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"

INSTITUTIONAL FRAMEWORK FOR AFRICAN MEDICINES AGENCY (AMA)

African Union
a United and Strong Africa

AFRICAN MEDICINES AGENCY

Institutional Framework

Version 5

26 January 2017

World Health Organization

NEPAD
TRANSFORMING AFRICA

Table of Contents

ACKNOWLEGEMENTS

The process of developing the African Medicines Agency (AMA) Institutional and Legal Framework is indebted to the guidance provided by the First African Ministers of Health meeting which was jointly organized by the African Union (AU) and World Health Organisation (WHO) on the 17 April 2014 in Luanda, Angola. The meeting endorsed the AMA Milestones. Subsequently, the Executive Council during its January 2015 meeting, endorsed the establishment of the Task Team and mandated the African Union Commission, NEPAD Agency and WHO to serve as a Joint Secretariat.

This work could not be carried out if it wasn't for invaluable inputs provided by key stakeholders including the AMA Task Team which has been operational since November 2014; the 4th African Medicines Regulators Conference convened in Addis Ababa, Ethiopia in December 2015; representatives of the African Union Commission (AUC); NEPAD Agency and the World Health Organization (WHO).

While the United Nations Development programme (UNDP) provided both financial and technical support required to accomplish the assignment, the general direction was provided by the AUC Director – Social Affairs.

LIST OF ABBREVIATIONS

AMA	--	African Medicines Agency
AU	--	African Union
AMRH	--	African Medicines Regulatory Harmonization
CEMAC	--	Central African Economic and Monetary Union
NEPAD	--	New Partnership for Africa's Development
PMPA	--	Pharmaceutical Manufacturing Plan for Africa
AIDS	--	Acquired Immune Deficiency Syndrome
TB	--	Tuberculosis
SADC	--	Southern African Development Community
MRH	--	Medicines Regulatory Harmonization
ECOWAS	--	Economic Community of West African States
EAC	--	East African Community
ECCAS	--	Economic Community of Central African States
WAEMU	--	West African Economic and Monetary Union
OCEAC	--	Organization for Coordination of the Fight Against Endemic Diseases in Central Africa
AUC	--	African Union Commission
CTDs	--	Common Technical Development
REC	--	Regional Economic Community
GMP	--	Good Manufacturing Practice
NMRAs	--	National medicines Regulatory Authorities
EVD	--	Ebola Virus Disease
RCOREs	--	Regional Centers of Regulatory Excellence
ICH	--	International Conference on the Harmonization of Technical Requirements for the Registration of medicines for human Use
PAHO	--	Pan American Health Organization
ASEAN	--	Association of South East Asian Nations
EMA	--	European Medicines Agency
ICDRA	--	International Conference for Drug Regulatory Authorities
ICMRA	--	International Coalition of Medicine Regulatory Authorities
IGDRP	--	International Generic Drugs Regulators Programme
IMDRF	--	International Medical Devices Regulators Forum
IPRF	--	International Pharmaceutical Regulators Forum
PIC/S	--	Pharmaceutical Inspection Cooperation Scheme
US-FDA	--	United States Food and Drugs Administration
UK-MHRA	--	United Kingdom Medicines and Health Products Regulatory Agency

1. BACKGROUND

The establishment of an African Medicines Agency (AMA) has become indispensable and has been discussed at various meetings and levels in a bid to harmonize the varied and diverse regulatory activities currently taking place in the African continent.

The AU Assembly Decision {**Assembly /AU/Dec.55 (IV**)} adopted during the Fourth Ordinary Assembly in Abuja in January 2005 requested the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the New Partnership for Africa's Development (NEPAD) Framework. The African Union Ministers of Health then took a decision in 2007 to develop a Business Plan for the PMPA which was later endorsed by the 19th AU Assembly and complemented by AU Roadmap on Shared Responsibility and Global Solidarity for the AIDS, TB and Malaria response in Africa {**Assembly AU/Dec.442 (XIX**)} in 2012. The decision stressed on the need to accelerate and strengthen regional medicines regulatory harmonization initiatives that lay the foundation for a single African regulatory agency.

The African Medicines Regulatory Harmonization (AMRH) Initiative, which was established in 2009 under the coordination of the NEPAD Agency came as a result of acknowledgement of the fact that, a favourable regulatory environment for local production and trade in pharmaceuticals on the African continent was needed and necessary. Subsequently and since 2012 regional economic communities (RECs) have embarked on implementation of Medicines Regulatory Harmonisation (MRH) Projects beginning with the East African Community (EAC). The Economic Community of West African States (ECOWAS) through its West African Health Organization (WAHO) in collaboration with the West African Economic and Monetary Union (WAEMU) are implementing MRH Project since February 2015. The Southern African Development Community (SADC) on its part integrated the ZAZIBONA approach for collaboration among the countries of the Community in July 2015. Other efforts include the endorsement of a regional pharmaceutical policy for Central African Economic and Monetary Community (CEMAC) through its Organization for Coordination in the Fight Against Endemic Diseases in Central Africa (OCEAC) and the initiation of discussion on implementation of the MRH Project by the Intergovernmental Development Authority in Northern-Eastern African region.

The guidance for the establishment of the African Medicines Agency (AMA) was made on the 17 April 2014 in Luanda, Angola, at the First African Ministers of Health meeting jointly organized by the African Union Commission and the World Health Organisation (WHO). The Ministers of Health committed themselves to prioritize investment for regulatory capacity development; to pursue the efforts towards convergence and harmonization of medical products regulation in RECs and to allocate adequate resources for AMA. They further endorsed the establishment of the AMA Task Team to spearhead the process.

Finally in January 2015, the Executive Council Decision, {**EX.CL/Dec.857 (XXVI**} endorsed the Milestones for the setting up of a single medicines regulatory agency in Africa within the context of the African Medicines Regulatory Harmonization (AMRH) Programme, which is a part of implementation of the PMPA Framework. The AUC, NEPAD Agency and WHO as a joint Secretariat for establishment of AMA are responsible for coordination of the work of the AMA Task Team, which started its work in November 2014. All these efforts have provided the foundation for establishment of the regional and continental medicines regulatory agency, AMA.

1.1 Aim

The overall aim of the AMA is to ensure the coordination and strengthening of ongoing initiatives to harmonize medicines regulation; provide guidance, complement and enhance the efforts of the African Union Regional Economic Communities (RECs) and Member States towards harmonization of medical products regulation; and contribute to improving access to medical products on the continent.

1.2 Functions of AMA

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.

2. SCOPE OF AMA ACTIVITIES

AMA's scope of activities shall include; promotion of policy, legal and regulatory reforms in AU Member States; development of technical guidelines; assessment of regulatory systems; strengthening capacity of national regulatory agencies (training, meetings, databases and exchange); resource mobilization; designation and resourcing of regional centres of regulatory excellence (RCOREs); and promotion of international cooperation and partnerships.

2.1 Policy, Legal and Regulatory Reforms

As a way of facilitating regional harmonization initiatives, the African Union shall require all member states to operate on the same rules, requirements and standards for regulation of medical products and technologies across the continent.

The AMRH Programme therefore initiated the development of a model law through a participatory and consultative process that involved regulatory experts, legal experts, lawmakers, policymakers, the private sector and civil society across Africa, African Diaspora and beyond. A continental Technical Working Group on Policy and Regulatory Reforms comprising legal experts and regulators representing regional economic community (REC) and African Medicines Regulatory Harmonization (AMRH) Partners guided the development of the Model Law. The Model Law which was adopted by the AU Summit in the January 2016, provides a comprehensive guide to member states and RECs in their quest to review or enact medicines laws and harmonize medicines regulation. It will help AU member states to fill the legislative gaps that hinder effective regulation of medical products and prevent harmonization of these regulations at the regional level.

In its operations, the AMA will therefore:

a) Continuously revise the model law taking into account emerging issues including public health threats and technological advances in the regulation of medical products and health technologies.
b) Promote the use of the model law to develop new medicines legislations in countries where such legislation do not exist or are out-dated.
c) Advocate the use of the model law at continental, regional and country levels to the highest decision makers in health, justice, trade and human rights.
d) Support the development of accompanying regulations in countries to facilitate the implementation of legislation.
e) Advocate the use of these legal instruments by Legislative Assemblies and Parliaments of Member States and Regional Economic Communities (RECs).

2.2 Development of Guidelines and Provision of Scientific Advice

AMA shall formulate scientific guidelines that reflect the current thinking on scientific developments and discoveries with the assistance and involvements of professionals and experts from its national medicines regulatory agencies (NMRAs) working through scientific committees and/or working groups. These guidelines shall be made available to all medicines developers across the world who desire to submit an application for a marketing authorization in the AU Member States and RECs to guide them in their development programs and to ensure that medicines development is conducted consistently and to the highest quality across the AU.

The AMA will from time to time constitute scientific advisory committees to provide opinions on existing and emerging issues on regulation of medicines, biopharmaceutical and other health technologies. Reports from such advisory committees will be shared with AU Member States and RECs, and the greater health and scientific community in order to guide activities responding to public health emergencies on the continent. AMA will also develop a framework for good manufacturing practice (GMP) guideline to be adapted and /or adopted to meet the needs of RECs and countries.

2.3 Market Authorization and Inspections

Through expert scientific advice, specific priority medicines or classes of medicines will be considered for assessment for marketing authorization and GMP inspections. Where new chemical entities or new combinations are introduced for these diseases, and for biotechnology products and products for neglected diseases affecting some populations on the continent, AMA will lead and coordinate a review of the dossiers and provide scientific advice and opinion to the RECs and member states as appropriate.

AMA will operate a database that will be publicly available to all manufacturers, importers and distributors of medicines on the continent. These products would have to be licensed by their national MRAs before they can operate in any jurisdiction. This database would also contain the list of products granted marketing authorization in all Member States.

All manufacturers whose products are available for marketing on the continent will be periodically inspected by a team of experts at the AU Member States and RECs level and the reports of such inspection will be made available in the database of the AMA to assist countries in regulatory decision making. AMA will ensure that inspectorates either at national or regional level operate in a standardized manner through technical support, meetings and internal and external audits that there are common legislation, common GMP guidelines, common procedure for inspections, and common reporting formats.

2.4 Safety Monitoring of Medicines

AMA will develop a web based information system to collect, manage and analyze reports of suspected adverse effects received from patients and healthcare professionals on medicines that are of public health concern.

An expert committee will be put together to provide guidance on the safety of medicines and provide a common framework for regulatory actions on safety for medicines that are registered in more than one country or in more than one REC.

2.5 Clinical trials

The advent of the Ebola Virus Disease (EVD) particularly in Central and West Africa brought to the fore the need for coordination on issues of clinical trials at the continental level. Several molecules and products came up for trials such that a more regional or continental approach was required.

Each member state within the AU shall be responsible for the oversight and authorisation and ethical approval of clinical trials. AMA shall establish a continental Technical Working Group on clinical trials oversight and ethics approval of multicentre trials and create a clinical trial database which will track each trial being undertaken on the continent to enable other member states to benefit from results and challenges faced in those clinical trials. AMA will provide scientific review and guidance to NMRAs and sponsors where necessary and also provide a platform for sharing of knowledge on specific trials to avoid duplication of efforts and avoidance of possible challenges. AMA will work closely with other organizations such as the Africa CDC, the European and Developing Countries Clinical Trials partnership (EDCTP) and the World Health Organization (WHO) in harnessing research and development and strengthening clinical trials oversight and ethics review capacity to facilitate approval of medical products and health technologies.

2.6 Capacity building

The effective regulation of medicines requires extensive theoretical and practical capacity building for regulatory staff. Over the years the human resource capacity of some NMRAs and the countries has improved significantly while others lag behind. Some regulatory authorities either on their own or in collaboration with academic institutions have been designated as Regional Centres of Regulatory Excellence (RCOREs) for specific regulatory functions under the African Medicines Regulatory Harmonization Initiative coordinated by NEPAD Agency.

AMA will continue to strengthen these RCOREs and create more, support them with curriculum development and training programs in order to train more specialized and certified regulatory officers for the AU Member States and RECs.

2.7 Assessment of National Medicines Regulatory Authorities

As science and new heath technologies evolve, NMRAs need to reform and improve regulatory systems to meet emerging challenges. Oftentimes in Africa, the NMRAs lag behind these developments as exemplified by the issues of clinical trials for vaccine candidates in the Ebola Virus Disease outbreak in West Africa.

As part of its mandate AMA will develop systems to monitor, evaluate and assess the comprehensiveness of existing legislation and effectiveness of national regulatory systems in terms of NMRAs regulatory functions and their implementation arrangements including human resources, among others, with the view to recommending interventions that will improve the efficiency and effectiveness of NMRAs.

2.8 Resource mobilization

Financial resources and technical assistance have been major challenging issues that militate against effective medicine regulatory structures and implementation processes in countries and the RECs. Currently initiatives are on-going with the AMRH Programme constituting a consortium of partners for coordination, implementation and funding to support regulatory harmonization at various RECs.

AMA will work with RECs in mobilising the needed technical and financial resources for regulatory systems strengthening and harmonization.

2.9 International Corporation

Medicines Regulation is a global phenomenon. Several other initiatives and institutions such as the WHO, International Conference on the Harmonization of Technical Requirements for the Registration of Medicines for Human Use (ICH**),** Pan American Health Organization (PAHO), Association of South East Asian Nations (ASEAN), European Medicines Agency (EMA), International Conference of Drug Regulatory Authorities (ICDRA), International Coalition of Medicine Regulatory Authorities (ICMRA), International Generic Drugs Regulators Programme (IGDRP), International Medical Devices Regulators Forum (IMDRF), International Pharmaceutical Regulators Forum (IPRF), Pharmaceutical Inspection Cooperation Scheme (PIC/S), and other national authorities like the US-FDA and UK-MHRA have standards that are continually changing due to improved scientific knowledge. In order that Africa is not left out in the global effort to ensure quality and efficacy of medicines, the AMA will have to engage such initiatives in discussions and exchanges by creating formal partnerships, and attending their conferences and meeting and seeking observer status where necessary.

AMA working in collaboration with RECs and member states will ensure timely and regular exchange of regulatory and scientific expertise and resources to ensure continuous development of medicines regulation on the continent. As part of this, AMA shall organize a Biennial Scientific Conference on Medicines Regulation in Africa and African Medicines Regulators Conference (AMRC) to share knowledge on regulatory science on the continent and the world at large.

3. GOVERNANCE STRUCTURE

3.1 THE CONFERENCE OF THE PARTIES

There shall be established the Conference of the Parties of the AMA responsible for providing policy direction.

3.2 THE GOVERNING BOARD

There shall be a Governing Board of the AMA to provide strategic direction by examining its strategic plans, work plans budgets, activities and reports emanating from the Secretariat, Advisory Committee and Technical Working Groups.

3.2.1 MEMBERSHIP OF THE GOVERNING BOARD

1. The Governing Board shall be composed of eleven (11) members, as follows:
   a) 5 (five) Ministers of Health – one from each of the five (5) AU Regions appointed by the Conference of the Parties;
   b) 2 (two) Representatives of the RECs on rotational basis appointed by the Conference of the Parties;
   c) 1 (one) Representative of Regional Health Organizations on rotational basis appointed by the Conference of the Parties;
   d) The Commissioner for Social Affairs, AUC
   e) The CEO of NEPAD Agency
   f) 1(one) representative of the Civil Society Organization in Health nominated by the Governing Board and endorsed by the Conference of the Parties;

2. The Legal Counsel of the African Union Commission or his/her representative shall attend the Board meetings to provide legal advice as may be required.

3. The Director General of the AMA shall serve as the Secretary of the Governing Board.

4. The Board may invite such experts as may be required, to its meetings

5. All members of the AMA Governing Board and their alternates, although representing various RECs, shall serve in their professional capacities on a part-time basis as required to carry out their functions.

3.2.2 FUNCTIONS OF THE GOVERNING BOARD

1. The Governing Board is responsible for providing strategic direction and guidance and monitor performance of the AMA.

2. The functions of the Governing Board shall be to:
   a) Approve the Strategic Plan, Programme of Work, budgets, activity and reports, submitted by the Director General;
   b) Approve reports of the Advisory Committee;
   c) Set up a panel to review complaints against the AMA decisions in line with laid out procedures.
   d) Recommend for endorsement by the Chairperson of the AUC in consultation with the Conference of the Parties, the appointment and dismissal of the Director General of AMA for endorsement by the
   e) Appoint and dismiss, if necessary, the independent auditor of the AMA;
   f) Assist the Secretariat in resource mobilization; and

g) Carry out any other functions as it may deem necessary or referred to it by the Conference of the Parties.

3.2.3 GOVERNING BOARD MEETINGS

a) The Governing Board shall meet in regular session once a year, and may convene an extraordinary session at the request of the Chairperson of the Governing Board or as otherwise requested by the Conference of the Parties.

b) The quorum for meetings of the Governing Board shall be two-thirds majority of the Members of the Governing Board.

c) The decision of the Governing Board shall be taken by consensus.

d) Alternate members will replace the Members of the Governing Board in the case of their unavailability.

e) The Board shall adopt its own Rules of Procedure and those of the Advisory and Scientific Committees.

f) All members of the Board shall be subject to rules of confidentiality, declaration of interest and conflict of interest.

g) All meetings shall be chaired by the Chairperson and in his/her absence, the Vice shall chair.

h) Invitations stating the agenda shall be sent to members by the secretariat at least 30 days before the due date.

i) Invitations shall include minutes of previous meetings with indication of action points and responsible persons.

NEPAD Agency and the African Union Commission (AUC) proposed and subsequently endorsed by the 5th Session of the Conference of Health Ministers (CAMH-5) held in Namibia from 20-21 April, 2011; the regional networks for implementation of AMRH as indicated hereunder:

EAC: Burundi, Kenya, Rwanda, Tanzania and Uganda

SADC/COMESA: Angola, Botswana, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Zambia, Zimbabwe.

OCEAC/ECCAS: Cameroon, Central Africa Republic, Congo Brazzaville, Equatorial Guinea, Gabon, Tchad, Congo Democratic Republic, Angola, Sao Tome Principe.

ECOWAS-WAHO/UEMOA: Benin, Burkina Faso, Cape Verde, Cote d'Ivoire, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, Togo.

CEN SAD/AMU: Algeria, Comoros, Egypt, Eritrea, Libya, Mauritania, Tunisia.

IGAD: Djibouti, Ethiopia, Somalia, Sudan.

3.3 STEERING COMMITTEE AND TECHNICAL WORKING GROUPS

AMA shall constitute a Steering Committee and Technical Working Groups (TWGs) which shall provide technical guidance as provided in the Agreement for AMA establishment. The TWGs shall be responsible for carrying out scientific assessments and submit opinions on specific areas of regulatory functions that will be assigned to them and advise the Steering Committee, Governing Board and Management accordingly.

3.3.1 STEERING COMMITTEE OF THE AMA

1. In the exercise of the functions of AMA, the Governing Board shall establish the Steering Committee as it may deem necessary.
2. The scope and functions of the Steering Committee will be in accordance with the AMA established rules and procedures approved by the Board.
3. Members of the Steering Committee shall be drawn from among Member States NMRAs, National Ethics Committees (NECs) RECs and RHOs.
4. The terms of office of Members of the Steering Committee shall be determined by the Governing Board.
5. Compensation for Steering Committee will be determined by the Governing Board.

3.3.2 FUNCTIONS OF THE STEERING COMMITTEE

a) Establish Technical Working Groups as it may deem necessary, to provide technical guidance on the functions of the AMA.
b) Establish rules governing the issuance of scientific opinions and guidance to AU Member States including fast tracking approval of products during health outbreaks;
c) Approve recommendations submitted by the Technical Working Groups and submit its report to the Governing Board for approval;
d) Provide scientific guidance to Member States on complex molecules, as well as priority and emerging issues and pandemics;
e) Approve the designation and re-designation of the Regional Centres of Regulatory Excellence;
f) Carry out any other functions as it may deem necessary or referred to it by the Governing Board or the Conference of the Parties.

3.3.3 COMPOSITION OF THE STEERING COMMITTEE

1. The Advisory Committee shall be composed of:
    a) 10 (ten) Heads NMRA – two (2) from each of the five (5 AU Regions appointed by the Governing Board;
    b) 2 (two) Representatives of RECs responsible for regulatory affairs, on rotational basis appointed by the Governing Board
    c) 1 (one) Representative of Regional Health Organizations responsible for regulatory affairs, on rotational basis appointed by the Governing Board
    d) 1 (one) Representative of National Ethics Committees (NEC) on rotational basis appointed by the Governing Board

3.3.4 ESTABLISHMENT OF TECHNICAL WORKING GROUPS OF THE AMA

1. There shall be established Technical Working Groups responsible for carrying out scientific assessments and conducting scientific reviews of dossiers and clinical trials applications; inspection of manufacturing facilities; and providing scientific opinion to facilitate the proper functioning of the AMA.

2. The Technical Working Groups shall submit opinions on specific areas of regulatory functions that will be assigned to them and advise the Steering Committee, Governing Board and Management accordingly.

3. The areas to be considered may include but not limited to: Dossier Assessment for Advanced therapies, Biologicals (including biosimilars and vaccines); Medicines for Emergencies, Orphan Medicinal Products; Clinical trials of medicines and vaccines; manufacturing site Inspections (API and Finished Products), Quality Control Laboratories; Pharmacovigilance Risk Assessment and African Traditional Medicines.

4. The work of the existing TWG on Regulatory Capacity Development and Policy and Regulatory Reforms under the AMRH Initiative will be taken up by the AMA TWGs.

3.3.5 FUNCTIONS OF THE TECHNICAL WORKING GROUPS (TWGS)

The TWGs shall:

- conduct scientific reviews and provide opinions relevant to the work of the AMA at the request of the Advisory Committee and the Governing Board in a timely manner;
- identify and advise the AMA on relevant scientific, regulatory, medical and public health issues;
- develop harmonized medical products regulatory policies and standards, scientific guidelines for consideration by the Advisory Committee and approval by the Governing Board;
- contribute to capacity development programmes for the AMA in their areas of expertise.
- Carry out any other functions as may be assigned to it by the Advisory Committee or the Governing Board.

3.3.6 COMPOSITION OF THE TECHNICAL WORKING GROUPS (TWGS)

- The TWGs shall be composed of not more than nine (9) experts representing a wide range of skills and experiences drawn from Member States NMRAs, appointed by the Steering Committee.
- The Steering Committee may also appoint additional experts from academia, research community, industry and consumer and patient groups.
- The Terms of Reference of the TWGs shall be determined by the Director General upon the recommendations of the Steering Committee.
- Each TWG shall be headed by a Chair and Vice Chair as specified in the Terms of Reference.
- All members of the TWGs shall be subject to rules of confidentiality, declaration of interest and conflict of interest.

3.4 THE SECRETARIAT

1. The Secretariat shall be responsible for the implementation of the decisions of the Conference of the Parties, the Policy organs of the Union, and the Board of the AMA.

2. The Secretariat shall be headed by the Director General, who shall act as the Chief Executive Officer of the AMA and shall report to the Board and the African Union, as appropriate.

3. The Director General shall be appointed by the Board and endorsed by the Conference of Parties and shall serve for a period of four (4) years, renewable once.

4. The Secretariat shall:
   a) Coordinate implementation of activities and ensure effective performance of the AMA in fulfilment of its objectives and functions as provided in Articles 3 and 4 respectively;
   b) Ensure effective implementation of the decisions of the Board and the Conference of the Parties;
   c) Draft polices and strategies aimed at the fulfilment of the functions of the AMA for adoption by the Board and the Conference of the Parties;
   d) Coordinate the programs and work of all Technical Working Groups and the Committee.
   e) Facilitate the development and implementation of capacity building and regulatory systems strengthening programs for the benefit of Member States;
   f) Facilitate implementation of regional regulatory harmonization programs;
   g) Prepare the strategic plan, work programmes, budget, financial statement and annual report on the activities of the AMA for consideration and approval by the Board and the Conference of the Parties;
   h) Perform any other duties as may be assigned by the Board and the Conference of the Parties and other relevant structures of the African Union.

The Secretariat of the AMA shall be situated within the NEPAD Agency until such time when the Agreement for AMA comes into force and the Conference of the Parties decides on its location. It shall comprise of the Director General and three departments with responsibilities as assigned below:

3.4.1 THE DIRECTOR GENERAL

a. The Director General shall be the Head of the Secretariat and shall be responsible for the day-to-day management of the AMA.

b. The Director General shall be a person of demonstrated competence, leadership ability and integrity, expertise and experience in the subject matter of this Agreement or related issues.

c. The Director General shall be a national of the Party to this Agreement appointed for a term of four (4) years, renewable once.

d. The Conference of the Parties shall adopt regulations setting out the powers, duties and conditions of service of the Director General in line with AU Rules and Regulations.

e. In the discharge of his/her duties the Director General shall not seek or accept instructions from any state, authority or individual external to the AMA.

The Director General shall be responsible for:

a) the overall management of the AMA;

b) implementing directives of the Governing Board and Conference of Parties as may be applicable;

c) preparing the program, financial and operational report of the AMA and submit to the Governing Board and the Conference of the Parties for approval;

d) appointing staff members of the Secretariat and determine their duties and conditions of service in accordance with AU rules and regulations; and

e) performing any other functions as may be assigned in line with the objectives and functions of the AMA.

f) effective resourcing and functioning of all the departments within the secretariat.

3.4.1.1 DEPARTMENT OF POLICY AND LEGISLATIVE REFORMS

- Advocate and promote Policy and legislative reforms
- Advocacy on the use of the Model Law
- Support for review of existing and development of new legislation in member states
- Development of model regulations to support implementation of the law
- Be in charge of all International Conferences to be organized by the AMA
- Be responsible for Communication and advocacy programs

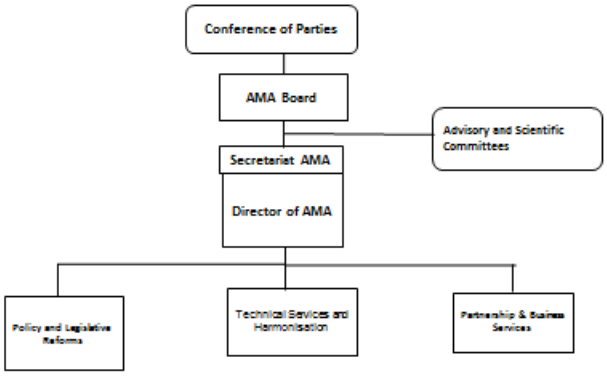
3.4.1.2 DEPARTMENT OF TECHNICAL SERVICES AND HARMONISATION

- Promote the use of model regulations and guidance documents by RECs and member state NMRAs
- Coordinate the activities of Advisory and Scientific Committees
- Facilitate creation, validation and maintenance of a common and integrated Information Communication Technology (ICT) platform for regulatory information exchange across NMRAs and RECs
- Publish the AMA newsletter
- Coordinate and monitor regulatory harmonization programs of RECs
- Coordinate all training programs
- Coordinate, monitor and appraise the programs of RCOREs
- Promote inter laboratory proficiency testing for capacity development.

3.4.1.3 DEPARTMENT OF PARTNERSHIPS AND BUSINESS SERVICES

- Seek Partnerships to advance the course of the AMA
- Promote international cooperation with UN Agencies, Technical and Financial Partners
- Be in charge of all internal accounting, human resource, and other administrative activities at the Secretariat
- Undertake the Planning, monitoring and evaluation activities
- Be responsible for seeking innovative and sustainable financing mechanisms and sources
- Be responsible for the Resource mobilization activities of AMA and properly accounting for same.

AMA ORGANOGRAM



4. REFERENCES

a) Abuja Declaration

b) Abuja Treaty

c) African Union Executive Council, Eleventh Ordinary Council 25 – 29 June, 2007 Accra, Ghana

d) EX.CL/Dec.348 = 377(XI)

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

f) African Union Treaty.

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

h) AU (Africa Union) 2007a Pharmaceutical Manufacturing Plan for Africa. Third Session of the African Union Conference of Ministers of Health, On the Theme "Strengthening of Health Systems for Equity and Development in Africa" held from 9-13 April 2007, Johannesburg, South Africa. CAMH/MIN/7(III).

i) AU (Africa Union) 2007b First Meeting of the Technical Committee on the Pharmaceutical Manufacturing Plan for Africa, 24-26 October 2007, Addis Ababa, Ethiopia.

j) AU (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.

k) AU, NEPAD and COHRED; Strengthening Pharmaceutical Innovation in Africa. Designing strategies for national pharmaceutical innovation: choices for decision makers and countries 2010.

l) Business Plan for Pharmaceutical Manufacturing Plan for Africa 2012.

m) Commitment on the establishment of the African Medicines Agency: setting milestones towards its establishment, AUC/WHO/2014/Doc.2 17 April 2014.

n) Compendium of Quality Management System (QMS) technical documents for harmonization of Medicine Regulation in the East African Community, version September 2014.

o) European Medicines Agency, International Generic Drug Regulators Programme (IGDRP)

p) Information Sharing Pilot: Information packet January 2015.

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

r) Grey, A. 2004. Access to Medicines and Medicine Regulation in Developing Countries: a Resource Guide for DFID. DFID Health Systems Resource Centre, October 2004.

s) Hill S. & Johnson, K. 2004. Emerging Challenges and Opportunities in Medicine Registration and Regulation in Developing Countries. DFID Health Systems Resource Centre Issues Paper. May 2004.

t) Kaplan, W. & Laing, R. 2005. Local Production of Pharmaceuticals: Industrial Policy and Access to Medicine. An Overview of Key Concepts, Issues and Opportunities for Future Research. World Bank Health, Nutrition and Population (HNP) Discussion Paper No. 32039, January 2005. http://wwww.worldbank.org, last accessed 4 February 2009.

u) Mac J. Roberts and Michael R. Reich, Pharmaceutical Reforms – A Guide to Improving Performance and Equity, The World Bank.

v) Medicines and HealthCare Products Regulatory Agency, (website).

w) NEPAD – ECOWAS Situational Analysis report 2011.

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

y) Pharmaceutical Manufacturing Plan for Arica 2007.

z) Report of the First Meeting of the Task Team to Facilitate the Establishment of the African
aa) Medicines Agency (AMA), AUCC, Addis Ababa, Ethiopia, 25-26 November 2014

bb) 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.

cc) 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.

dd) WHO Regional Office for Africa, Conference report on the Third African Medicines Regulatory

ee) Authorities Conference, Johannesburg (South Africa), 4-6 December 2013.