AFRICAN MEDICINES REGULATORY HARMONISATION PROGRAMME

STRATEGIC PLAN

2011-2015

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AFRICAN UNION

TABLE OF CONTENTS

LIST OF TABLES

FOREWORD

Africa's regions have similar health and technological challenges including relatively low levels of investment in health research, drug discovery and pharmaceutical development compared to other continents. Countries in Africa are all struggling to produce, procure and make safe and essential medicines available to their populations. This is mainly because of limited budgets, lack of adequate infrastructure and human resources and a range of regulatory barriers including weak and/or absent medicines legislation and legal framework.

Ineffective regulatory systems not only pose public health risk but also create technical barriers to the free movement of products within and across regions. The regulation of medicines and harmonization of technical standards and legislative frameworks have emerged as important components of the regional economic integration efforts. This fact has also been emphasised in the Pharmaceutical Manufacturing Plan for Africa (PMPA) which among other things recognises that sound medicines regulatory systems compose one of the important elements in achieving local production policy priorities. In addition, success of local production depends, to an extent, on intra- regional and intra- continental trade in creating a viable market size.

To this regard the New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency, together with the Pan African Parliament (PAP) undertook to convene a consultative conference of representatives of regional economic communities (RECs) and National Medicines Regulatory Authorities (NMRAs) in Johannesburg, in 2009. This meeting, which was organised in collaboration with the World Health Organization (WHO), Bill and Melinda Gates Foundation, the UK Department for International Development (DFID) and Clinton Health Access Initiative (CHAI) explored the potential for supporting medicines registration harmonization within African RECs and organizations and initiated a strategic approach to developing project proposals to mobilize resources needed to support RECs harmonization initiatives. The African Medicines Regulatory Harmonization (AMRH) initiative therefore culminated from this conference.

The NEPAD Agency being the technical arm of the African Union is spearheading coordination and political advocacy for the AMRH initiative. The aim is to assist RECs and respective member states in Africa in their endeavour to improve access to quality, safe and efficacious essential medicines for treatments of priority diseases through harmonization of medicines registration as a pathfinder to a broader scope in regulatory functions and product types. In order to ensure success in the implementation of the AMRH programme, a 5 years strategic plan has been developed with a view to assist the NEPAD Agency and its collaborating partners in overseeing its implementation.

Dr. Ibrahim Assane Mayaki
Chief Executive Officer
NEPAD Planning and Coordinating Agency

ACKNOWLEDGEMENT

This five year strategic plan (2011-2015), has been developed through a series of workshops and meetings conducted in Pretoria, South Africa by selected staff members of the NEPAD Planning and Coordinating Agency and representatives of RECs and NMRAs from different African regions. The strong political constituency built between the NEPAD Agency through the AMRH Programme, RECs and NMRAs served as foundation in the development of this strategic plan

This plan will assist in providing a clear vision and mission, strategic objectives and indicators that will be used to assess performance of the AMRH initiative and its impact on strengthening the African regulatory capacity and consequently increasing access and improve the quality, safety and efficacy of essential medicines in Africa. Success in the implementation of this five year strategic plan is dependent on the interactive relationship between the AMRH Programme Team and other Programmes and Directorates within the NEPAD Agency, In addition, the NEPAD Agency partnership with the Pan African Parliament (PAP), the African Union Commission (AUC), RECs, NMRAs, the pharmaceutical industry, academia, research institutions, Non-Governmental Organizations (NGOs), civil society and other AMRH partners is critical for programme success.

In view of the foregoing, I wish to thank all who have worked as a team in the process of developing this five year strategic plan. Special thanks go to Margareth Ndomondo-Sigonda, Aziz Jardine, Chimwemwe Chamdimba, Mercy Fomundam and Nthabiseng Legodi for their tireless effort in making the AMRH Strategic Plan a reality. Without their commitment and team spirit this would not have happened. In the same vein, I wish to acknowledge the good work by the facilitator Dr. Mutumba, who besides his busy schedule accepted to facilitate the development of this five year strategic plan. The balanced scorecard framework applied in this plan translates our strategy into operational objectives that drive both our behaviour and performance over the next five years.

Mrs Estherine Lisinge-Fotabong

Director, Programme Implementation and Coordination Directorate

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

In the development of this five year (2011-2015) AMRH strategic plan, we adopted the balanced scorecard as a framework for translation of our strategy into operational objectives that drive both performance and behaviour of team members of the programme and related directorates within NEPAD Agency. This strategic plan outlines its purpose and major achievements of the AMRH programme. Further it outlines the strategic objectives, measures and targets set for the five year period, 2011-2015.

It is important to note that high level statements of AMRH namely the mission statement originate directly from the NPCA mandate. The plan points out the strategic issues that were identified as challenges faced by NEPAD Agency in implementing the AMRH Programme. These are issues identified following a critical environmental scanning of both internal and external environments under which AMRH operates. To ensure coordination of the operations of the AMRH programme, themes that serve as NEPAD Agency key focus areas for the next five years were carefully selected and enabled participants to cluster the strategic objectives in a manner reflecting the cause and effect relationship.

The last part of this strategic plan illuminates the corporate scorecard of AMRH. Depicted in the scorecard are strategic objectives, measures, targets, key initiatives and resource estimates of this five year strategic plan. These are further detailed in the AMRH results framework to reflect how the AMRH programme shall be measured based on the NEPAD Agency performance indicators.

1. INTRODUCTION

The NEPAD Planning and Coordinating Agency in collaboration with its partners[1] is currently spearheading and coordinating the African Medicines Regulatory Harmonization (AMRH) initiative through the regional economic communities and countries. This initiative is being implemented under the framework of the Pharmaceutical Manufacturing Plan for Africa (PMPA) which was endorsed by the AU Conference of Ministers of Health in 2007 in response to a call by the African Heads of States in 2005. 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 NMRAs in February, 2009. The joint consensus meeting agreed on the need to develop medicines registration harmonization projects as a pathfinder to a broader regulatory harmonization. Furthermore, a meeting of the African NMRAs in sub-saharan region which was held in Maputo-Mozambique in November 2009 called for NEPAD Agency to establish a Secretariat to spearhead the AMRH initiative.

So far, the NEPAD Agency in collaboration with its collaborating partners has been able to develop a fundable medicine registration harmonization (MRH) project proposal for the East African Community (EAC) which is due for funding in 2011. In addition MRH project proposals for Southern African Development Community (SADC) and Economic Community of West African States/West African Economic and Monetary Union (ECOWAS/UEMOA) have been finalised while proposals for the Organization for the fight Against endemic diseases in Central Africa/Economic Community of Central African States (OCEAC/ECCAS) and the Common Market for Eastern and Southern Africa (COMESA), Intergovernmental Authority on Development (IGAD) and the Community of Sahel-Saharan States/Arab Maghreb Union (CEN-SAD/AMU) are at different levels of development. Furthermore, the AMRH Advisory Committee is due to be established to provide leadership and policy guidance on implementation of the AMRH programme. The AMRH Advisory Committee shall be supported by Technical Working Groups and the AMRH Operations Committee which will provide the necessary technical input to drive the African Medicines Regulatory Development agenda.

The NEPAD Commissioned situation analysis on medicines regulation and harmonization provides a baseline status of the existing situation in African RECs and the NMRAs. The situation analysis report recommends the development and implementation of a long term strategy to address medicines regulatory challenges facing African countries. In view of this, the NEPAD Agency embarked on a process to develop a comprehensive five year strategic plan that will provide direction in the implementation of the AMRH programme including new areas of focus such as regulation of clinical trials of vaccines and medicines, effective market control and related strategies to combat counterfeit medicines, and pharmacovigilance programmes just to mention a few.

[1] The current AMRH partners include the African Union Commission (AUC), Pan African Parliament (PAP), the World Health Organization (WHO), the World Bank (WB), the Bill and Melinda Gates Foundation (BMGF), the UK Department for International Development (DFID), the Clinton Health Access Initiative (CHAI) and the Joint United Nations Programme on HIV/AIDS (UNAIDS)

2. MAJOR ACHIEVEMENTS

Over the period of 3 years (2007-2010) of consultative and endorsement meetings at various levels, a number of milestones have been attained under the AMRH Programme including:

a. A fundable project proposal for medicines registration harmonization (MRH) in the East African Community (EAC) Partner States has been developed and funding committed for 2011.
b. Situation analysis of medicines regulation and harmonization in the EAC, Southern African Development Community (SADC) and the Economic Community of West African States (ECOWAS) has been conducted and reports are available.
c. MRH project proposals for SADC and ECOWAS completed, pending funding commitment from the donors.
d. NEPAD Agency engagement with the African Union Commission (AUC) as part of implementation of PMPA.
e. NEPAD Agency engagement with PAP as part of AMRH political advocacy.
f. Establishment of the AMRH Trust Fund under the World Bank Governance structures.
g. Endorsement of the AMRH Advisory Committee by the AMRH partners.

3. PURPOSE OF THE STRATEGIC PLAN

The five year strategic plan was developed using the Balanced Scorecard as a planning tool as well as a framework. The balanced scorecard is a management system that will enable NEPAD Agency and its collaborating partners to clarify the AMRH vision and strategy and translate them into action. It will provide feedback around both the internal business processes and external outcomes in order to continuously improve strategic performance and results. As a framework, this strategic plan shall serve as the basis upon which management business plans shall be based.

The purpose of this strategic plan is to guide NPCA in monitoring the performance of the AMRH programme for the next five years (2011-2015). This will be done through the established governance and management structures namely the AMRH Advisory Committee, the AMRH Operations 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 be delegated to Technical Working Groups to be composed on ad-hoc basis based on identified needs.

The governance and management action plans shall be formulated in line with the four strategic themes based on NPCA mandate namely, knowledge management, advocacy, monitoring and evaluation and partnership. These strategic themes will enable the AMRH programme to focus resources and efforts towards driving the NEPAD Agency vision and delivering on its mandate for the period of implementation of this plan.

4. HIGH LEVEL STATEMENTS

The high level statements for the AMRH Programme are derived from, and support the NEPAD Agency **Mission** and **Vision Statements**

NPCA Vision:

To become a leading African think-tank that initiates and promotes the development and implementation of flagship programmes and projects in support of NEPAD and AUC vision and priorities.

NPCA Mission:

1. To facilitate and coordinate the implementation of continental and regional priority programmes and projects and to mobilise resources and partners in support of their implementation.
2. To conduct and coordinate research and knowledge management, monitor and evaluate the implementation of programmes and advocate on the AU and NEPAD vision, mission and core values

Mission Statement of AMRH

The mission statement of AMRH defines the nature and core purpose of this programme and is:

To coordinate and facilitate project development and management in partnership with stakeholders towards harmonization of medicines regulation and improved access to quality, safe, efficacious and affordable medicines in Africa

Core Values of AMRH

The core values of AMRH are based on the principles of the NEPAD Secretariat which was established to spearhead the NEPAD Programme. Table 1 below provides a summary of the NEPAD Secretariat's value proposition, which is based on four key elements – the facilitator, mobiliser, agent of change and learning organisation.

Table 1: AMRH Core Values

Value Statement	Focus	Descriptor
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

NPCA Core Functions: Service Lines

The core functions or service lines of NPCA are derived from its mandate, and aim 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.

5. AMRH STRATEGIC ISSUES, THEMES AND OBJECTIVES

Strategic issues are challenges faced by the NPCA in managing the AMRH Programme resulting from its internal and external environment. Strategic themes on the other hand 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 as listed here below:

Table 2: Strategic Themes and Issues

STRATEGIC THEMES	STRATEGIC ISSUES
❖ Research and Knowledge Management	▪ Weak governance and management structures ▪ Lack of codified information and knowledge e.g. manuals ▪ Language barriers ▪ Weak medicines regulatory capacity ▪ 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 ▪ Language barriers
❖ Advocacy	▪ Inadequate medicines legislations ▪ Conflicting regulatory requirements ▪ Multi membership to RECs ▪ Lack/inadequate access to quality, safe, efficacious and affordable essential medicines by African patients
❖ Monitoring and evaluation	▪ Low implementation rate of AU decisions ▪ Lack/inadequate access to quality, safe, efficacious and affordable essential medicines by African patients

AMRH Strategic Themes and Objectives

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
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
Advocacy	To influence public-policy and resource allocation decisions within political, economic, and social systems and institutions
Monitoring and evaluation	To institute performance measurement tools based on NPCA indicators

Table 4: Strategic objectives linked to themes

STRATEGIC THEME	STRATEGIC OBJECTIVES
Research & Knowledge Management	1. Improve medicines regulatory capacity & systems 2. Improve access to knowledge and skills for regulatory science & production of pharmaceuticals 3. Strengthen Governance and Management 4. Strengthen AMRH human capital management and development
Partnership with Stakeholders & Resource Mobilisation	5. Improve collaboration with partners 6. Diversify revenue sources 7. Manage operational costs
Advocacy	8. Build political & policy leadership in the AU and its organs to remove barriers to harmonization of medicines regulations
Monitoring & Evaluation	9. Strengthen AMRH Monitoring & Evaluation system

6. AMRH STRATEGY MAP

The strategy map aims to communicate the five years strategic plan on one page and indicates the cause-effect relationship of the strategic objectives linked in line with the four balanced scorecard perspectives.

Table 5: AMRH Strategy Map

Our Mission:	To coordinate and facilitate project development and management in partnership with stakeholders towards harmonization of medicines regulation and improved access to quality, safe, efficacious and affordable medicines in Africa			
Our Vision:	To become a leading African think-tank that initiates and promotes the development and implementation of flagship programmes and projects in support of NEPAD and AUC vision and priorities			
	Research & Knowledge Management	**Partnership & Resource Mobilisation**	**Advocacy**	**Monitoring & evaluation**
Customer	C.1 Strengthen medicines regulatory capacity & systems C.2 Improve access to knowledge and skills for regulatory science & production of pharmaceuticals		C.3 Build political & policy leadership in the AU and its organs to remove barriers to harmonization of medicines regulations	
Internal Processes	I.1 Strengthen Governance and Management	I.2 Improve collaboration with partners		!.3 Strengthen AMRH monitoring & evaluation system
Learning & Growth	L.1 Develop and Strengthen AMRH human capital			
Financial		F.1 Diversify revenue sources F.2 Manage operational costs		
Core Values	**Pan-Africanism**	**Accountability & Transparency**	**Professionalism**	**Effective Delivery & Results Oriented**

7. AMRH BALANCED SCORECARD

In this strategic plan, the balanced score card is used as a framework that translates AMRH strategy into operational objectives that drive performance and behaviour. This framework is multidimensional as it depicts how the strategic plan will be implemented in the course of 5 years period by way of linking the objectives, measure, initiatives and resources requirements as provided in Table 6 below.

Table 6: AMRH Balanced Scorecard

Business perspective	Objectives	Measurements	Baseline data	Targets					Initiatives	Accounting unit	Budget/ Resources (US$)
				Y1 2011	Y2 2012	Y3 2013	Y4 2014	Y5 2015			
Customer Perspective	C.1Strengthen medicines regulatory capacity & systems	Baseline data on competences for NMRA in their respective RECs established by end of year 2	0	1	2	3	4	5	C.1.1 Conduct competence profiling of the NMRAs in their respective RECs to establish baseline data based on situation analysis results	AMRH	300,000
		Needs based training offered to RECs, NMRAs & industry	0	1	2	2	2	2	C.1.2 Coordinate & facilitate needs based training to RECs, NMRAs & industry	AMRH	500,000
		A pool of regulatory experts in Africa and Diaspora identified to support RCORE by end of year 2	0	0	6	8	10	12	C.1.3 Identify a pool of regulatory expertise in Africa & diaspora	AMRH	0
		Technical Working Groups established & operational by year 2	0	0	4	4	4	4	C.1.4 TWG on Quality Management System (QMS) to set benchmark/standard for regulatory approval processes & systems	AMRH	57,960
									C.1.5 QMS- TWG to conduct assessment of existing regulatory approval processes & systems in the 5 regions	AMRH	250,000

Business perspective	Objectives	Measurements	Baseline data	Targets					Initiatives	Accounting unit	Budget/ Resources (US$)
				Y1 2011	Y2 2012	Y3 2013	Y4 2014	Y5 2015			
									C.1.6 TWG on Information Management System (IMS) to conduct assessment & recommend the appropriate IMS software in the 5 regions	AMRH	300,000
		Regional Centres of Regulatory Excellence established by end of year 3	0		1				C.1.7 Technical Working Group (TWG) to develop & endorse criteria for establishing regional centres of regulatory excellence	AMRH	57,960
					1				C.1.8 TWG to review applications and select Regional Centres of Regulatory Excellence (RCORE)	AMRH	57,960
					2	2	3	3	C.1.9 Facilitate the establishment of 10 RCORE	AMRH	1,159,200
						1	1	1	C.1.10 TWG to assess performance of RCORE & provide technical support (including establishment of regulatory affairs professional society)	AMRH	250,000

Business perspective	Objectives	Measurements	Baseline data	Targets					Initiatives	Accounting unit	Budget/ Resources (US$)
				Y1 2011	Y2 2012	Y3 2013	Y4 2014	Y5 2015			
		5 academic institutions identified and supported to develop curriculum on post-graduate courses in regulatory science by end of year 5	0	1	1	1	1	1	C.1.11 Identify and support 5 academic institutions to develop curriculum to offer post-graduate courses in regulatory science	AMRH	500,000
	C.2 Improve access to knowledge and skills for regulatory science and production of pharmaceuticals	Studies to assess progress on AMRH, identify gaps and new areas of focus conducted annually	0	3	3	2	2	2	C.2.1 Conduct annual studies to assess progress on AMRH, identify gaps and new areas of focus	AMRH	250,000
		AMRH newsletters produced and published biannually	1	2	2	2	2	2	C.2.2 Produce & publish AMRH newsletters biannually	AMRH	0
		Information, Education & Communication (IEC) Package developed & disseminated	0	1	1	1	1	1	C.2.3 Develop & disseminate Information, Education & Communication (IEC) Package	AMRH	400,000
		An interactive & vibrant AMRH website maintained annually	1	1	1	1	1	1	C.2.4 Regularly update & maintain an interactive & vibrant AMRH website	AMRH	150,000
		A portal for information sharing	0	0	1	1	1	1	C.2.5 Establish a portal for information sharing	AMRH	50,000

Business perspective	Objectives	Measurements	Baseline data	Targets					Initiatives	Accounting unit	Budget/ Resources (US$)
				Y1 2011	Y2 2012	Y3 2013	Y4 2014	Y5 2015			
		established by year 2									
		Scientific conferences conducted biennially	0	0	1	0	1	0	C.2.6 Conduct biennial scientific conferences	AMRH	500,000
	C.3 Build political & policy leadership in the AU and its organs to remove barriers to harmonization of medicines regulations	A consultant to develop a model law commissioned by end of year 1	0	1	1	0	0	0	C.3.1 Commission a Consultant to develop a model law	AMRH	100,000
		# of TWG meetings convened per annum to discuss the draft model law	0	0	2	2	1	1	C.3 2 Convene TWG meetings per annum to discuss the draft model law	AMRH	695,520
		# of PAP Health Committee meetings convened to discuss and endorse model law by end of year 2	1	2	2	1	1	1	C.3.3 Convene PAP Health Committee meetings to discuss & endorse the AMRH model law	AMRH	330,000
		Regional consultation meetings on the AMRH model law convened in year 2 and year 3	0	0	3	3	1	1	C.3.4 Convene regional consultation meetings on the AMRH model law	AMRH	850,000
		# of countries & regions endorsed & adopted the Model Law	0	0	5(1)	15(3)	25(5)	35(6)	C.3.5 Solicit endorsement & adoption of the AMRH model law at country, regional and continental levels	AMRH	300,000

Business perspective	Objectives	Measurements	Baseline data	Targets					Initiatives	Accounting unit	Budget/ Resources (US$)
				Y1 2011	Y2 2012	Y3 2013	Y4 2014	Y5 2015			
		Countries in group 1 and 2 assisted to establish NMRAs by end of year 4	0	0	40%	60%	80%	100%	C.3.6 Support countries in Group 1 & 2 to establish NMRAs	AMRH	150,000
Internal Process Perspective	I.1 Strengthen governance & management	AMRH Advisory Committee established by end of year 1	0	Yes	0	0	0	0	I.1.1 Establish & launch AMRH Advisory Committee to provide strategic leadership on AMRH	AMRH	150,000
		AMRH advisory committee meetings conducted annually	0	0	1	1	1	1	I.1.2 Conduct annual AMRH Advisory Committee meetings	AMRH	414,000
		AMRH staff recruited as appropriate	0	5	6	7	8	8	I.1.3 Recruit & Manage AMRH staff	AMRH	3,000,000
	I.2 Improve collaboration with partners	# of additional partners engaged on AMRH	6	4	2	2	2	2	I.2.1 Engage AUC, PAP, SARPAM, WHO-HQ, WHO-AFRO, WHO-EMRO, World Bank, US-FDA, EDCTP, PDPs, Chirac Foundation & other interested partners on AMRH	AMRH	150,000
		Agreed MoUs with AMRH partners	2	4	4	2	2	2	I.2.2 Develop MoUs with partners	AMRH	0
		% performance if service level agreements with AMRH Partners	0	60%	70%	80%	90%	100%	I.2.3 Develop and implement service level agreements on MoUs	AMRH	0
	I.3 Strengthen AMRH Monitoring & Evaluation System	AMRH monitoring and evaluation (M&E) system	0	Yes	Yes	Yes	Yes	Yes	I.1.2 Develop monitoring and	AMRH	15,000

Business perspective	Objectives	Measurements	Baseline data	Targets					Initiatives	Accounting unit	Budget/ Resources (US$)
				Y1 2011	Y2 2012	Y3 2013	Y4 2014	Y5 2015			
		established and implemented by end of year 2							evaluation (M&E) system		
		% performance of AMRH programme	0	60%	70%	80%	90%	100%	I.1.3 Conduct M&E reviews and produce reports	AMRH	300,000
Learning and Growth Perspective	L.1 Develop & strengthen AMRH human capital	# of Management development programmes for NPCA AMRH staff implemented annually	0	50%	70%	80%	90%	100%	L.1.1 Implement management development programmes for AMRH staff	AMRH	150,000
Financial Perspective	F.1. Diversify revenue sources	Project proposals for Central, North/North-Eastern regions finalized by end of year 2	0	2	0	0	0	0	F.1.1 Finalise project proposals for Central, North/North-Eastern regions	AMRH	1,000,000
		# of RECs receiving Implementation support from year 2	0	0	3	4	5	6	F.1.2 Support implementation of RECs projects	AMRH	4,000,000
		# of Additional projects for expanded regulatory functions and products developed annually from year 2	0	0	2	2	2	2	F.1.3 Prepare project proposals for expanded regulatory functions and products for integration in the existing RECs projects	AMRH	150,000

Business perspective	Objectives	Measurements	Baseline data	Targets					Initiatives	Accounting unit	Budget/ Resources (US$)
				Y1 2011	Y2 2012	Y3 2013	Y4 2014	Y5 2015			
		Donors engaged	1m	1m	2.5m	5m	10m	17m	F.1.4 Engage donors	AMRH	150,000
	F.2. Manage operational costs	Budget variance %	0	47%	30%	20%	10%	5%	F.2.1 Implement an effective financial control system	AMRH	0
Grand Total:											**16,687,600.00**

8. AMRH RESULTS FRAMEWORK

The AMRH results Framework is derived from the NEPAD Agency Performance indicators for Human Development thematic area which are:

a. Increased availability of regional programmes/projects and policy frameworks for implementation by member States and RECs;
b. Enhanced mechanisms for mobilising internal and external resources for member States and RECs to implement national and regional programmes and projects;
c. Enhanced capacity of member States and RECs to implement AMRH Programme;
d. Enhanced capacity of NPCA, member States and RECs to monitor and evaluate implementation of NEPAD AMRH Programme;
e. Enhanced private sector involvement in regional programmes and projects; and

Consequently, the AMRH programme results areas are provided in the results matrix table as indicated below:

Table 7: AMRH Results Framework

Level I Health Outcomes	Level II Project Outcomes	Level III Outputs: Services	Level IV Outputs : Institutional	Level V Inputs
• Improved access to safe, efficacious and good quality essential medicines • Increased market for domestic pharmaceutical industry • Timely registration of new and generic medicines for the treatment of priority and neglected diseases	• Increased number of NMRAs' effectively participating in the regionally harmonized joint assessment for medicine registration ***Target to be set based on baseline*** • Reduced registration time for medicines in NMRAs Target: Year 2 (25% by Group 3 and 10% annually thereafter); Year 4 (25% by Group 2 and 10% annually thereafter); Year 5 (25% by Group 1) • Reduced back-log in registration of medicines in NMRAs Target: Year 2 (25% by Group 3 and 10% annually there after); Year 4 (25% by Group 2 and 10% annually thereafter); Year 5 (25% by Group 1)	• NMRA CEOs trained in project management by the end of year 2 • NMRA staff trained in finance management and information management systems (IMS) by and of year 3	• 10 Regional Centres of Regulatory Excellence (RCORE) established Target: 6 by and of Year 3; 4 by and of year 5) • Post graduate courses in regulatory science established and institutionalized in 5 academic institutions by end of year 5 • A database of regulatory experts to support RCORE activities established by end of year 2	**<u>Regulatory capacity building & systems strengthening</u>** • Baseline data on competences for NMRA in their respective RECs established by end of year 2 • A pool of regulatory experts in Africa and Diaspora identified to support RCORE by end of year 2 • Technical Working Groups established & operational by year 2 • Regional centers of regulatory excellence established by end of year 3 • 5 academic institutions identified and supported to develop curriculum on post-graduate courses in regulatory science by end of year 5 • Need based training offered to RECs, NMRAs & industry annually
	• Information exchange and linkage between NMRAs and industry strengthened • Access to knowledge and skills for regulatory science and	• Information sharing portal for NMRAs and pharmaceutical industry established by year 2	• AMRH study reports produced annually • Newsletter produced biannually • IEC materials developed and disseminated amongst NMRAs and pharmaceutical industry annually	**<u>Access to knowledge and skills for regulatory science and production of pharmaceuticals</u>** • Studies to assess progress on AMRH, identify gaps and new areas of focus conducted annually • AMRH newsletters produced and published biannually

	production of pharmaceuticals increased		• A scientific publication for regulators and pharmaceutical producers produced annually • A vibrant interactive website maintained	• Information, Education & Communication (IEC) Package developed & disseminated • Scientific conferences conducted biennially • An interactive & vibrant AMRH website maintained • A portal for information sharing established by year 2
	• National medicines laws for 35 countries reviewed/ developed based on the model law by end of year 5 • NMRAs of countries in group 1 and 2 countries successfully registering medicines **(Target to be set based on baseline)** • Countries in group 1 and 2 effectively participating in the MRH programme at regional level **(Target to be set based on baseline)**	• Model law domesticated by 35 countries by and 6 RECs by and of year 5. • NMRAs established in group 1 and 2 countries **(Target to be set based on baseline on existence of NMRAs)**	• Model law developed and adopted by at least 35 countries and 6 RECs by end of year 4	**<u>Policy, Legal & regulatory framework for harmonisation</u>** • A consultant to develop a model law commissioned by end of year 1 • TWG meetings convened per annum to discuss the draft model law • PAP Health Committee convened to discuss and endorse model law by end of year 2 • Regional consultation meetings on the AMRH model law convened in year 2 and year 3 • Endorsement & adoption of the AMRH model law at country, regional and continental levels solicited by end of year 4 • Countries in group 1 and 2 assisted to establish NMRAs by end of year 4
	• AMRH programme effectively implemented at continental and regional level	• AMRH performance reviews conducted and reports produced annually • Monitoring and evaluation systems for AMRH and REC	• Key linkages with strategic partners in MRH project established • MoUs with AMRH Partners: SARPAM, WHO-HQ, WHO-AFRO, WHO-EMRO, World	**<u>AMRH Governance and Management; and Partnerships</u>** • AMRH Advisory Committee established by end of year 1 • AMRH advisory committee meetings conducted annually

		Projects developed and implemented by end of year 2	Bank, US-FDA, EDCTP and PDPs developed and implemented by end of year 2	• Management development programmes for NPCA AMRH staff implemented annually • AMRH staff recruited as appropriate • AMRH monitoring and evaluation (M&E) system established and implemented by end of year 2 • MoUs and agreements with partners developed, implemented and evaluated annually
	• AMRH focus expanded to cover 4 additional regulatory functions and products by end of year 5 • AMRH programme implemented continentally	• Resources mobilized for the implementation of MRH in 6 RECs: 3 RECs by year 2 and 3 RECs by year 4 • Resources mobilized for one additional project annually	• One additional project developed annually from year 2 • RECs supported to implement MRH: 3 RECs by year 2 and 3 RECs by year 4 • Project proposals for Central and North/North-Eastern regions finalized by year 2	**AMRH Resource mobilization** • Project proposals for Central, North/North-Eastern regions finalized by end of year 2 • Implementation support provided to RECs from year 2 • Additional projects for expanded regulatory functions and products developed annually from year 2 • Donors engaged

Key: *Country Groupings based on agreed criteria among NMRAs and NEPAD Agency commissioned situation analysis as shown in Table 8 below:

Table 8: Criteria for categorizing NMRAs

Criteria	REC	Category 1 (meeting less than 3 criteria)	Category 2 (meeting 3 – 4 criteria)	Category 3 (meeting all 5 criteria)
• Existing NMRA • Existing legal framework	SADC	Lesotho, Swaziland, Seychelles, DRC, Angola	Malawi, Mozambique, Zambia, Botswana, Mauritius, Namibia	South Africa, Tanzania, Zimbabwe

• Performance of full regulatory functions (dossier evaluations and registration, GMP inspections) • Existing Management Information System • Available HR	EAC		Burundi, Rwanda, Tanzania-Zanzibar	Kenya, Tanzania-Mainland, Uganda
	ECOWAS-WAHO/UEMOA	Benin, Cote D'Ivoire, Guinea Bissau, Sierra Leone	Cape Verde, Gambia, Liberia, Mali, Republic of Guinea, Togo	Burkina Faso, Ghana, Niger, Nigeria, Senegal

9. AMRH STRATEGIC PLAN BUDGET

The AMRH five years strategic plan budget is **USD 16,687,600.00.** The resource requirement contained in this strategic plan requires concerted effort by all the NEPAD Agency Directorates. To implement all the envisaged project and programmes, the AMRH Programme strives to focus on strengthening partnerships, diversification of revenue and employing innovative approaches to create new projects and programmes.