AFRICAN UNION

الاتحاد الأفريقي

UNION AFRICAINE

UNIÃO AFRICANA

Addis Ababa, ETHIOPIA **P. O. Box 3243** **Telephone : 011-551 7700** **Fax : 011-551 7844**

website : www. africa-union.org

SECOND SESSION OF THE SPECIALISED TECHNICAL COMMITTEE ON HEALTH, POPULATION AND DRUG CONTROL (STC-HPDC-2)
ADDIS ABABA, ETHIOPIA
20-24 MARCH 2017

Theme: "Youth, Health and Development: Overcoming the Challenges towards Harnessing the Demographic Dividend"

BUSINESS PLAN FOR AFRICAN MEDICINES AGENCY (AMA)

African Union
a United and Strong Africa

AFRICAN MEDICINES AGENCY

Business Plan

Version 05

26 January 2016

World Health Organization

NEPAD
TRANSFORMING AFRICA

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The African Heads of State and Government as well as the World Health Organization (WHO) Regional Committee for Africa decided on the establishment of the African medicines agency (AMA) in response to the enormous health challenges and lack of access to affordable, quality essential medicines.

Africa has a high disease burdens and high mortality from preventable and curable diseases, which affects populations at various levels, rural and urban. This is compounded by weak health systems, scarce financial and human resources and unavailable and unaffordable medicines that are good quality, safe and efficacious. Lack of access to quality essential medicines and health products is just one of the contributing factors to the enormous health challenges that Africa faces. Further, the regulation of pharmaceuticals is an essential part of improving health care while supporting social and economic productivity of the African population.

Therefore, the AMA is a Specialized Agency of the African Union (AU), legally mandated by Member States (MS) to improve their capabilities to regulate medical products. This will be achieved through coordinating and strengthening continental initiatives to harmonize medical products regulation, providing guidance, complementing and enhancing the efforts of the AU-recognized Regional Economic Communities (RECS) and MS, and contributing to improving access to medical products on the continent. AMA will serve as a catalyst for stronger regulatory oversight to curtail medical products that are SSFFCs, enable competitiveness of locally produced medicines particularly of those for diseases that disproportionately affect Africa.

It is increasingly becoming evident that no single country including well-resourced countries, can single handily regulate its own market efficiently and effectively in this era of globalization without relying on others. As such, AMA as a continental agency would galvanize technical support, expertise in various countries and RECs, and resources more effectively at levels that may not be possible for individual countries on their own. However, AMA will not replace National medicines regulatory Authorities (NMRAs) or regional Medicines Regulatory Authorities, which will be established by the Regional Economic Communities (RECs).

The desired outcomes for AMA includes increased number of manufacturing facilities that are compliant to good manufacturing practices (GMP), number of MS & RECs with appropriate policies, legal and regulatory frameworks, increased number of NMRAs and RECs with sustainable financing, and increased market share (value and volume) of local manufacturers. AMA will achieve these desired results through the following strategies: (1) regional integration and harmonization, (2) policy, legal and regulatory reforms at national and regional level, (3) regulatory capacity building (4) advocacy and knowledge management.

AMA's financing model is based on multiple sources of funding to ensure ownership and sustainability. The financial mechanisms are (1) annual assessed contribution to be paid by the Members, (2) grants and donations, and (3) innovative financing mechanisms such as endowment fund and use of social impact bonds and (4) proceeds for its activities. It is expected that contribution from the innovative resource mobilization will reach 25% of the annual program costs by 2022 and Member States (Parties) contribution will reach 100% of the operating costs by 2022.

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS AND ACRONYMS

ACTs	Artemisinin-combination therapies
AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonization
AMU	The Arab Maghreb Union
API	Active Pharmaceutical Ingredient
ARVs	Antiretrovirals
AU	African Union
AUC	African Union Commission
CEN-SAD	The Community of Sahara-Sahel States
COMESA	The Common Market for Eastern and Southern Africa
EAC	The East African Community
ECCAS	The Economic Community of Central African States
ECOWAS	The Economic Community of West African States
FPP	Finished Pharmaceutical Product
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
ICH	The International Council on Harmonization of Technical Requirements for Registration Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Agencies
IGAD	The Intergovernmental Authority on Development
IGDRP	International Generic Drugs Regulators Programme
IPTp	Intermittent preventive therapy in pregnancy
IVD	In vitro diagnostics
LDCa	Least Developed Countries
LICs	Low-income Countries
MD	Medical devices

MDG	Millenium Development Goals
MDR-TB	multidrug-resistant tuberculosis
MRA	Medicines Regulatory Authority
MS	Member States
NCD	Non communicable diseases
NEPAD	The New Partnership for Africa's Development
NMRA	National Medicines Regulatory Authority
NPCA	NEPAD Planning and Coordinating Agency
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme
PMPA	Pharmaceutical manufacturing Plan for Africa
PMS	Post marketing surveillance
RCORE	Regional Center of Regulatory Excellence
REC	Regional Economic Community
SADC	The Southern African Development Community
SSFFCs	substandard, spurious, falsely-labeled, falsified and counterfeit products
TB	Tuberculosis
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

ACKNOWLEDGEMENTS

The process of developing the AMA business plan was guided by a participatory approach through consultations with key stakeholders through online platforms, meetings and workshops, and interviews. The exercise was overseen by the World Health Organization (WHO) Regional Office for Africa, the NEPAD Agency and the African Union Commission. The work was carried out under the general direction of the AUC Director – Social Affairs.

WHO, the NEPAD Agency and AUC provided the necessary financial resources required to finance the development of the business plan, including the consultation process throughout the Member States, and the publishing of the final draft.

1. INTRODUCTION

Africa's leadership remains concerned about the disproportionately high burden of communicable and non-communicable diseases affecting the continent, compared to other regions of the world.[1] Coupled with the sub-optimal investment in health systems, this has a potential negatively impact on Africa's economic development. Moreover, the proliferation of substandard, spurious, falsely labeled, falsified, counterfeit (SSFFCs) medical products[2] in the market is a major concern to public health.

The African Union (AU) Executive Council on recommendation from the AU Conference of Ministers of Health[3], endorsed the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 to address the lack of access to quality, affordable medical products, low economic development, and reduce the overdependence on imported medical products[4]. It is within this framework of creating an enabling regulatory environment for PMPA that the African Medicines Regulatory Harmonization (AMRH) Programme under the New Partnership for Africa's Development (NEPAD) was initiated. The goal for the AMRH is to strengthen the capacity for regulation of medical products in Africa and the promotion of harmonization of medicines regulatory systems.

Additionally, the African Heads of State and Government as well as the World Health Organization (WHO) Regional Committee for Africa decided on the establishment of the African medicines regulatory agency in response to the enormous health challenges including lack of access to affordable, quality essential medical products[1, 5,, 6]. Subsequently, the AU Executive Council endorsed the roadmap for the establishment of the African Medicines Agency (AMA)[7] based on the recommendation of the first African Ministers of Health meeting jointly convened by the African Union Commission (AUC) and the WHO[8].

In line with the Ministerial commitment, the AUC and WHO established a Task Team to facilitate the establishment of the AMA. The first Task Team meeting was held in November 2014 in Addis Ababa and adopted its terms of reference and a four-year action plan (2015 - 2018) for the operationalization of the AMA. The AUC, the WHO and NEPAD Planning and Coordinating Agency serve as a joint secretariat for the Task Team. Development of the AMA business plan for the AUC is one of the AMA's four-year action plans to operationalize the continental agency.

The AMA business plan provides the rationale for the continental agency, background to the genesis of AMA, the business model and financial plan, and monitoring and evaluation.

1.1 Problem Statement

Africa suffers high burdens and mortality of preventable and curable diseases, affecting, rural and urban communities. In addition, health systems are weak, financial and human resources are scarce and quality, safe and efficacious medicines are unavailable or unaffordable. For instance, only 7.6 million (36%) of the 21.2

1 The African Union Assembly Decision No: Assembly/AU/Dec 413 (XVIII): Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa, July 2012

2 WHO definition; medical products include medicines, vaccines, pharmaceutical ingredients, medical devices, and diagnostics.

3 The African Union, Third Session of The AU Conference of Ministers of Health, Johannesburg, South Africa, 9 – 13 April, 2007

4 African Union Executive Council, Eleventh Ordinary Council 25 – 29 June, 2007 Accra, Ghana EX.CL/Dec.348 - 377(XI)

5 WHO Regional Committee for Africa, Sixtieth Session: Report of the Regional Task Force on the Prevention and Control of Substandard/Spurious/Falsely labelled/Falsified/Counterfeit Medical Products in the Africa Region. Malabo, Equatorial Guinea 30 August–3 September 2010

6WHO Regional Committee for Africa, Sixty-third session Agenda item 11: Strengthening The Capacity for Regulation of Medical Products in The African Region Brazzaville, Republic of Congo, 2–6 September 2013

7 African Union Executive Council, Twenty-Sixth Ordinary Session, 23 – 27 January 2015 Addis Ababa, Ethiopia EX.CL/Dec.851-872 (XXVI)

8 First meeting of African Ministers of Health jointly convened by the AUC and WHO Luanda, Angola, 16–17 April, 2014

million people in Africa eligible for antiretroviral therapy in 2013 were receiving HIV treatment[9]. Further, compared to two-thirds of adults, only a third of children needing antiretroviral therapy are receiving it.

Despite the fall in malaria mortality rates, Africa alone, accounts for 90% of malarial deaths – a preventable and curable disease due to poor access to insecticide-treated mosquito nets (ITNs), and artemisinin-combination therapies (ACTs) among other factors[10]. Although, women and children are at high risk, only 57% of pregnant women receive at least one dose of intermittent preventive treatment in pregancy (IPTp), while use of ACTs in children is below 20%. Availability of generic medicines in WHO Africa region is less than 60% in private sector and 30% in public sector[11]. One in 5 children do not receive all childhood vaccines. On average, patients in the WHO Africa region pay 2.3 times and 6.7 times for the lowest-priced generic compared to the international reference price in public and private sector respectively[12]. Consequently, poor access to affordable, quality medical products is one of the determinants of the preventable productivity loss, poverty and poor health outcomes on the continent.

The causes of lack of access to affordable, quality medical products are varied (Annex I). Inadequacy of health care systems including inefficient supply and distribution systems also contributes to shortages particularly at lower levels of care. Medical products are often unaffordable, partly because of adequate financial resource allocation. For instance, only six Member States (MS), reached the agreed Abuja Declaration target of 15% of budget allocations to health evidence that health is apparently not prioritized by policy and decision makers across the continent[13]. Together with poverty, there is *insufficient financial resources* to spend on health. In addition, inadequate institutional arrangements, the lack of required skills and competences contributes to inefficiency and ineffective regulatory and supply chain systems.

Patent and intellectual property rights, especially on newer treatments and *lack of local manufacturing* capacity for generic medicines contributes to the high cost of medical products. Local pharmaceutical manufacturing is impacted by the lack of enabling regulatory environment, among other factors. The disparate systems of regulation create a complex, inefficient and ineffective regulatory environment, which culminates in non-tariff barriers impacting on availability and affordability of quality medical products to Africans.

9 UNAIDS. Access to Antiretroviral Therapy in Africa: Status Report on Progress Towards the 2015 Targets. http://www.unaids.org/sites/default/files/media_asset/20131219_AccessARTAfricaStatusReportProgresstowards2015Targets_en_0.pdf (last accessed 20 October 2015)

10 World Malarial Report 2014a

11 A Cameron, M Ewen, D Ross-Degnan, D Ball, and R Laing. Medicines prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. Lancet 2009; 373: 240-49. DOI:10.1016/S0140- 6736(08)61762-6

12 Alexandra Cameron, Margaret Ewen, Martin Auton and Dele Abegunde. Medicines Prices, Availability and Affordability in The World Medicines Situation 2011. World Health Organization (WHO) http://apps.who.int/medicinedocs/documents/s18065en/s18065en.pdf (last accessed 20 October 2015)

13 UNAIDS & African Union Commission. Abuja +12 Shaping the future of health in Africa, 2013.

1.2. Rationale for African Medicines Agency

The statement of the problem has clearly highlighted the major challenges facing the continent. The solution is the AMA, a specialized agency of the AU, which is legally mandated by MS with the goal of increasing availability of affordable, quality, safe and efficacious medicines and other health products on the continent.

The AMA will provide the coordination needed to ensure better regulatory oversight. It will galvanize technical support, expertise in various countries and RECs, and resources at a scale that cannot be matched at national or regional levels and strengthen harmonization leading to agreement across the continent. The AMA will complement and not replace the NMRAs or regional regulatory systems.

1.3 Vision

To be the leader in creating an enabling regulatory environment for medical products in Africa.

1.4 Mission

To protect public health and promote pharmaceutical sector development in Africa by ensuring that medical products in use meet internationally recognized standards of quality, safety and efficacy.

1.5 Goal

To coordinate national and regional regulatory systems for medical products, strengthen regulatory oversight, and promote cooperation and harmonization in Africa.

1.6 Objectives of AMA

The Agency will coordinate national and regional regulatory systems for medical products, strengthen regulatory oversight, promote cooperation and harmonization in Africa.

The objective of the AMA is to coordinate on-going regulatory systems strengthening and harmonization efforts of the African Union-recognized RECs, Regional Health Organizations (RHOs) and Member States; provide regulatory guidance; complement and enhance collaboration; and contribute to improving patients' access to quality, safe and efficacious medical products and health technologies on the continent.

2 EXPECTED IMPACT

The AMA business model is built on a social enterprise business model[14] to deliver measurable social and economic impact in return for financial investments.

2.1 Social Impact

The value proposition for AMA is to improve the health of Africans through working with MS and RECs to ensure that medical products are affordable, accessible, safe, efficacious and of good quality. This will in turn lower the disease burden and mortality on the continent leading to improved developmental indicators. People will have improved wellbeing thus, remain more productive and hence reduce poverty.

2.2 Economic impact

Public – high cost of medicines and ill health drives people into poverty especially in developing countries as available limited resources are diverted to healthcare, conversely, improved access to affordable, good quality medicines will ensure good health and people remain economically productive reducing poverty.

[14] Social Enterprises apply effective business model to social problems with the goal of achieving sustainability by enabling non-profits to support themselves financially in innovative ways instead of relying solely on grants and donations. The return on investment or outcomes is measured in terms of social value (social impact) and economic value (revenue).

MS Governments: high cost of medicines reduces coverage of healthcare services, especially for most African governments were resources are scarce. Moreover, this also diverts funding from other priority areas. High prevalence of SSFFCs in the continent results in wasted resources on ineffective medicines, drug resistance, loss of economic productivity and ultimately unnecessary deaths. Thus, reducing the prevalence of SSFFCs leads to costs savings. Expansion of national into regional markets through harmonization will reduce costs of medicines due to economies of scale, increased competition and reduced regulatory costs. In addition, increasing access to affordable good quality medicines will improve the health of the nation, which improves economic productivity (e.g. lower healthcare costs, absenteeism and deaths).

NMRAs: Most NMRAs in the continent have challenges with recruiting and maintaining skilled and competent regulatory staff. Further, most NMRAs in the continent lack the required expertise in some areas such as innovative therapies, bio-therapeutics, vaccines and African traditional medicines, good clinical practice (GCP) inspections of contract research organization (CROs) or GMP inspections of active pharmaceutical ingredient (API) manufacturing facilities. By pooling the available expertise and resources in the continent, AMA will provide the outcomes for use by NMRAs. For example, inspection reports for API or CRO facilities, regulatory guidance on innovative therapies or bio-therapeutics. Further, cooperation and collaboration through work sharing, joint activities and information sharing will enable NMRAs to remove duplication, regulatory burden thus efficiently utilize their available resources for maximum impact. Participating in the regulatory activities at continental level will develop regulatory capacity of existing NMRA staff through networking, cross-learning and exposure.

Pharmaceutical Industry: Harmonization and collaboration among NMRAs is expected to streamline the registration processes, consolidate the fragmented national markets into regional ones thereby reducing the regulatory burden on industry and faster access to a wider pharmaceutical market. Introduction of the common technical document (CTD) by ICH was noted to reduce the resources and time required by both industry and regulators in the ICH regions in approving a single product[15][16]. While the interventions would reduce SSFFCs and increase business for legitimate pharmaceutical companies that invest in quality systems, the same interventions would result in some companies driven out of business due to failure to upgrade to required standards and increased competition through market consolidation.

Partners/Impact investors:

The International finance facility for immunization (IffIm) Bonds ($3.7B raised)

- *Innovative financing mechanism that has been hailed by the The Financing for Development Conference 2015 as a model for addressing other global issues.*
- *Launched to support the GAVI (Global Alliance for Vaccines and Immunisation) Initiative, these bonds use the public markets to support vaccination efforts in the developing world*
- *IFFIm raises money in capital markets by converting long term government or donor commitments into immediate cash. These bonds have been issued at market rates to both commercial and retail investors and hold a AAA/Aaa rating*
- *The offering has allowed GAVI to frontload committed funds (that have been guaranteed over a 20 year time horizon), facilitating more lives to be saved in the near years and creating the infrastructure to more efficiently administer vaccinations across the*

Figure 1: Innovative financing model for immunization. Adapted from IFFIm evaluation report 2011

[15] Betty R. Kuhnert, ICH at 20 an Overview. April 2011, Vol 3 Issue 2 Global Forum

[16] Caroline Nutley. The Value Benefits of ICH to Industry, IFPMA 2000

The International Finance Facility for Immunization (IFFIm) utilizes innovative financing model of social impact bonds to fund vaccination programmes[17]. Similarly, as part of the resource mobilization, AMA would explore social impact bonds to raise private sector capital to expand to support the expansion and implementation of regional and continental harmonization programmes. This mechanism allows private investors to fund the strengthening of regulatory activities to improve access and affordability to quality essential medicines, and the partners and governments to repay the investors based on the success in achieving predetermined outcomes[18].

Like any business and investments, the investors can recoup their principal plus a potential rate of return if AMA succeeds in meeting its targets, while if it does not achieve the desired outcomes, the partners and the governments are not obliged to repay the investors.

Additionally, the AMA business model is designed to deliver value for money and focus on interventions that have specific measurable outcomes (quantifiable social value) to ensure the desired impact for the social investors and partners.

2.3 Expected Value Addition of African Medicines Agency

The NMRAs will retain all their regulatory functions and their decision-making roles and exercise market controls for their specific markets. However, for certain functions such as GMP inspection of foreign manufacturing sites, review of complex medical products, the regional agencies and AMA would assist by optimizing the available resources within the regions and harmonization through convergence/harmonization of technical requirements, joint activities, work and information sharing arrangements, and facilitating technical support to countries. For example, while the WHO Prequalification (WHO PQ) prequalifies manufacturing sites of APIs and finished pharmaceutical products (FPP), and the products, the NMRAs still retain the right to give national authorizations for prequalified products. AMA will build on the AMRH work under NEPAD Agency and continue to galvanize political and partner support at continental level, resource mobilization and coordination of the harmonization activities in the regions. Moreover, the work at RECs is intended to be a stepping-stone to harmonize activities on the continent. In addition, AMA will provide regulatory guidance on specific problematic issues for which technical expertise and capacity is limited at national or regional level such as medical devices and diagnostics, e-commerce of pharmaceuticals, complex therapies such as vaccines, biologics and investigative innovative therapies for pandemics as well as African traditional medicines.

Figure 1 shows the conceptual framework for medicines regulation. This framework links the inputs, regulatory activities, outputs, outcomes and the goal or impact of medicines regulation in terms of public health. The input factors include human and financial resources, legislative framework, infrastructure and equipment as well as political will or support.

The regulatory activities are divided into activities that are primarily national level responsibility i.e., activities that cannot be delegated to third parties or rely on others. These activities represent the minimum level that all the countries should be able to perform notwithstanding other factors. The review of multi-country clinical trials, GxP inspections of external facilities e.g., GMP inspection of manufacturing facilities, GCP and GLP inspection of contract research organisations external to their jurisdictions, review of dossiers for dossiers for registration of medicines, laboratory testing of medicines, and registration of medicines in centralized procedures may be delegated or rely on third parties or shared through collaboration with other NMRAs, at REC or continental level.

[17] Mark Pearson, Jeremy Clarke, Laird Ward, Cheri Grace, Daniel Harris, Matthew Cooper. Evaluation of the International Finance Facility for Immunisation (IFFIm) June 2011

[18] This model of investments is also referred to as impact investments, which combines a return on investment with non-financial impacts

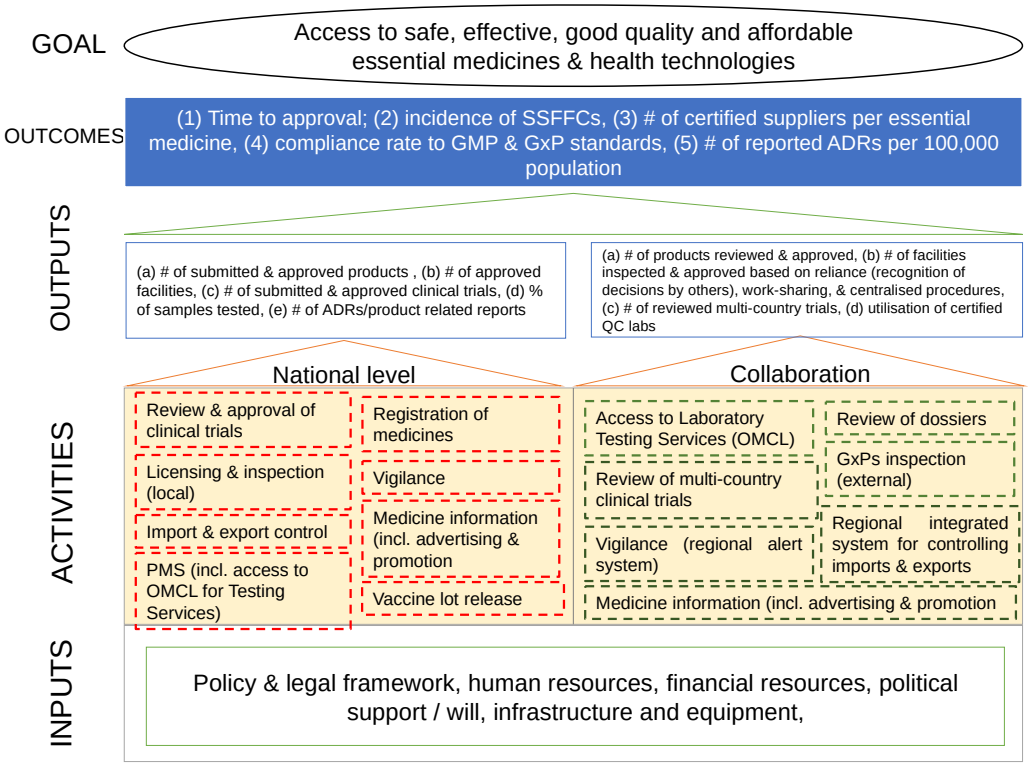


Figure 2: Conceptual framework for medicines regulation

Table 1: Level of coordination and implementation of regulatory activities at national, regional and continental level.

Regulatory function	**National Agency**	**Regional Agency**	**AMA**
Review of dossiers for complex molecules, as well as priority and emerging issues and pandemics.	X	X	X
Issuing Marketing Authorization for medical products	X	X[a]	NA
GMP Inspection of manufacturers	X	X[b]	X[c]
GCP of CROs	X	X[b]	X[c]
Inspection of supply chain (importers, wholesalers, retail facilities)	X	NA	NA
Vigilance (post marketing surveillance & pharmacovigilance)	X	X[d]	X[d]
Clinical trial regulation	X	X[e]	X[f]
Quality control	X	X[h]	X[h]
Medicine information	X	X	X

[a] Depending on the specific regional context, centralized registration may not be possible in some RECs. Moreover, the centralized registration will only be for selected products for which there are comparative advantage to have centralized registrations.

[b] Few national agencies have the resource capacity to perform GMP inspections, thus this function is ideal to be done at national and regional level, though the final approval is left to national authorities.

[c] GMP inspection of API manufacturers, biologics and vaccines as well as GCP inspections of CROs is almost none existing in African countries, therefore, this is ideal regulatory function to be coordinated and performed at regional and continental level, though the final approval is left to the national authorities.

[d] Regional and continental agency play a coordination role and facilitating information exchange at national, regional and continental level especially for SSFFCs.

[e] Review and / or coordination of regulatory guidance of multi-country clinical trial studies

[f] Regulatory guidance and / or coordination of regulatory guidance of clinical trials of investigative and innovative therapies (e.g. for pandemics such as EBOLA)

[n] Networking of quality control laboratories

Figure 3 shows the logic model for AMA. The model focus on pharmaceutical regulatory issues to resolve the identified problem of high disease burden and high mortality from preventable and curable diseases, partly due to inadequate health systems, scarce financial and human resources and unavailable and unaffordable medicines that are good quality, safe and efficacious.

Within this context, the following limiting factors are influential in AMA's success:

1) Language barriers – AU has at least six official languages Arabic, English, French, Portuguese, Spanish, and Kiswahili. In some cases, within the same RECs more than two official languages are recognized;
2) Creation of the African Common market and achievement of common markets in the RECs. AMA's activities are conducted within the context of regional and continental integration, thus progress in the creation of the common markets in the RECs and at continental level will have a bearing on AMA's progress.
3) Functionality of the Regional Centres Of Regulatory Excellence (RCORE) – utilisation of the established RCOREs to build regulatory capacity at NMRAs.
4) Other capacity building platforms supported by WHO and partners

5) Political and policy leadership at AU and RECs to support harmonization efforts
6) Sustainable financing mechanisms for AMA, RECs and NMRAs

The value addition of AMA is based on the assumptions that; NEPAD Agency, AUC, WHO, MS, partners, and stakeholders will continue to provide the required support for harmonization activities on the continent. In addition, that MS and RECs have the capacity to implement the recommendations/strategies within the given timeframes and that increasing the efficiency and effectiveness of regulation systems will promote local manufacturing and increase access to affordable, and acceptable medicines.

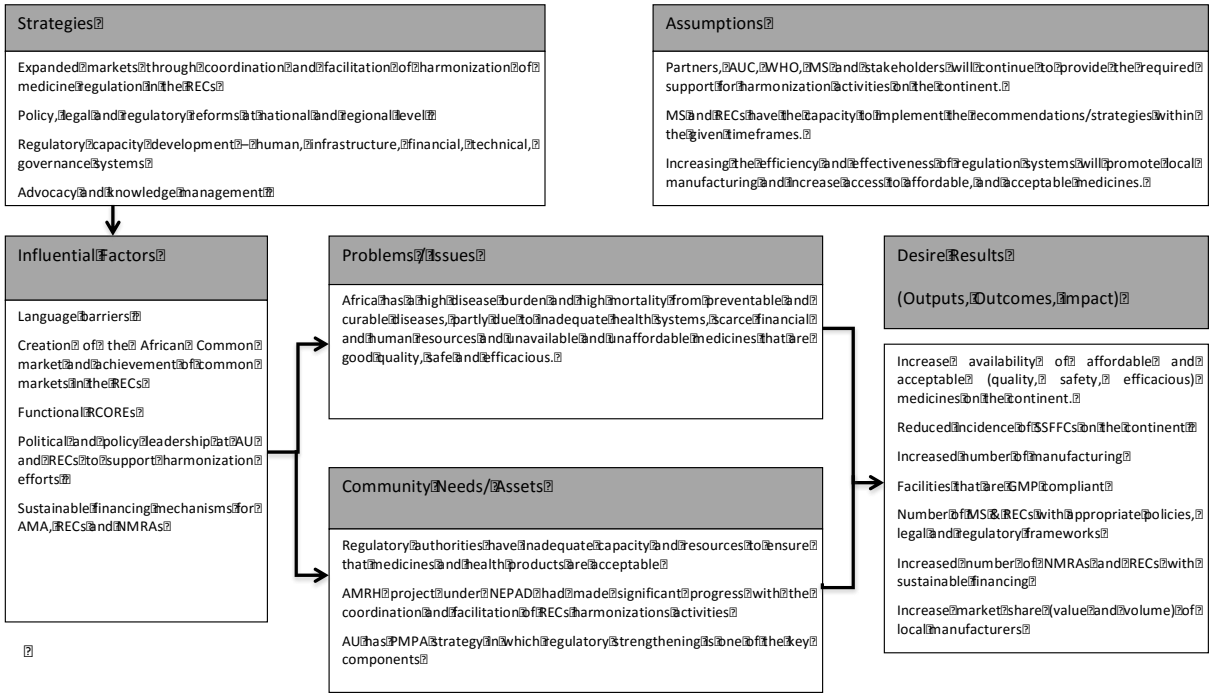


Figure 3: Logic Model for the African Medicines Agency

3 FUNCTIONS OF AMA

The AMA shall exercise the following functions:

a. Promote the formulation and harmonization of medical products regulatory policies, standards and scientific guidelines and coordinate existing regulatory harmonization efforts at the RECs and RHOs.
b. Provide regulatory guidance, scientific opinions and common framework for regulatory actions on complex molecules, as well as priority and emerging issues and pandemics.
c. Examine, discuss and/or express regulatory guidance on any regulatory matter within its mandate, either on its own initiative or at the request of the African Union, Regional Economic Communities, or Member States.
d. Provide guidance on regulation of traditional medicines.
e. Provide guidance on regulation of clinical trials on medical products and health technologies.
f. Designate, promote, strengthen, coordinate and monitor regional centres of regulatory excellence (RCOREs) with the view to develop the capacity of medical products regulatory professionals.
g. Promote International Cooperation and seek partnerships that will lead to effective mobilization of financial and technical resources to ensure sustainability.
h. Promote and advocate for the use of the AU Model Law on medical products regulation in member states and RECs to ensure regulatory and legal reforms at continental, regional and national levels.
i. Convene in collaboration with WHO, the African Medicines Regulators Conference (AMRC), and other meetings related to medical products regulation in Africa.

j. Collect, manage and disseminate relevant information and knowledge.
k. Develop systems to monitor, evaluate and assess the comprehensiveness of national medical products regulatory systems with the view to recommending interventions that will improve efficiency and effectiveness.
l. Mobilize expertise across the continent and beyond to provide scientific opinion in consultation with affected Member State NMRAs, in the event of a public health emergency affecting the continent with cross border or regional implications where new medical products are to be deployed for investigation and clinical trials.

Most African NMRAs have not prioritized the regulation of traditional medicines and do not have the capacity to review these products and the facilities where they are made. The First AUC/WHO Ministers meeting agreed that the scope of functions of AMA should be extended to cover the Traditional Medicine, as this was the first point of call for a large proportion of Africans.

3.1 Theory of Change

The theory of change model (Figure 4) tries to link the different outputs and outcomes to the desired goal (pathway of change) and how this would be achieved. The first level of intervention is advocacy especially at continental and regional level, partners and key stakeholders, resource mobilization, and coordination of RCOREs. It is anticipated that advocacy will increase the number of regional & national policies, legal frameworks & technical standards adopted. In addition, the RCOREs if effectively utilized, will increase the number of relevant experts (NMRAs, academia and industry) in all the key regulatory functions including the specialized areas. One of the key functions of AMA is to mobilize financial resources through innovative mechanisms such as social impact bonds, and endowment funds that will improve the mix of financing mechanisms not only for AMA, but also for the RECs and possibly NMRAs to ensure sustainability and massive scaling of regulatory interventions.

Through coordinating and facilitating regional harmonization activities and strengthening NMRAs as requested by MS, the number of RECs implementing medicines regulatory harmonization is expected to increase as well as the number of functional NMRAs in MS. On the back of strengthened institutional architecture at national and regional level, coupled with the delegated regulatory functions for AMA for specialized areas, this will increase the number of facilities and products that are approved through mutual recognition, work-sharing, & centralized procedures because of increased collaboration among NMRAs. Ultimately, these interventions will lead to increased number of suppliers for essential medical products[19] that drives competition and lowers medicines prices, at the same time improving product availability; increased number of facilities that are GMP compliant and reduced incidence of SSFFCs on the continent thereby ensuring that Africans have access to affordable, quality, safe and efficacious medicines and health product.

[19] Essential medical products are products that satisfy the healthcare needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford. WHO EML plus additional products would constitute these essential medical products.

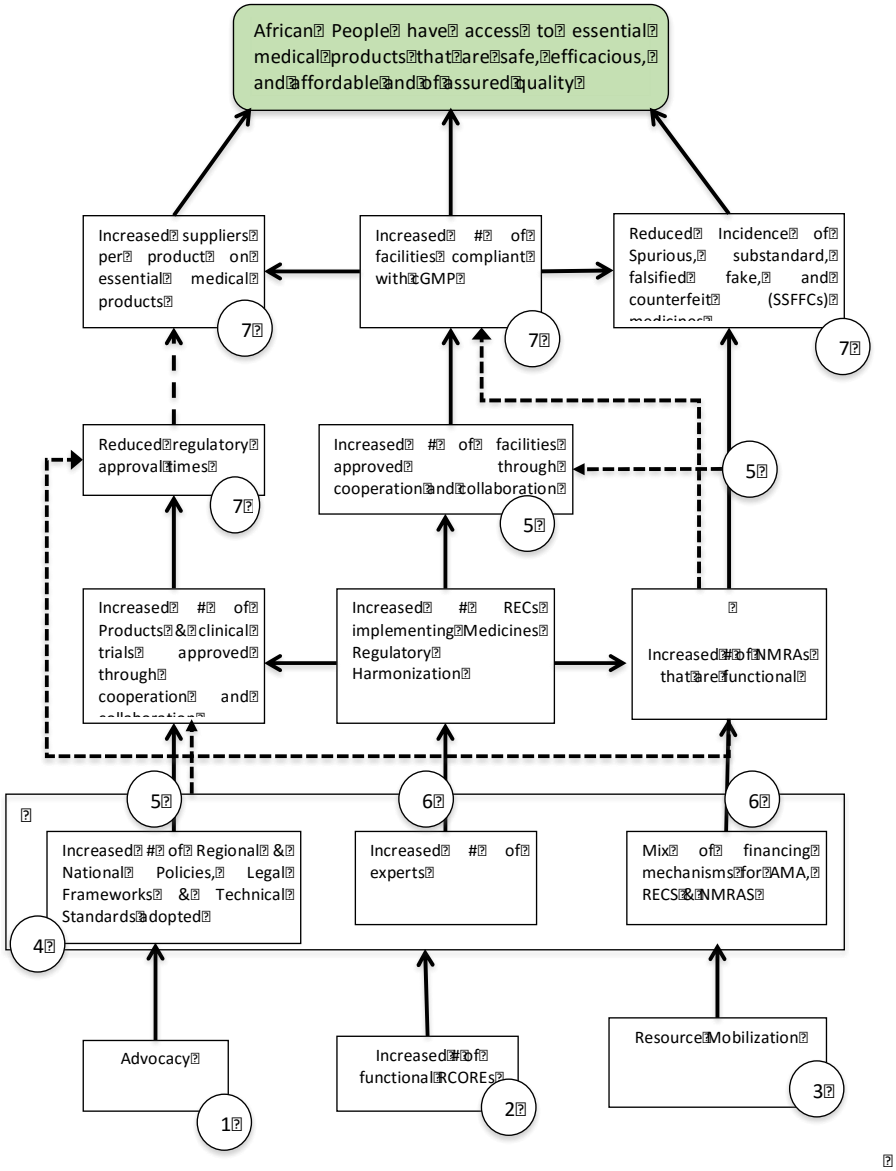


Figure 4: Theory of Change linking the interventions, outputs, outcomes and desired goal.

NB: The numbers represent the key activities to be performed by AMA

Key Activities in Figure 4

1. Advocacy to AUC, RECs, partners and stakeholders for the policy, regulatory and legal reforms at continental, regional and national levels.
2. Coordinate, designate and monitor the regional centres of regulatory excellence (RCOREs)
3. Governance, partnerships and resource mobilisation for regulatory activities including sustainable finance mechanisms at all levels
4. Custodian of the Model Law, development of policies, legal and technical standards in collaboration with WHO.
5. Regulatory guidance for AMA:
   - regulatory guidance and the continent's voice on emerging issues and pandemics particulaly with respect to investigational therapies
   - regulatory guidance on complex molecules (biotherapeutics, innovative new therapies, vaccines)

- coordination of GMP inspections of API manufacturing sites, complex molecules and priority products
- GCP of contract research organizations
- coordination and provision of regulatory guidance as required by RECs and Member States where capability at national or regional level is lacking, e.g. emerging issues such as regulation of e-commerce businesses

6. Coordinate and facilitate regional harmonization activities and strengthen NMRAs as requested by Member States, where applicable.
7. Establishment and maintance of accurate information and market intelligence on regulatory and pharmaceutical market (knowledge and information management).

The AMA's logical framework in presented as Annex 2 linking the outcomes, outputs, and activities to be performed by AMA.

3.2 Stakeholders Analysis

For AMA to achieve its mandate, the following target groups are identified: (1) policy and decision makers, (2) regulators, academia and pharmaceutical industry), (3) partners and social investors (4) and consumer, patient groups and civil society. Table 2 below shows analysis of these target groups including mapping common interests of the target Stakeholders and the Agency.

Table 2: Target Stakeholders Segment Analysis

Classification	Target group	Descriptions	Intervention	Interests
Category 1	Policy & decision makers	AU organs: Senior Officials at AUC, NEPAD Agency, PAP	Advocacy for policy, & legal reforms; financial resources	Competing priorities, a healthy continent, Minimizing costs, economic development,
		RECs	Advocacy for policy, legal and regulatory reforms	Regional integration; Economic development of the regions,
		National Government	Advocacy for policy, & legal reforms; financial resources	National economic development, Sovereignty, Getting re-elected (politicians), Healthy nation, Minimizing costs, Competing priorities
		Host country/institution	Impact investment	relevance, contribution, exposure, economic benefits
Category 2	Collaborators and implementing institutions	Regulators	Technical assistance – policy, legal and regulatory reforms, Capacity building, Collaboration / participation as experts, regulatory guidance	Relevance, Benefits, Efficiency and effectiveness, Managing costs, Reputation
		Pharmaceutical industry	Minimize the regulatory barriers,	Maximize returns to shareholders,

Classification	Target group	Descriptions	Intervention	Interests
			harmonization of requirements, market intelligence / information, regulatory guidance	Minimal regulatory barriers, Reputation,
		Academia	Capacity building (RCOREs), expertise in regulatory sciences, research	Relevance, Benefits, Contribution
Category 3	Technical Partners	WHO, NMRAs outside Africa, USP, UNIDO, UNDP, UNAIDS, UNFPA, EDCTP, MSH, etc.	Normative standards, technical cooperation, capacity building	Relevance, reputation, cooperation
Category 4	Partners and Social investors	African Development Bank, World Bank	Resource mobilization, impact investment,	Inclusive and sustainable economic growth, social development, poverty reduction, attainment of sustainable development goals, gender, regional economic integration, economic & political stability
		Bilateral, multi-lateral institutions and development partners	Resource mobilization, impact investment, Resource mobilization, impact investment,	Value for money, Specific programme areas, Impact, Developmental agendas, Relevance
Category 5	Civil Society	Patient and consumers groups, NGOs	Advocacy for reforms at continental, regional and national level	Relevance, Participation, accountability, health

4 LEGAL AND INSTITUTIONAL FRAMEWORK

AMA would be a specialized agency of the African Union like other organs such as Africa Center for Diseases Control (CDC). Further details on the legal and institutional framework are provided in the AMA Institutional & Legal Framework.

4.1 Hosting the African Medicines Agency

AMA is an offshoot of the AMRH Initiative. This is based on the 26th Ordinary Session of the AU Executive Council decision EX.CL/Dec.857(XXVI), which recognized the need to strengthen regulatory capacity and harmonization of regulation of medical products in Africa, and further emphasized the need for the African Medicines Regulatory Harmonization Programme to serve as a foundation for establishment of AMA within the context of PMPA.

In line with AU policies, the host Government shall at the initial stage, provide a secure, dedicated, equipped and furnished permanent structure at its expense, for the AMA to be its Headquarters, which shall be

exclusively occupied by the AMA and its personnel in accordance with the AU-Host Government Agreement. The furniture and equipment shall be in accordance with the specifications of the AU.

5. STRATEGIC ACTIVITIES

5.1 Operating Model

The proposed business model for AMA is one that produces both a social value and ensures sustainability.

Africa is the second most populous continent in the world, which is expected to continue to grow, accounting for 25% and 40% by 2050 and end of the century respectively. Thus, harnessing this potential economic market will require elimination of the fragmentation of the market for viable pharmaceutical manufacturing business on the continent. Therefore, accelerating harmonization activities and ensuring one common market is crucial for PMPA. To achieve these results would require significant investment in policy, regulatory and legal reforms at national level and regional level, strengthening of the capacity of national and regional regulatory systems and developing and mobilization of resources for sustainability. Table 3 below shows the proposed strategic themes, the target problems to be addressed, the value proposition, priorities and principal activities. AMA in collaboration with the regional agencies will focus on regulatory needs for which national authorities lack capacity such as innovative investigative therapies, GMP for other health products and APIs, and review of complex therapies among other activities. Regulatory authorities lack adequate funding as most are depended on government budgets or from fees for services or combination of both including some support from partners. It is becoming apparent that these financing models are not adequate to finance regulatory activities at the scale that is required to ensure access, and quality medicines. Moreover, the current MRH activities are 100% partner supported. Therefore, part of AMA's responsibility with respect to resource mobilization is to develop sustainable innovative funding mechanisms for regulatory activities. Further, Africa lacks adequate regulatory capacity, thus AMA is uniquely positioned to harness the available resources in the continent and facilitate collaboration that reduces duplication, and optimize the available regulatory capacity.

Table 3: Proposed Strategic Themes, Priorities and Principal Activities for AMA

Strategic Themes	**Problem (s)**	**Value Proposition**	**Priorities**	**Principal Activities**
Regional integration and harmonization	▪ Limited local pharmaceutical manufacturing ▪ Territorial jurisdictions ▪ Conflicting regulatory requirements ▪ Language barriers	Social and financial benefits	Towards a common market for pharmaceuticals at RECs	▪ Funded regional harmonization projects in all the RECs ▪ Documenting & promoting best practices
Policy, legal and regulatory reforms at national and regional level	▪ Inadequate medicines policies and legislations ▪ Conflicting regulatory requirements ▪ Territorial jurisdictions ▪ Weak governance and management structures	Social value	Legal reforms - Custodian of the Model Law	▪ Domestication and implementation of the AU Model Law, ▪ Technical assistance to MS on legal & regulatory reforms
Regulatory Capacity Development – human, infrastructure, financial, technical, governance systems	▪ Dependence on development partner funding ▪ Lack of adequate financial resources ▪ Limited local pharmaceutical manufacturing ▪ Lack of training opportunities in regulatory science, chemical and	Social value and financial benefits	▪ Facilitate capacity development ▪ Resource mobilization	▪ Coordinate, designate and monitor the regional centres of regulatory excellence (RCOREs) ▪ Facilitate twinning and exchange ▪ Guidance on complex or innovative therapies & continents voice on emerging issues and pandemics with respect to investigational therapies

	pharmaceutical manufacturing ▪ Weak governance and management structures			▪ Develop policies, guidance and standards ▪ GMP inspection of API site(s), biotech products, medical devices ▪ GCP inspections for CROs ▪ Developing sustainable financing models
Advocacy and knowledge management	▪ Low implementation rate of AU/REC decisions ▪ Priorities of policy and decision makers	Social value	▪ Strengthen the legal and regulatory framework for harmonization ▪ Resource mobilization	▪ Advocacy to AUC, RECs, partners and stakeholders for the policy, regulatory and legal reforms at continental, regional and national levels. ▪ Developing sustainable financing models. ▪ Information repository

5.2 Mapping of Key Players in Medical Product Regulation

Several players are involved in ensuring that medicines and other health products are accessible, affordable and of acceptable quality, safety and efficacious. Annex III shows mapping of the current key players in this field, areas of overlap and value proposition for AMA. Key players include the NMRAs, the RECs, WHO, UNFPA, USP and academic institutions. As noted earlier, NMRAs have the legal mandate at national level to perform regulatory functions. Therefore, AMA's role is more advisory to NMRAs and promoting best practices, standards, pooling of resources beyond MS level. AMA will use experts in the NMRAs on the continent and will not duplicate work done by NMRAs but play a supportive role and guidance on complex issues for which resources and expertise is unavailable at national level.

The work of AMA will leverage on creation of regional agencies within the identified RECs. The key function of AMA with respect to these regional entities is to coordinate and facilitate their establishment including resource mobilization, a function that is currently performed by AMRH under NEPAD Agency. Like the NMRAs, there is no duplication of the work done by RECs, but AMA plays a supportive role and guidance on complex issues such as innovative investigative therapies for pandemics, for which resources and expertise is unavailable at regional level.

Setting standards and norms and capacity building is WHO's area of expertise. WHO is already a partner in the AMRH programme, providing the technical expertise to the harmonization programme. AMA will continue to work with WHO in this regard facilitating domestication of WHO norms and standards at regional and national level. Likewise, with respect to capacity building, the concept of RCOREs is done within framework of AMRH programme in which WHO is a key partner. Prequalification systems such as WHO PQT for medicines, vaccines and diagnostics and UNFPA for condoms and devices are quality assurance systems that support procurement decisions of UN Agencies. With respect to WHO PQT, and UNFPA for prequalification of condoms / devices the role of AMA would be to complement these systems which are presently disease or therapeutic area focused, by focusing on coordinating harmonization at regional level to streamline regulatory processes.

Medicines regulatory science is a very specialized field, for which training capacity on the continent is very limited evidenced by the limited academic institutions that offer postgraduate regulatory science related training programmes. Moreover, AMA is focused on development of the regulatory science practitioner. The RCORE model promotes and utilize collaborative network and partnerships of regulatory institutions and academic institutions for capacity building activities.

5.3 Added Value

It is increasingly becoming evident that no single country, including well-resourced countries, can efficiently and effectively regulate its own market alone in this globalized market. Collaboration and cooperation is the option regardless of well-resourced or poorly resourced authorities or countries. Therefore, compared to having 54 different agencies and requirements, a single coordinating continental agency in collaboration with RECs and existing national authorities can deliver value for money, reduce the high cost of medicines, and streamline regulatory processes to enhance timely evaluation and registration of medicines and approval of clinical trials. Furthermore, speaking with one single voice has more weight compared to individual voices.

5.4 Marketing strategy

Table 4 below shows the segmented target market and strategies to reach these target groups. The identified targets including policy and decision makers, collaborators and implementing institutions and lastly partners and social investors. Depending on the target group, the marketing strategies include policy briefs, meetings / sensitization workshops, value proposition, electronic platforms, investment briefs and case studies.

Table 4: Marketing Strategies for each target group

Classification	Target group	Descriptions	Interests	Marketing Strategies
Category 1	Policy & decision makers	Senior Officials at AUC & its organs including NEPAD NPCA,	Competing priorities, a health continent, Minimizing costs, economic development,	Policy briefs, meetings/sensitization workshops
		Senior Officials at RECs	Regional integration, Economic development of the regions,	
		Senior Government Officials	National economic development, Sovereignty, getting re-elected (politicians), Health nation, minimizing costs, Competing priorities	
		Legislators	Getting re-elected, Relevance,	
Category 2	Collaborators and implementing institutions	Regulators	Relevance, Efficiency and effectiveness, Managing costs, Reputation	Value proposition, meetings/workshops, electronic platforms
		Pharmaceutical industry	Maximize returns to shareholders, Minimal regulatory barriers, Reputation,	Electronic platforms,
		Academia	Relevance, Participation	Electronic platforms
Category 3	Technical Partners	WHO, US FDA, EMA	Relevance and participations on normative standards, technical cooperation, capacity building	Policy briefs, meetings, workshops
Category 4	Partners and Social investors	African Development Bank,	Inclusive and sustainable economic growth, social development, poverty reduction, attainment of Millennium development goals, gender, regional economic integration,	Investment briefs, meetings, case studies
		Donors	Value for money, Specific programme areas, Impact	
		Multi-lateral institutions and development agencies	Developmental agendas, Value for money, Relevance, Impact	
		Civil Society	Relevance, Participation,	Policy briefs, sensitization workshops, electronic platforms
		Host country	Participation, relevance	Investment briefs, meetings, electronic platforms.

5.5 Milestones – Outputs & Outcomes

The long-term goal is to increase the availability of affordable, quality, safe and efficacious medical products including African traditional medicines on the continent. The Logical framework is presented as Annex II. Table 5 below shows a summary of the key milestones (outputs and outcomes).

Table 5: Milestones – Outputs and Outcomes

Strategic Themes	Principal Activities	Outputs	Outcomes
Regional integration and harmonization	▪ Funded regional harmonization projects in all the RECs ▪ Documenting & promoting best practices	▪ Increased # RECs implementing Medicines Regulatory Harmonization ▪ Increased # of Products & facilities approved through mutual recognition, work-sharing, & centralized procedures	▪ Increase market share (value and volume) of local manufacturers ▪ Reduced time to approval & responsiveness of NMRAs
Policy, legal and regulatory reforms at national and regional level	▪ Approval of the Model Law, ▪ Technical assistance to MS on legal & regulatory reforms	▪ Increased # of Regional & National Policies, Legal Frameworks & adopted	▪ Number of MS & RECs with appropriate policies, legal and regulatory frameworks
Regulatory Capacity Development – human, infrastructure, financial, technical, governance systems	▪ Coordinate, accredit and monitor the regional centres of regulatory excellence (RCOREs) ▪ Guidance on complex or innovative therapies & on emerging issues and pandemics with respect to investigational therapies ▪ Develop policies, guidance and standards ▪ GMP inspection of API site(s)	▪ Increased # of functional and utilized RCOREs ▪ Increasing # of Technical Standards adopted ▪ Increased # of regulatory experts ▪ Increased # of NMRAs that are fully capacitated and functional	▪ Reduced incidence of SSFFCs on the continent ▪ Increased number of manufacturing facilities that are cGMP compliant ▪ Reduced time to approval & responsiveness of NMRAs
Advocacy and knowledge management	▪ Advocacy to AUC, RECs, partners and stakeholders for the policy, regulatory and legal reforms at continental, regional and national levels. ▪ Developing sustainable financing models. ▪ Information repository	▪ Information repository established and accessible ▪ Amount of funds raised through resource mobilisation	▪ Number of MS & RECs with appropriate policies, legal and regulatory frameworks ▪ Proportion of the budget funded from sustainable funding mechanisms

6 FINANCIAL PLAN

The global development sector is shifting from donor driven models to sustainability and impact investments[20]. For sustainability, developing a business model for the AMA as a continental agency that reduces dependence on donations, grants and subsidies would be essential. This integrated hybrid model produces both social value and position the continental agency to tap into the growing sector of impact investments which is expected to reach at least $500 billion USD within the next decade.

6.1 Diversified Multiple sources of funding

The AU Heads of State and Government recently decided to implement the decision of the Assembly (Assembly/AU/Dec. 561(XXIV)) on Alternative Sources of Funding where Member States enhance ownership of the budget of the Union by financing 100% of the Operating budget, 75% of Programs and 25% of Peace and Security Budget effective January 2016 to be phased incrementally over a five-year period. Further, the Assembly adopted a new AU scale of assessment, which constitutes a hybrid of pure capacity to pay for some Member States and equal payment scales for others in accordance with the percentage of the budget under each tier. On this key milestone decision, AMA as an AU organ is expected to follow multiple funding mechanisms to ensure ownership and sustainability. The financial mechanisms are (1) annual assessed contribution to be paid by the Members, (2) grants and donations, and (3) innovative financing mechanisms such as endowment fund and use of social impact bonds. It is expected that contribution from the innovative resource mobilization will reach 25% of the annual program costs by 2022 and Member States (Parties) contribution will reach 100% of the operating costs by 2022.

6.1.1 Annual assessed contributions

Member States will provide contributions to the operating budget. Presently, the AMRH activities are largely funded by partners. Therefore, by the end of five-year period, it is expected that like other AU institutions, 100% of the operating budget will be funded from Member States. The total operating costs over the five-year period is US$ 9,56m. The initial annual operating budget for 2018 is US $ 1.73m. The contribution from Member States is expected to increase from zero in 2018 to 100% of the annual operating budget (US$ 2,10m) by 2022.

6.1.2 Grants and donations

As noted before, partners are largely funding the AMRH activities. It is expected that by adopting other funding mechanisms, the proportion of direct contribution from partners could be reduced over time to ensure sustainability. Presently, most AU institutions programmes are largely funded by partners. It is proposed that proportion of funding from partners could decrease from 100% to 75% of programme budget by year five, and 100% of the operating budget assumed by the MS. It is anticipated that a target of US$10.65m will be mobilized from partners for the five-year period.

6.1.3 Innovative financing mechanism

One of the key functions of AMRH is to mobilize financial resources to support harmonization activities on the continent. As such, AMA as successor of AMRH should develop innovative financial mechanisms to complement the direct support from partners. Two strategies will be pursued:

Social Impact Bonds (SIBs)

[20] "Impact investments are investments made into companies, organizations, and funds with the intention to generate a measurable, beneficial social and environmental impact alongside a financial return. Impact investments can be made in both emerging and developed markets, and target a range of returns from below-market to above-market rates, depending upon the circumstances." Global Impact Investing Network (GIIN)

Social Impact Bonds (SIBs) as evidence by the IFFIm Bond for immunization, for which the World Bank is the Treasury Manager, have the potential to unlock a new and vast pool of investment capital to finance the expansion of effective, preventive social services focusing on measurable outcomes and generating social and financial returns to investors. The SIBs have potential to raise funds from capital markets based on commitments from partners and MS. Using this innovative financing mechanism, the following benefits are envisaged:

1) The investor may earn an acceptable rate of capital return;
2) AMA and regional harmonization activities are financed using new, sustainable capital which enables scale-up of these interventions;
3) The partners enjoy a cost-saving (with no up-front investment);
4) Financial risk is transferred to the private investor, therefore, partners will only pay for the demonstrated results; and
5) The "underlying" social-issue of lack of access to affordable quality assured medicines and health products is improved.

Therefore, the Social Impact Bond uniquely links the monetary return on the financial product with its social delivery. In addition to the partners, the MS should also provide commitments to support the SIB. For example, South Africa is the only African country that is part of the nine IFFIm sponsors with a USD 20 million commitment. Therefore, African countries, and private sector will invest in such SIBs to fund regulatory strengthening activities on the continent to complement donor support.

Endowment Fund

Creation of an endowment fund that will ensure AMA's independence and sustainability is proposed as a second funding strategy. Notably, creation of a collection fund that will evolve to an endowment fund is one of the funding mechanisms for The African Network for Drugs and Diagnostics Innovation (ANDi)[21] to ensure sustainability and independence of ANDi.

These two strategies will be created within the first two-years and expected to contribute 12.5% and 25% of programme costs in 2021 and 2022 respectively. Total contribution over the five-year period is US$0.54m.

The hybrid financial model for the African Medicines Agency is developed with a sustainability business model in mind. First, the hybrid model will enable the Agency to carefully select innovative interventions that have the greatest measurable impact on public health of Africans. Second, the model will ensure that from its launch, AMA has diversified funding model that will ensure sustainability by not depending on one funding stream either revenue from fees, AU budget allocation, Member States contributions, partner support or impact investments[22].

6.1.5 Measurable outcomes

To convince Member States, partners, and to venture into raising capital from capital markets for social development programmes, there is need to clearly identify measurable social outcomes for the proposed interventions that leads to the desired results of access to affordable, quality, safe and efficacious medicines for Africans.

[21] WHO-TDR, Strategic and business plan for the African Network for Drugs and Diagnostics Innovation (ANDI), 2009.

[22] "Impact investments are investments made into companies, organizations, and funds with the intention to generate a measurable, beneficial social and environmental impact alongside a financial return. Impact investments can be made in both emerging and developed markets, and target a range of returns from below-market to above-market rates, depending upon the circumstances." *Global Impact Investing Network (GIIN)*

6.2 Start-up funding requirements & budget

In line with AU policies, the host Government shall at the initial stage, provide a secure, dedicated, equipped and furnished permanent structure at its expense, for the AMA to be its Headquarters, which shall be exclusively occupied by the AMA and its personnel in accordance with the AU-Host Government Agreement. The furniture and equipment shall be in accordance with the specifications of the AU. The costs for furniture and equipment have not been included in the budget.

6.3 Sustainable funding mechanism

The targets on diversified funding by the end of five-year period are as follows:

- MS direct contributions to reach 100% of operating budget;
- Direct contributions from partners reduced from 100% to 75% of programme budget; and
- Programme funding from innovative funding mechanisms (SIBs and endowment fund) to reach 25%.

6.4 Resource mobilization strategy

NEPAD Agency will take the lead on resource mobilization in the initial phase for establishing AMA. By creating a variety of funding mechanisms (e.g. SIBs, endowment) will tap into new potential partners in addition to the traditional donor supporters. The AMA will target MS for direct contributions to the operating budget in line with AU's decisions as well as commitments to the SIB and endowment fund. Additionally, traditional donors or partners will be targeted for continued direct contributions to the programme budget, at the same time imploring them to consider the alternative sustainable funding mechanisms. The African Development Bank, World Bank and other international institutions could be targeted for the development of the bonds and endowment funds. These institutions, already have experience with such funding mechanisms. Investors would be given an opportunity to invest for both social impact and financial return. With the advent of crowd funding, companies, individuals or foundations could be targeted as new funding options for social cause.

6.5 Funding Forecast requirements

Table 6: AMA Five-Year (2018-2022) Activity Budget

Strategic Themes	Priorities	Principal Activities	Target	Budget	R
Regional integration and harmonization	▪ Towards a common market for pharmaceuticals at RECs	▪ Funded regional harmonization projects in all the RECs ▪ Documenting & promoting best practices	▪ Increased # RECs implementing Medicines Regulatory Harmonization ▪ Increased # of Products & facilities approved through mutual recognition, work-sharing, & centralized procedures	$2,021,198.55	▪ ▪ ▪ ▪
Policy, legal and regulatory reforms at national and regional level	▪ Legal reforms - Custodian of the Model Law; domestication of AU Model Law	▪ Approval of the Model Law, ▪ Technical assistance to MS on legal & regulatory reforms	▪ Increased # of Regional & National Policies, Legal Frameworks & adopted	$1,287,472.08	▪ ▪

Regulatory Capacity Development – human, infrastructure, financial, technical, governance systems	▪ Facilitate capacity building of regulatory authorities ▪ Resource mobilization	▪ Coordinate, accredit and monitor the regional centres of regulatory excellence (RCOREs) ▪ Facilitate twinning and exchange ▪ Guidance on complex or innovative therapies & continents voice on emerging issues and pandemics with respect to investigational therapies ▪ Develop policies, guidance and standards ▪ GMP inspection of API site(s), biotech products, medical devices ▪ Developing sustainable financing models.	▪ Increased # of functional and utilized RCOREs ▪ Increasing # of Technical Standards adopted ▪ Increased # of regulatory experts ▪ Increased # of NMRAs that are fully capacitated and functional ▪ Increased number of manufacturing facilities that are cGMP compliant ▪ Number of scientific opinions issued	$1,214,948.17	▪ ▪ ▪ ▪ ▪ ▪
Advocacy and knowledge management	▪ Strengthen the legal and regulatory framework for harmonization ▪ Resource mobilization	▪ Advocacy to AUC, RECs, partners and stakeholders for the policy, regulatory and legal reforms at continental, regional and national levels. ▪ Developing sustainable financing models. ▪ Information repository	▪ Information repository established and accessible ▪ Amount of funds raised through resource mobilisation	$2,113,553.95	▪ ▪
Operating budget for AMA		▪	▪	$9,561,552.32	▪
TOTAL				**$16,198,725.07**	

Table 7 and

Table 7 is the funding forecast for AMA's activities from for the first five years of operation. This is based on the proposed activities of AMA in the business plan.

Table 6: AMA Five-Year (2018-2022) Activity Budget

Strategic Themes	Priorities	Principal Activities	Target	Budget	Result
Regional integration and harmonization	▪ Towards a common market for pharmaceuticals at RECs	▪ Funded regional harmonization projects in all the RECs ▪ Documenting & promoting best practices	▪ Increased # RECs implementing Medicines Regulatory Harmonization ▪ Increased # of Products & facilities approved through mutual recognition, work-sharing, & centralized procedures	$2,021,198.55	▪ 5 RECs implementing AMRH framework ▪ At least 2 regional medicines agencies established ▪ # of countries participating in joint reviews and GMP inspections ▪ Mutual recognition procedures implemented in 3 RECs and Member States
Policy, legal and regulatory reforms at national and regional level	▪ Legal reforms - Custodian of the Model Law; domestication of AU Model Law	▪ Approval of the Model Law, ▪ Technical assistance to MS on legal & regulatory reforms	▪ Increased # of Regional & National Policies, Legal Frameworks & adopted	$1,287,472.08	▪ 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
Regulatory Capacity Development – human, infrastructure, financial, technical, governance systems	▪ Facilitate capacity building of regulatory authorities ▪ Resource mobilization	▪ Coordinate, accredit and monitor the regional centres of regulatory excellence (RCOREs) ▪ Facilitate twinning and exchange ▪ Guidance on complex or innovative therapies	▪ Increased # of functional and utilized RCOREs ▪ Increasing # of Technical Standards adopted ▪ Increased # of regulatory experts	$1,214,948.17	▪ 80% of pharmaceutical manufacturers complying with regional and continental GMP certification schemes ▪ 50% of regional harmonized guidelines endorsed by the REC Policy Organs ▪ 50% of countries implementing regional harmonized guidelines

		& continents voice on emerging issues and pandemics with respect to investigational therapies ▪ Develop policies, guidance and standards ▪ GMP inspection of API site(s), biotech products, medical devices ▪ Developing sustainable financing models.	▪ Increased # of NMRAs that are fully capacitated and functional ▪ Increased number of manufacturing facilities that are cGMP compliant ▪ Number of scientific opinions issued		▪ Agreed framework for benchmarking NMRAs in Africa ▪ 50% African NMRAs meeting internationally acceptable standards of Good Regulatory Practice ▪ RCOREs adopted harmonized regulatory science curricula ▪ 20% increase in regulatory workforce in Africa
Advocacy and knowledge management	▪ Strengthen the legal and regulatory framework for harmonizatio n ▪ Resource mobilization	▪ Advocacy to AUC, RECs, partners and stakeholders for the policy, regulatory and legal reforms at continental, regional and national levels. ▪ Developing sustainable financing models. ▪ Information repository	▪ Information repository established and accessible ▪ Amount of funds raised through resource mobilisation	$2,113,553.95	▪ Information repository established and accessible ▪ Programme funding from innovative funding mechanisms (SIBs and endowment fund) to reach 25%.
Operating budget for AMA		▪	▪	$9,561,552.32	▪ 100% of operating budget funded by AU
TOTAL				**$16,198,725.07**	

Table 7 : AMA Financial Forecast 2018-2022

	2018	2019	2020	2021	2022	TOTAL
INCOME						
African Union	-	454.230,00	953.883,00	1.502.365,73	2.103.312,02	**5.013.790,74**
Development Partners (direct contributions)	2.931.561,00	2.623.909,05	2.278.163,00	1.717.470,83	1.095.014,03	**10.646.117,91**
Voluntary contributions from Member States						**-**
Investment Income	-	-	-	173.811,75	365.004,68	**538.816,43**
Other						**-**
TOTAL INCOME	**2.931.561,00**	**3.078.139,05**	**3.232.046,00**	**3.393.648,30**	**3.563.330,72**	**16.198.725,07**
EXPENDITURE						
Operational Costs						
Employment Costs	1.081.500,00	1.135.575,00	1.192.353,75	1.251.971,44	1.314.570,01	**5.975.970,20**
Consultancy Services	100.000,00	105.000,00	110.250,00	115.762,50	121.550,63	**552.563,13**
Travel & Subsistence (Staff)	352.800,00	370.440,00	388.962,00	408.410,10	428.830,61	**1.949.442,71**
Travel & Subsistence (Board members)	72.000,00	75.600,00	79.380,00	83.349,00	87.516,45	**397.845,45**
Meeting Costs (Board)	44.100,00	46.305,00	48.620,25	51.051,26	53.603,83	**243.680,34**
Admin & Office expenses (stationary, technology, printing)	80.000,00	84.000,00	88.200,00	92.610,00	97.240,50	**442.050,50**
Total Operating Expenses	**1.730.400,00**	**1.816.920,00**	**1.907.766,00**	**2.003.154,30**	**2.103.312,02**	**9.561.552,32**
Programme Expenses						

Regional harmonization	365.786,00	384.075,30	403.279,07	423.443,02	444.615,17	**2.021.198,55**
Policy, legal and regulatory reforms	233.000,00	244.650,00	256.882,50	269.726,63	283.212,96	**1.287.472,08**
Regulatory capacity development	219.875,00	230.868,75	242.412,19	254.532,80	267.259,44	**1.214.948,17**
Advocacy & knowledge management	382.500,00	401.625,00	421.706,25	442.791,56	464.931,14	**2.113.553,95**
Total Programme Costs	**1.201.161,00**	**1.261.219,05**	**1.324.280,00**	**1.390.494,00**	**1.460.018,70**	**6.637.172,76**
TOTAL EXPENDITURE	**2.931.561,00**	**3.078.139,05**	**3.232.046,00**	**3.393.648,30**	**3.563.330,72**	**16.198.725,07**

7 MANAGERIAL, TECHNICAL AND ADMINISTRATIVE REQUIREMENTS

AMA should be structured in such a way as to maintain a lean staff and utilize a combination of internal staff and experts in the MS NMRAs. Similar approaches have been used elsewhere such as EMA. Notably, in the survey there was virtually no support for AMA to rely entirely on its own internal staff or to use only outside experts for its functions.

7.1 Managerial requirements

The structure of AMA is to ensure it operates as independently (with respect to managing conflict of interest) as possible so that it can set its own oversight strategy, and make decisions with respect to budgets, talent hiring, retention and development. While credibility before partners and investors is important, this should be balanced by ensuring it operates in the least bureaucratic environment as possible. The governance structure includes MS through the African Union, Board with strong African government and technical representation, and key stakeholders, and Secretariat lead by the Director of the institution. The Board will be responsible for the strategic oversight and direction of AMA, financial performance and account to the Member States through the AUC. The Secretariat is responsible for the operational performance and implementation of the strategy or business plan.

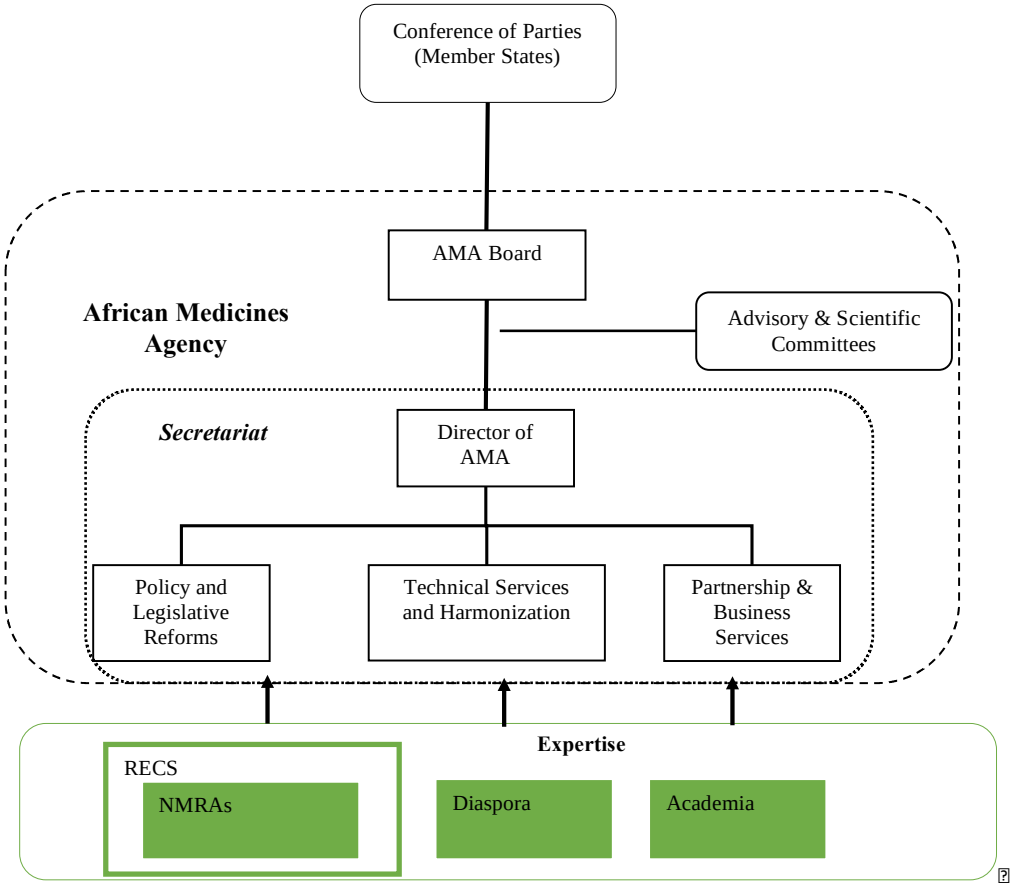


Figure 5: Proposed Structure of African Medicines Agency

7.2 Technical Requirements

The structure for AMA will be small and lean as it utilizes the experts within the RECs and NMRAs**Error! eference source not found.**. Thus, the role of key staff will be coordination of the AMA's activities. The Director General of AMA will be supported by a Partnership and Business Support team, Technical Services and

Harmonization team and a Policy and Legislative Reforms team. At most the team at AMA will be 10 or less and will work in collaboration with the established regional agencies.

7.3 Scheduling tasks and responsibilities

The role of the Secretariat will be coordination and facilitation of medicines regulatory activities and harmonization. The experts for any given activities will be drawn from the Member States.

8. ROAD MAP FOR ACHIEVING OBJECTIVES 2016 – 2022

Roadmap of activities for AMA Task Team are already developed leading to the official launch of AMA in 2018. In summary, the work of the Task Team is to develop the appropriate legal framework, and business plan for AMA include advocacy and regional consultations leading to review by the Health Ministers and finally approval by the Heads of States and Governments in 2018. In addition to the Task team activities, Table 8 lists the activities to be done in preparation for the launch of AMA.

Table 8: Road Map for establishment & operationalization of AMA 2016 – 2022

Phase	Activities	Year	Output indicators
1. Preparatory phase 2015– 2018	1.1 Development of the legal framework and business plan including consultations	2016	Legal framework and business plan for AMA available
	1.2 Advocacy & communication strategy	2016	Advocacy and communication strategy on AMA in place
	1.3 Facilitating the hosting arrangements	2017	Host country for AMA identified
	1.4 Groundwork for the formation of the Board	2017	Terms of reference and composition of the Board in place
	1.5 Governance structure and process for identifying the Head of AMA	2017	Governance structure and terms of reference for the Head available
	1.6 Legal agreements on endowment fund and / or social impact bonds. Thus AMA could prepare MS on how to handle the transitional phase	2017	Funding Model finalized (endowment fund & social impact bond framework/agreements)
2. Approval	2.1 Approval by AU Heads of State and Government	2018	AMA approved by AU and launched
3. Initial operationalization phase 2018 – 2020	3.1 Transitioning of the AMRH under NEPAD Agency into AMA	2018	Transition of AMRH into AMA completed by 2020
	3.2 Endowment fund establishment, and or issue of the social impact bonds	2019	First issue of social impact bonds and / or endowment fund established

4. Future perspective 2020 and beyond	4.1 Full implementation of activities under AMA	2020	AMA fully established and full implementation of activities.

9. MONITORING AND EVALUATION FRAMEWORK

Annex II is the Log Frame that will form the main Monitoring & Evaluation (M & E) tool, which is guided by the principles of Results – based Management (RBM) and by the AUC Policies on Monitoring and Evaluation. The objectives of the monitoring and evaluation mechanism of the Business Plan are to:

- Ensure that the outputs and outcomes are achieved as planned.
- Provide regular information to all stakeholders on progress that would, among others, inform the basis for any reviews.

9.1 Output monitoring

In line with the Logical Framework of the Business Plan, AMA will put in place the following measures to ensure implementation of the planned activities and delivery of the outputs:

1. Set baselines and targets on access to affordable, quality, safe, efficacious medicines;
2. Develop relevant M&E tools and templates (such as M&E plan at continental, regional level & national level, standard progress report) that will guide the collection, analysis, dissemination and utilization of data on key indicators and targets;
3. Conduct periodic review meetings of relevant stakeholders to assess progress; and
4. Produce standard progress reports one a year. This will be specifically produced by the AMA's Board and submitted annually to the AU Ministers of Health and made public.

9.2 Outcome and Impact evaluation

The Board will facilitate an external mid-term review, and an end-term evaluation, of the business plan. In line with accounting standards, AMA will be required to produce audited financial reports annually. The external reviews will provide feedback on the efficiency, effectiveness and relevance of the Business plan in achieving the intended objectives. The report of findings and recommendations of the mid-term review will be used to modify outputs as may be necessary. The outcome of the end-term evaluation will be used to design and inform plans and strategies.

10. RISK MANAGEMENT

New business and financial model for AMA – faces challenges at continental level where programme activities are dependent on donors or grants. Advocacy is required and social marketing. However, this approach is not new for medicines agencies as most perform a social obligation but rely on fees or adopt a hybrid model of fees, subventions from governments and donors.

REFERENCES

A Cameron, M Ewen, D Ross-Degnan, D Ball, and R Laing. Medicines prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. Lancet 2009; 373: 240-49. DOI:10.1016/S0140-6736(08)61762-6

Africa Economic Outlook 2014 published by African Development Bank, Organisation for Economic Co-operation and Development, United Nations Development Programme (2014).

African Pharmaceutical Manufacturing Plan for Africa, 2005

African Union Executive Council, Eleventh Ordinary Council 25 – 29 June, 2007 Accra, Ghana EX.CL/Dec.348 – 377(XI)

African Union Executive Council, Twenty-Sixth Ordinary Session, 23 – 27 January 2015 Addis Ababa, Ethiopia EX.CL/Dec.851-872 (XXVI)

African Union Summit, Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases, Abuja, Nigeria 24 – 27 April 2001 African Union Conference of Ministers of health. Africa Health Strategy 2007 – 2015, Third Session, Johannesburg, South Africa, 9 – 13 April 2007

African Union. Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa, January 2012 http://www.au.int/en/sites/default/files/Shared_Res_Roadmap_Rev_F%5B1%5D.pdf (last accessed 19 August 2015)

Akuse RM et al. Diagnosing renal failure due to diethylene glycol in children in a resource-constrained setting. Pediatric Nephrology. 2012 ;27(6) :1021–1028. ;

Alexandra Cameron, Margaret Ewen, Martin Auton and Dele Abegunde. Medicines Prices, Availability and Affordability *in* The World Medicines Situation 2011. World Health Organization (WHO) http://apps.who.int/medicinedocs/documents/s18065en/s18065en.pdf (last accessed 20 October 2015)

Betty R. Kuhnert, ICH at 20 an Overview. April 2011, Vol 3 Issue 2 Global Forum

Stuart D. Blacksell, et al Evaluation of Six Commercial Point-of-Care Tests for Diagnosis of Acute Dengue Infections: The Need for Combining NS1 Antigen and IgM/IgG Antibody Detection to Achieve Acceptable Levels of Accuracy. Clin Vaccine Immunol. 2011 Dec; 18(12): 2095–2101. Doi: 10.1128/CVI.05285-11

Caroline Nutley. The Value Benefits of ICH to Industry, IFPMA 2000

Colin D Mathers & Dejan Loncar. Projections of Global Mortality and Burden of Disease from 2002-2030. PloS Medicine Nov 2006, Vol. 3, Issue 11

Constitutive Act of the African Union, Adopted by the Thirty-Sixth Ordinary Session of the Assembly of Heads of State and Government 11 July, 2000 – Lome, Togo

El-Jardali F, Akl EA, Fadlallah R, et al. Interventions to combat or prevent drug counterfeiting: a systematic review. BMJ Open 2015; 5: e006290. Doi:10.1136/bmjopen-2014- 006290

European Medicines Agency, International Generic Drug Regulators Programme (IGDRP) Information Sharing Pilot: Information packet January 2015

First meeting of African Ministers of Health jointly convened by the AUC and WHO Luanda, Angola, 16–17 April, 2014

Gaurvika M L Nayyar, Joel G Breman, Paul N Newton, and James Herrington. Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa. Lancet Infect Dis 2012; 12: 488–96

http://apps.who.int/prequal/ (last accessed 21 October 2015)

http://www.au.int/en/about/nutshell (Last accessed 19 August 2015)

http://www.who.int/mediacentre/factsheets/fs355/en/ (last accessed 19 August 2015)

Kreher, Alexander. Agencies in the European Community – A Step Towards Administrative Integration in Europe. Journal of European Public Policy, 1997, 4, 2, 225-245. http://hdl.handle.net/1814/17044

Kyriacos S, Mroueh M, Chahine RP, Khouzam O. Quality of amoxicillin formulations in some Arab countries. Journal of Clinical Pharmacy and Therapeutics. 2008 ;33(4) :375–379.

Marcella Mori, Raffaella Ravinetto and Jan Jacobs. Quality of medical devices and in vitro diagnostics in resource-limited settings. Tropical Medicine and International, volume 16 no 11 pp 1439–1449 November 2011 http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3156.2011.02852.x/pdf

Mark Pearson, Jeremy Clarke, Laird Ward, Cheri Grace, Daniel Harris, Matthew Cooper. Evaluation of the International Finance Facility for Immunisation (IFFIm) June 2011

Chaccour, C., et al. Travel and fake artesunate : a risky business. Lancet 2012 ; 380 :1120. Sep 22, 2012.

NEPAD Agency, Situational Analysis study on Medicines Registration Harmonization in Africa: Final Report for the Southern African Development Community (SADC), November 2010

PMPA Business Plan, 2012

Southern African Development Community (SADC), November 2010 Nirmalya Syam. Transition Period for Trips Implementation for LDCs: Implications for Local Production of Medicines in the East African Community. Research paper 59, South Centre. December 2014

Stanton C, Koski A, Cofie P, Mirzabagi E, Grady BL, Brooke S. Uterotonic drug quality : An assessment of the potency of injectable uterotonic drugs purchased by simulated clients in three districts in Ghana. BMJ Open. 2012 ;2(3) :1–7

Tania Holt, Mehdi Lahrichi, Jean Mina and Jorge Santos da Silva. Insights into Pharmaceuticals and Medical Products. Africa: A Continent of Opportunity for Pharma and Patients McKinsey & Company. April 2015

Tenu Avafia (PhD Thesis). Public Health Related Trips Flexibilities and South-South Co-Operation as Enablers of Treatment Access in Eastern and Southern Africa: Perspectives from Producing and Importing Countries, Centre for Commercial Law Studies, Queen Mary, University of London. February 2015 https://qmro.qmul.ac.uk/jspui/bitstream/123456789/8945/1/Avafia_Tenu_PhD_030815.pdf (last accessed 23 October 2015)

The African Union Assembly Decision No: Assembly/AU/Dec 413 (XVIII): Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa, July 2012

The African Union, Third Session of The AU Conference of Ministers of Health, Johannesburg, South Africa, 9 – 13 April, 2007

Treaty Establishing the African Economic Community (Abuja Treaty) Abuja, Nigeria 3 June 1991. http://www.au.int/en/sites/default/files/TREATY_ESTABLISHING_THE_AFRICAN_ECONOMIC_COMMUNITY.pdf (last accessed 19 August 2015)

UNAIDS & African Union Commission. Abuja +12 Shaping the future of health in Africa, 2013.

UNAIDS China and WHO China. Promoting Access, quality and Technology Transfer between Africa and China. November 2014

UNAIDS. Access to Antiretroviral Therapy in Africa: Status Report on Progress Towards the 2015 Targets. http://www.unaids.org/sites/default/files/media_asset/20131219_AccessARTAfricaStatusReportProgresstowards2015Targets_en_0.pdf (last accessed 20 October 2015)

UNICEF Levels & Trends in Child Mortality Report 2014 Estimates Developed by the UN Inter-Agency Group for Child Mortality Estimation

UNICEF, Generation 2030, Africa 2014

United Nations Human Rights Council, 23rd Regular Session (A/HRC/23/2) 27 May – 14 June 2013, Agenda Item 3, Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health Available from http://www.ohchr.org/EN/HRBodies/HRC/RegularSessions/Session23/Pages/ResDecStat.aspx

United Nations, Department of Economic and Social Affairs, Population Division, World Population Prospects: The 2012 Revision, United Nations, New York, 2013.

WHO List of Prequalified Quality Control Laboratories, Version: 36th Edition, 15/05/2015 http://apps.who.int/prequal/lists/PQ_QCLabsList.pdf accessed 27 June 2015

WHO Regional Committee for Africa, Sixtieth Session: Report of the Regional Task Force on the Prevention and Control of Substandard/Spurious/Falsely labelled/Falsified/Counterfeit Medical Products in the Africa Region. Malabo, Equatorial Guinea 30 August–3 September 2010

WHO Regional Committee for Africa, Sixty-third session Agenda item 11: Strengthening The Capacity for Regulation of Medical Products in The African Region Brazzaville, Republic of Congo, 2–6 September 2013

WHO-TDR, Strategic and business plan for the African Network for Drugs and Diagnostics Innovation (ANDI), 2009.

WHO. The World Medicines Situation 2011. 3rd Edition. http://www.who.int/medicines/areas/policy/world_medicines_situation/en/ (accessed October 2015)

World Bank estimates 2014 http://data.worldbank.org/ accessed 7 August 2015

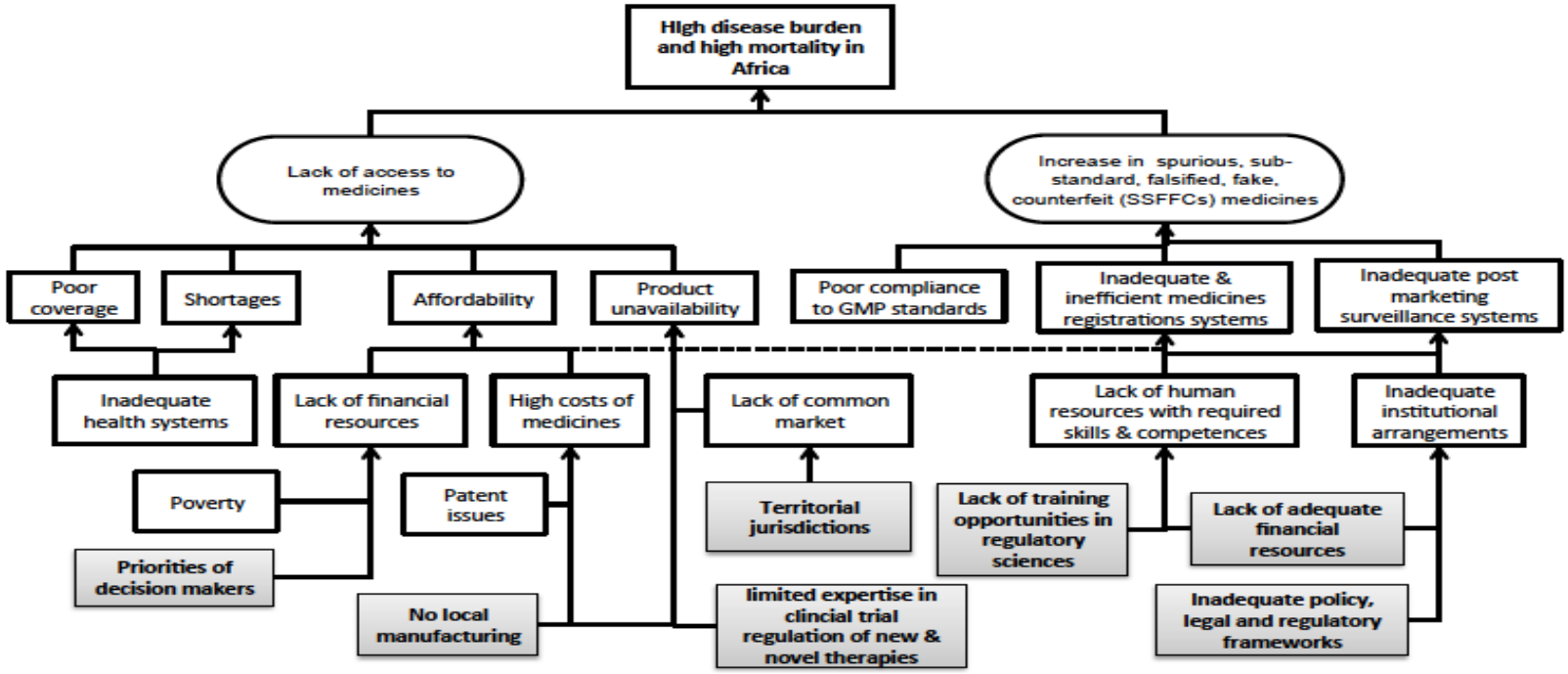
World Health Organization. "Collaborative Registration". Accessed 10, August 2015. http://apps.who.int/prequal/

World Health Organization. Assessment of medicines regulatory systems in sub-Saharan African countries, an overview of findings from 26 assessment reports. Geneva: World Health Organization, 2010

World Malarial Report 2014

ANNEXES

Annex I: Root Cause Analysis



Root Cause Analysis. It is based on a literature review and focus group discussion with regulators in SADC. The grey shaded boxes highlight the root causes targeted by the African Medicines Agency

Annex II: Logical Framework for AMA

	Description	Indicator	Means of Verification	Assumptions
GOAL	A healthy African population with access to affordable, quality, safe and efficacious medical products and technologies	Proportion of population with access to affordable, essential medicines on a sustainable basis (SDG indicator)	National surveys of medicines prices and availability using WHO methodology	Countries will conduct surveys
LONG TERM OUTCOMES	Reduced Incidence of Spurious, substandard, falsified fake, and counterfeit (SSFFCs) medicines	• Incidence of reported SSFFCs • % failure rate of products in Post Marketing Surveillance Activities (PMS)	Reports from WHO Member States Mechanism and NMRAs	Effective PMS activities in MS
	Increased suppliers per product on essential medicines	• # of suppliers per product for key essential medicines	NMRAs registers	Information is up to date and readily available
	Increased # of facilities compliant with cGMP	• # of facilities compliant with cGMP	NMRAs reports	Information is readily available from NMRAs; common standards adopted
IMMEDIATE OUTCOMES	Reduced time to approval by NMRAs	• % of medicines registered within the planned timeframe • Reduction in medicines registration backlog	NMRAs databases	Tracking mechanisms in place; data is readily available and databases up to date
	Increased # of facilities approved through mutual recognition, work-sharing, & centralized procedures	• # of facilities approved through harmonization processes	NMRAs and RECs reports	Functional Regional MRH programmes
	Increased # of Products approved through mutual recognition, work-sharing, & centralized procedures	• # of products registered through harmonization processes	NMRAS and RECs reports and databases	
OUTPUTS	Increased # of Regional & National Policies, Legal Frameworks & Technical Standards adopted	• # of member states that have reviewed their policies and legal frameworks to enable	Reports from Ministries of Health in the Member States	Political will by member states

		participation in harmonization activities		
	Mix of financing mechanisms for AMA, RECS & NMRAs	• Diversified funding sources for the budget • Proportion of budget funded by MS	AMA, RECs and NMRAs Budget	
	Increased # of regulatory experts	• # of specialised experts in specific regulatory fields	NMRAs, RECs and AMA database	
	Increased # RECs implementing Medicines Regulatory Harmonization	• # of joint assessments and inspections conducted	RECs reports	
	Increased # of functional RCOREs	• # of functional RCOREs	AMAs and RCORE reports	
	Increased # of NMRAs that are functional	• # of functional NMRAs	Assessments reports	
ACTIVITIES	**1.** Advocacy to AUC, RECs, partners and stakeholders for the policy, regulatory and legal reforms at continental, regional and national levels. **2.** Coordinate, designate and monitor the regional centres of regulatory excellence (RCOREs) **3.** Governance, partnerships and resource mobilisation for regulatory activities including sustainable finance mechanisms at all levels **4.** Custodian of the Model Law, development of policies, legal and technical standards in collaboration with WHO. **5.** Regulatory guidance for AMA: - regulatory guidance and the continent's voice on emerging issues and pandemics particulaly with respect to investigational therapies - regulatory guidance on complex molecules (biotherapeutics, innovative new therapies, vaccines) - coordination of GMP inspections of API manufacturing sites, complex molecules and priority products - GCP of contract research organizations - coordination and provision of regulatory guidance as required by RECs and Member States where capability at national or regional level is lacking, e.g. emerging issues such as regulation of e-commerce businesses **6.** Coordinate and facilitate regional harmonization activities and strengthen NMRAs as requested by Member States, where applicable. **7.** Establishment and maintance of accurate information and market intelligence on regulatory and pharmaceutical market (knowledge and information management).			

Annex III: Mapping of Key players in medicines regulatory strengthening

Key Current Players – Names of Organizations	Aspect of overlap	How will AMAs approach be different from and achieve greater results than others working in your field?	How can AMA work with, leverage, and/or improve on the work that is currently being done?
AMRH Programme	○ Working with same population ○ Working on same issue area ○ Using a similar model of change	Sustainability, Regulatory guidance, Institutionalization of the AMRH programme	Continue and expand the AMRH work and mandate
NMRAs	○ Working with same population ○ Working on same issue area ○ Using a similar model of change	Coordination and facilitation role, best practices, standards, market integration (harmonization); pooling of resources	Use experts in the NMRAs, no duplication of the work done by NMRAs, supportive role and guidance on complex issues for which resources and expertise is unavailable at national level
RECs (coordination, facilitation, harmonization etc.)	○ Working with same population ○ Working on same issue area ○ Using a similar model of change	Coordination and facilitation role, resource mobilization; cross-REC learning	No duplication of the work done by RECs, supportive role and guidance on complex issues for which resources and expertise is unavailable at regional level
WHO PQT (prequalification, capacity building)	○ Working with same population ○ Working on same issue area ○ Using a similar model of change	Focus on market integration at regional level and continental level, target areas/ disease which disproportionately affect Africa; using RCOREs for capacity building	Supporting role on regulatory guidance for specific products, expand the scope that is covered by WHO PQ especially for African manufacturing companies
WHO (standards & norms, capacity building)	○ Working with same population ○ Working on same issue area	Using existing capacities on the continent through the RCORE model for capacity building	Facilitate domestication of WHO norms and standards at regional and national level.
UNFPA (Prequalification of condoms/devices)	○ Working with same population ○ Working on same issue area ○ Using a similar model of change	Focus on market integration at regional level and continental level, target areas/ disease which disproportionately affect Africa; using RCOREs for capacity building	Supporting role on regulatory guidance for specific products, expand the scope that is covered by WHO PQ especially for African manufacturing companies
Academic Institutions (on capacity building)	○ No overlap	Utilizing RCORE and academic institutions for training	Use existing institutions in partnership with regulatory authorities to training, promote and enhance (curriculum development) the existing pre and post graduate training in regulatory science.