy	To influence public-policy and resource allocation decisions within political, economic, and social systems and institutions

Table 4: Strategic objectives linked to themes

STRATEGIC THEME	STRATEGIC DIRECTION	STRATEGIC OBJECTIVES
1. Facilitate and coordinate implementation of continental and regional programmes and projects 2. Research & Knowledge Management 3. Partnership with Stakeholders & Resource Mobilisation 4. Monitoring, evaluation & impact assessment 5. Policy & Advocacy	1. Policy alignment 2. Regional integration and harmonization 3. Human and institutional capacity development	1. Enhanced policy coherence in RECs and Member States for public health and pharmaceutical industry development 2. Increased use of harmonized policies and regulatory frameworks for faster, quality, predictable and transparent approval of medical products and technologies 3. Increased human and institutional capacity for regulation of medical products and technologies

6. STRATEGIC FRAMEWORK



Objective: Effective coordination and alignment of regulatory interventions with AMRH Framework & AMA

Targets:

- 50% of NMRA resources mobilized locally or through broadened bilateral and multilateral sponsors by 2019
- 50% of NEPAD Agency 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-ennially
- AMRH Secretariat capacity strengthened by 2017
- AMRH Advocacy and Communication strategy implemented from 2016
- AMRH Advisory committee and at least 4 Technical Working Groups operational by 2018

7. RESULTS FRAMEWORK

Objective	Target	Initiative	Activities	Timelines	Budget	Results
Direction 1: Policy Alignment & Regulatory Reforms					**$1 386 526**	
Enhanced policy coherence in RECs and member states for public health and pharmaceutical industry development	1.1.1 At least 3 regions have adopted regional policies and legal frameworks for regulation of medicines by 2020 1.1.2 At least 25 countries have domesticated the Model Law on Medical Products regulation by 2020	• Adoption and domestication of AU Model Law on medical products regulation	• Adoption of the Model Law by the African Union	2016		• 50% of African countries with comprehensive pharmaceutical policies and legal frameworks aligned to AU Model law • 3 RECs implementing pharmaceutical policies and legal frameworks aligned to the AU Model • Mutual recognition procedures implemented in 3 RECs and Member States
			• Conduct a rapid assessment on the current status of National Medicines Laws and pharmaceutical policies in Member State to update the existing date	2016		
			• Implement a Model Law adoption and advocacy strategy in support of Member States domestication, in collaboration with AUC and PAP	2016-2020		
			• Develop required Model Regulations in support of implementation of the AU Model Law on Medical Products Regulation	Ongoing		
			• Develop a Continental Pharmaceutical Policy	2016		
			• Support the REC TWGs on Policy and Legal Frameworks to align the regional policy and legal frameworks with AU Frameworks	Ongoing		
	1.1.3 At least 10 countries implementing pharmaceutical innovation framework and PMPA by 2020	• Alignment of public health, pharmaceutical, STI and industrial development policies with pharmaceutical manufacturing plans at national,	• Develop criteria for selection of RECS and countries to engage in PMPA activities and identify 2 RECs and 10 AU Member States as pilots for implementation based on expression of interest.	2016		• 20% of the AU countries implementing comprehensive pharmaceutical production strategies in alignment with the PMPA
			• Engage with high level policy makers in the identified Member States to create ownership	2016		
			• Assess national pharmaceutical innovation systems	2016		
			• Collect data using the identified tool	2016		

Objective	Target	Initiative	Activities	Timelines	Budget	Results
		regional and continental levels	• Map regional and national pharmaceutical production capacities and possible collaborations for industrial clusters, produce and validate reports, identify follow up steps based on the findings	2017		
			• Support the alignment of public health, pharmaceutical, STI and industrial development policies with pharmaceutical manufacturing plans at national, regional and continental levels and development of national strategies in 10 countries	2016 – 2018		
			• Develop a monitoring and evaluation system including a database for continuous monitoring of the national innovation systems	2016		
			• Leverage governments' commitment to build conducive policy and regulatory systems for successful and sustainable pharmaceutical industry	Ongoing		
	1.1.4 At least 3 regions have implemented Innovative GMP Certification Schemes by 2020	• Implementation of Innovative GMP Certification Schemes at regional and national level	• Support two RECs to design a regional GMP roadmap and certification scheme	2016 -2017		80% of pharmaceutical manufacturers complying with regional and continental GMP certification schemes
			• Mobilize resources (technical and financial) for strengthening the capacity of local manufacturers in complying to GMP requirement	Ongoing		
			• Conduct advocacy for the regional certification schemes for GMP and compliance by manufactures	Ongoing		
	1.1.5 Policy, legal and institutional framework for the establishment of AMA endorsed by	• Development of policy, legal and institutional framework for the establishment of AMA	• Develop a draft policy, legal and institutional framework for AMA	2015		AMA Legal & Institutional Framework endorsed by AU Policy Organs
			• Present the draft policy, legal and institutional framework for AMA to the Technical team	2015		
			• Present the draft policy, legal and institutional framework for AMA to Ministers of Health	2016		

Objective	Target	Initiative	Activities	Timelines	Budget	Results
	AU Policy Organs by 2018		• Present the draft policy, legal and institutional framework for AMA to Ministers of Justice	2016		
			• Submit the policy, legal and institutional framework for AMA to AU organs for adoption	2016		
Direction 2: Regional integration and harmonization					**$838 677**	
2.2 Increased use of harmonized policies and regulatory frameworks by member states for faster, quality, predictable and transparent approval of medical products	2.2.1 MRH projects developed for 5 RECs by 2020 2.2.2 AMRH project scope expanded to cover clinical trials oversight, post-marketing surveillance and pharmacovigilance, medical devices and diagnostics in 5 regions by 2020	• Development and institutionalization of REC MRH Projects	• Finalise and facilitate utilization of the AMRH Implementation Tookit	2016		• # of RECs implementing AMRH framework • # and types of regional harmonized guidelines endorsed by the REC Policy Organs • # of countries implementing regional harmonized guidelines • # of countries participating in joint reviews and GMP inspections • % of products registered using regional harmonized guidelines • Agreed framework for benchmarking NMRAs in Africa • African NMRAs meeting internationally acceptable standards of Good Regulatory Practice
			• Develop and finalize project dossiers for SADC, ECOWAS/UEMOA, ECCAS/OCEAC, IGAD and AMU in the 5 RECs in collaboration with WHO	2016-2017		
			• Develop programme for post marketing surveillance, pharmacovigilance , clinical trials, medical devices and diagnostics for the EAC region in the 5 RECs in collaboration with WHO	2016		
			• Facilitate the expansion of project scope for SADC, ECOWAS/UEMOA, ECCAS/OCEAC, IGAD and AMU in the 5 RECs in collaboration with WHO	2016-2017		
	2.2.3 At least 5 regions and 25 countries have adopted regionally agreed regulatory technical guidelines	• Development and adoption of regionally agreed regulatory technical guidelines and standards	• Support regional Expert Working Groups (EWG), Technical Working Groups (TWGs), Steering Committees and Regulators Forum in the 5 RECs in collaboration with WHO	2016-2020		
			• Support implementation of regionally agreed regulatory technical guidelines and standards in the 5 RECs in collaboration with WHO	2016-2020		

Objective	Target	Initiative	Activities	Timelines	Budget	Results
	and standards by 2020		• Facilitate adoption and implementation of regionally agreed regulatory technical guidelines and standards by the industry in the 5 RECs	2016-2020		
	2.2.4 At least 3 regions have implemented Innovative GMP Certification Schemes by 2020	Implementation of Innovative GMP Certification Schemes at regional and national level	• Support two RECs to design a regional GMP roadmap and certification scheme	2016 -2017		
	2.2.5 AMRH M&E framework implemented in 3 regions by 2020	Conduct M&E of RECs MRH projects	• Pilot the AMRH indicators tracking and data collection tool in the EAC region	2016		
			• Develop an electronic data management system for AMRH indicators	2016		
			• Collect data on AMRH indicators and assess the status of implementation of agreed harmonised guidelines in the SADC, ECOWAS/UEMOA, ECCAS/OCEAC, IGAD and AMU in collaboration with WHO	2017 – 2020		
			• Produce annual performance reports and policy documents	2016-2020		
Direction 3: Human and institutional capacity development					**$1 250 673**	
Increased human and institutional capacity for regulation of medical products and technologies	• Curricula on Regulatory Science in alignment with Global Curricula Framework by 2018	• Streamlining Curricula on Regulatory Science in alignment with Global Competency and Curricula Framework	• Review the Body of Knowledge for RCOREs in alignment with the Global Regulatory Competency and Curricula			• Harmonized curricula in regulatory science approved by appropriate competent authorities • RCOREs adopted harmonized regulatory science curricula
			• Conduct annual review of performance of designated RCOREs	2016-2020		Regulatory training programmes

Objective	Target	Initiative	Activities	Timelines	Budget	Results
	• 15 regional centres of regulatory excellence operational by 2020	• Coordination of Regional Centres of Regulatory Excellence (RCOREs)	• Develop and publish Expression of interest to designate the planned 5 additional RCOREs in identified regulatory functions and review applications	2018		institutionalized in the RCOREs
			• Support RCOREs and Regulatory Professionals Fellowship Programmes	2016-2020		
	• 50% of experts in the "Pool of Regulatory Experts" utilized by 2020	• Coordination of a pool of regulatory experts	• Redesign a user friendly Pool of Regulatory Experts portal and interface	2016		Regulatory pool of Experts providing training in RCOREs
			• Re-launch the Pool of Regulatory Experts portal	2017		
			• Review applications received for entry into the pool of regulatory experts database and maintain a register	2016-2020		
	• 10% increase in the number of regulatory experts in Africa by 2020	• Facilitate the establishment of African Regulatory Professional Fellowship Programme (ARPFP)	• Conduct and assessment to determine the existing regulatory workforce in Africa	2016		% increase of number of regulatory workforce in Africa
			• Commission consultancy to carry out feasibility study/options analysis for establishment of the Governing Body for the African Regulatory Fellowship Programme	2016		
			• Review the Consultants Options Analysis Report and elaborate the governance structures and anchorage of the ARPFP within AU structures	2016 – 2017		
			• Develop a Resource Mobilization/viability/sustainability strategy for the ARPFP governing body/college/society/association	2017		
			• Establish the Governing body/college/society/association to administer the African Regulatory Professional Fellowship Programme	2017-2018		
			• Develop and publish guide for administering African Regulatory	2017		

Objective	Target	Initiative	Activities	Timelines	Budget	Results
			Professional Fellowship Programme(ARPFP)			
			• Launch programmes administered by African Regulatory Professional Fellowship Programme (ARPFP)	2018		
	• Align regulatory systems strengthening programmes with AMRH and AMA by 2018	• Scale up successful national & regional regulatory interventions	• Coordinate scale-up of regulatory interventions in alignment with AMRH and AMA	2016-2020		• Regulatory systems strengthening programmes aligned with AMRH and AMA
Direction 4: Enabling Environment: Coordination, partnership and resource mobilization					**$5 114 013**	
Effective coordination and alignment of regulatory interventions with AMRH Framework and AMA.	• At least 4 functional Technical working Groups (TWGs) by 2018 • African Medicines Conference aligned with the AMRH governance structure and AU Institutional Framework by 2016 • Scientific Conference convened bi-ennially	• Strengthen AMRH governance structures	• Convene meetings for TWGs on Policy and Regulatory Reforms; Regulatory Capacity Development and Specialised Regulatory Expert Committees	2016 – 2020		• AMRH transitioned into AMA
			• Convene the Advisory Committee meetings to deliberate on recommendations from the TWGs	2016 - 2020		
			• Integrate the AMRC into the AU Institutional Framework and convene bi-ennially Scientific and AMRC conferences in collaboration with the AUC and WHO	2017, 2019		
			• Draft and publish Scientific and AMRC conference reports	2016-2020		
	• Partnership Platform Accountability	• Development and implementation	• Conduct mapping of partners engaged in regulatory interventions in Africa, identify those with interest and agree on areas of collaboration on AMRH	2016		• Streamlined medicines regulatory interventions and partners in Africa

Objective	Target	Initiative	Activities	Timelines	Budget	Results
	Framework developed and implemented by 2020	of the AMRH Partnership Accountability Framework	• Develop AMRH Partnership Accountability Framework	2016		
			• Convene a Partnership platform meeting on regulation of medical products and technologies alongside the Scientific and AMRC conferences	2016-2020		
	• AMRH/AMA Secretariat capacity strengthened by 2016	• Support human resource development for the coordination of AMRH	• Recruit an intern for data collection	2016		• AMRH transitioned into AMA
			• Support a Senior Programme Officer to Support PMPA implementation			
			• Support personnel for the AMRH programme at the NEPAD Agency			
			• Identify training needs and facilitate AMRH Staff development programmes			
	• AMRH/AMA advocacy strategy implemented from 2016	• Advocate for AMRH as a foundation for AMA	• Develop the AMA Advocacy strategy • Design branding concept and produce advocacy and communication materials • Support design and hosting of the AMA website • Produce and disseminate a brochure on the role of AMRH in the establishment of AMA • Advocate for AMA at national, regional, continental and partners meetings			
	• NMRA Financing Models advocated by 2018	• Advocate for sustainable financing of NMRAs	• Scale-up NMRA financing studies to West, Southern, Central and North/North-Eastern African regions in collaboration with AMRH Partners	Ongoing		• NMRA Financing Models adopted at national and regional levels
			• Convene high level policy dialogues on sustainable financing for NMRAs in collaboration with AMRH Partners	Ongoing		
TOTAL					**$9 792 472**	

8. STRATEGIC PLAN BUDGET

The five years strategic plan budget is **US$9 792 472.** The resource requirement contained in this plan requires concerted effort by all stakeholders. The AMRH Programme strives to focus on strengthening partnerships, diversification of revenue and employing innovative approaches to create new projects and programmes.