



African Union
a United and Strong Africa

**DRAFT TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES
AGENCY**

Revision 14 July 2017



World Health Organization



**DRAFT TREATY FOR THE ESTABLISHMENT OF THE AFRICAN
MEDICINES AGENCY
(AMA)**

PREAMBLE

THE PARTIES,

AWARE THAT, weak regulatory systems have resulted in the circulation of substandard and falsified (SF) medical products in many of the African Union Member States;

COGNIZANT THAT the existence of SF products poses a risk to public health, harms patients and undermines confidence in healthcare delivery systems;

RECALLING the 55th Decision of the African Union (AU) {Assembly /AU/Dec.55(IV)} taken during the Abuja Summit in January 2005, which requested the AU Commission to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the framework of the New Partnership for Africa's Development (NEPAD), aimed to improve access to good quality, safe and efficacious medical products and health technologies for the African population;

FURTHER RECALLING the Eighteenth Ordinary Session of the Heads of State and Government Orientation Committee 29 – 30 January 2012 Decision {Assembly/AU/DEC-413(XVIII)} Para 6 which endorsed the African Medicines Regulatory Harmonization (AMRH) Programme implemented through the regional economic communities (RECs);

RECOGNIZING the aspirations of the AU Roadmap on Shared Responsibility and Global Solidarity for the AIDS, tuberculosis and malaria response in Africa {Assembly AU/Dec.442 (XIX)}, Pillar II on access to medicines which aims to accelerate and strengthen regional medicines regulatory harmonization initiatives and lay the foundation for a single African regulatory agency;

BEING COGNIZANT of the challenges posed by the lack of availability of medicines and vaccines during public health emergencies of international concern and, in particular, during the recent outbreak of the Ebola virus disease (EVD) in Africa and the attendant dearth of medical product candidates for clinical trials;

RECOGNIZING the contribution of the African Vaccines Regulatory Forum (AVAREF) in facilitating approval of EVD candidate therapies and vaccines and efforts undertaken by the African Union (AU), regional economic communities (RECs) and regional health organizations (RHOs) to mobilize human, financial and material resources and continental expertise to deal with the outbreak of EVD; and subsequent establishment of regional expert working groups (EWGs) on clinical trials oversight in East African Community (EAC) and the Economic Community of West African States (ECOWAS) as part of the implementation of the decision of the 24th Ordinary Session of the NEPAD Heads of State and Government Orientation Committee of January 2015 decision {Assembly/AU/Dec.563(XXIV) Para 11};

DESIRING the use of continental institutional, scientific and regulatory resources to improve access to safe, efficacious and quality medicines; **and AWARE OF** the establishment of the African Medicines Regulatory Harmonization (AMRH) in 2009, under the management and guidance of the NEPAD Agency working with RECs and RHOs, to facilitate harmonization of regulatory requirements and practice among the national medicines regulatory authorities (NMRAs) of the AU Member States to meet internationally acceptable standards, and provide a favourable regulatory environment for pharmaceutical research and development, local production and trade across countries on the African continent;

APPRECIATING the launch and subsequent implementation of Medicines Regulatory Harmonization (MRH) Programmes and collaborative efforts in and between the East African Community (EAC); Economic Community of West African States (ECOWAS) and the West African Economic and Monetary Union (WAEMU); and the Southern African Development Community (SADC);

RECOGNIZING other on-going efforts on cooperation between the Economic Community of Central African States (ECCAS) and the Organization for Coordination in the Fight against Endemic Diseases in Central Africa (OCEAC) on implementation of the AMRH Programme in

the Central African region; and the North-Eastern Africa regional collaboration and harmonization under the leadership of the Intergovernmental Authority on Development (IGAD);

NOTING the commitment made by the African Ministers of Health during their First meeting held on 17 April 2014 in Luanda, Angola, jointly organized by the African Union Commission and World Health Organisation (WHO) to prioritize investment in regulatory capacity development; to pursue efforts towards convergence and harmonization of medical products regulation in RECs; to allocate adequate resources for the establishment of the African Medicines Agency (AMA), and the subsequent endorsement of the establishment of the AMA Task Team to spearhead the process;

RECALLING the AU Executive Council Decision EX.CL/Dec.857 (XXVI) in which the Council decided that African Medicine Regulatory Harmonization (AMRH) Initiative shall serve as a foundation for the establishment of AMA.

FURTHER RECOGNIZING the AU Assembly Decision Assembly/AU/Dec.1-17(XXVI) and Declaration Assembly/AU/Decl.1-2(XXVI) of January 2016 which adopted the AU Model Law on Medicines Regulation as an instrument to guide AU Member States in the enactment or review of national medicines laws, and a call to Member States to sign and ratify the said legal instrument, where applicable, as expeditiously as possible to enable its entry into force;

CONVINCED that the efforts to coordinate the regulatory systems strengthening and harmonization initiative under the leadership of African Medicines Agency will provide improved sovereign control and regulation of medical products that will allow African Union Member States to provide for efficient and effective protection of public health against risks associated with use of SF, and will facilitate expeditious approval of products that address the health needs of the African populace, especially for diseases that disproportionately affect Africa.

HAVE AGREED AS FOLLOWS:

PART ONE

THE AFRICAN MEDICINES AGENCY AND ITS OBJECTIVES

ARTICLE 1

Acronyms

“**AMRH**” means the African Medicines Regulatory Harmonization Initiative of the African Union;

“**Africa CDC**” means the Africa Centres for Disease Control and Prevention;

“**AMA**” means the African Medicines Agency;

“**AMRC**” means the African Medicines Regulators Conference;

“**NEPAD**” means New Partnership for Africa’s Development;

“**NMRA**” means National Medicines Regulatory Authority;

“**REC**” means Regional Economic Community recognized by the African Union;

“**RCOREs**” means Regional Centres of Regulatory Excellence;

“**RHOs**” means the regional health organizations;

“**TWGs**” means the Technical Working Group comprised of experts constituted under this Treaty;

“**WHO**” means the World Health Organization.

Definitions

For the purpose of this Treaty, the terms and expressions below shall have the following meanings:

“**Agency**” means the Agency established under Article 2;

“Assembly” means the Assembly of Heads of State and Government of the African Union;

“blood products” means any therapeutic substance prepared from human blood for use in the treatment of diseases or other medical conditions.

“Board” means the Governing Board of the AMA;

“Bureau” means the Bureau of the Conference of the State Parties;

“Commission” means the African Union Commission;

“complementary medicines” means any of a range of health therapies that fall beyond the scope of conventional medicine but may be used alongside it in the treatment of diseases and other medical conditions.

“Constitutive Act” means the Constitutive Act of the African Union;

“Conference of the Parties” means the Conference of the Parties to this Treaty;

“Director General” means the Director General of the AMA;

“diagnostic” means a medicine or medical device or substance used for the analysis or detection of diseases or other medical conditions.

“food supplement” means a product intended for ingestion that contains a **dietary** ingredient intended to add further **nutritional** value to (**supplement**) the **diet**.

“medical device” means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:-

- a) intended by the manufacturer to be used, alone or in combination, for humans or animals for:-
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

- (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
 - (iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
 - (iv) supporting or sustaining life;
 - (v) control of conception;
 - (vi) disinfection of medical devices; or
 - (vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and
- b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;

“medical Products”¹ include medicines, vaccines, blood and blood products, diagnostics and medical devices;

“medicine” means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in:-

- a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
- b) restoring, correcting or modifying any somatic or psychic or organic function in humans, and includes any veterinary medicine;

“Member States” means Member States of the African Union;

“other regulated products” include complementary medicines, traditional medical products, cosmetics, food supplements and related products;

“Party” means an AU Member State that has ratified or acceded to this Treaty;

“Secretariat” means the Secretariat of the AMA;

“traditional medical product” means an object or substance used in traditional health practice for:

- (a) the diagnosis, treatment or prevention of a physical or mental illness; or

(b) any curative or therapeutic purpose, including the maintenance or restoration of physical or mental health or well-being in human beings, but does not include a dependence-producing or dangerous substance or drug.

“Treaty” means a treaty to establish the African Medicines Agency

ARTICLE 2

Establishment of the AMA

The African Medicines Agency is hereby established as a Specialized Agency of the AU.

ARTICLE 3

Objectives

1. The main objective of AMA is to improve access to quality, safe and efficacious medical products on the continent through:
 - a) coordination and strengthening of ongoing initiatives to harmonize medicines regulation, promote cooperation and mutual recognition of regulatory decisions.
 - b) carrying out regulatory oversight of selected medical products and providing technical guidance to State Parties and RECs.
 - c) pooling expertise and capacities and strengthening networking for optimal use of the limited resources available.

ARTICLE 4

Functions

1. The AMA shall have a coordination and stewardship function for the regulatory activities of the State Parties.
2. The AMA shall undertake such functions among the core regulatory functions, as may be necessary to achieve its objectives and shall perform the following:

- a. **Marketing authorization:** The AMA shall be responsible for evaluation and decision-making with regard to selected medical products for treatment of priority diseases/conditions as determined by the African Union.
 - b. **Inspection:** The AMA shall undertake coordination on the inspection of manufacturing sites, and share information on a regular basis in regard to all products that it has authorized for marketing.
 - c. **Market surveillance:** The AMA shall coordinate the collection and sharing of information on all medical products including SF medical products.
 - d. **Safety monitoring:** The AMA shall be responsible for making regulatory decisions concerning products selected for treatment of priority diseases/conditions as determined by Member States, based on available safety information. In addition, the AMA will collect and store information on the quality and safety of medical products and share them with all its States Parties as well as globally. It will also establish collaboration with global and regional centres in the area of safety monitoring.
 - e. **Oversight of clinical trials:** The AMA shall coordinate joint reviews of applications for the conducting of clinical trials.
 - f. **Quality control:** The AMA shall coordinate and network quality control laboratory services for national and regional regulatory authorities.
3. Without departing from the generality of the foregoing, the AMA shall undertake the following functions:
- a. Promote the adoption and harmonization of medical products regulatory policies and standards, as well as scientific guidelines, and coordinate existing regulatory harmonization efforts in the RECs and RHOs;
 - b. Provide regulatory guidance, scientific opinions and a common framework for regulatory actions on medical products, 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, RECs, or State Parties;
 - d. Provide technical assistance, where possible, on regulatory matters to State Parties that lack the capacity and resources to do so themselves;
 - e. Provide guidance on regulation of traditional medical products;
 - f. Provide guidance on regulation of clinical trials on medical products;

- g. Designate, promote, strengthen, coordinate and monitor RCOREs with a view to developing the capacity of medical products regulatory professionals;
- h. Promote international cooperation and seek partnerships that will lead to effective mobilization of financial and technical resources to ensure sustainability of the AMA;
- i. Promote and advocate the adoption of the AU Model Law on medical products regulation in State Parties and RECs to facilitate regulatory and legal reforms at continental, regional and national levels;
- j. Convene in collaboration with the WHO, the AMRC and other bodies, meetings related to medical products regulation in Africa;
- k. Collect, manage and disseminate relevant information and knowledge;
- l. 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;
- m. Mobilize regulatory expertise across the continent and beyond to provide scientific opinions in consultation with affected State Party NMRAs, in the event of a public health emergency on the continent with cross border or regional implications where new medical products are to be deployed for investigation and clinical trials.
- n. Provide advice on the marketing authorization application process for the priority drugs described by the State Parties or on the products proposed by the pharmaceutical laboratories.
- o. Monitor the medicines market through the collection of samples in every State Party to ensure the technical control of selected drugs, have them analysed and provide the results to State Parties. Each State Party will thus have reliable information on the quality of the drugs circulating in its country and, where necessary, will take appropriate measures.
- p. Provide technical support in quality control of drugs at the request of Member States which do not have the structures to carry out these examination/controls/checks.
- q. Where required, undertake the inspection of drug manufacturing sites as determined by State Parties and/or the AMA, and make reports available to State Parties.

ARTICLE 5

Guiding Principles

The guiding principles of the AMA shall be as follows:

1. **Leadership:** The AMA is an institution that provides strategic direction and promotes good public health practice in State Parties through capacity building, and the promotion of continuous quality improvement in the delivery of medical products regulation.
2. **Credibility:** The AMA's strongest asset is the trust it cultivates with its beneficiaries and stakeholders as a respected, evidence-based institution. It will play an important role in championing effective communication and information-sharing across the continent.
3. **Ownership:** The AMA is an Africa-owned institution. Parties will have primary ownership of AMA to ensure that the financial, human, infrastructural and other resources are adequate for performing its functions.
4. **Transparency and accountability:** The AMA shall operate in accordance with generally accepted international standards of good governance, transparency and accountability.
 - a. Timely dissemination of information, an open interaction and unimpeded information exchange between the AMA on the one hand, and RECs and Member States on the other, is inherent in the mission of the AMA.
 - b. The AMA shall be accountable to Parties in all its operations.
 - c. The AMA shall make its decisions independently, based on current scientific evidence, professional ethics and integrity. The detailed evidence of its decision-making process and the justification for its decisions shall be fully respected.
5. **Value-addition:** In every strategic aim, objective or activity, the AMA will demonstrate how its initiative adds value to the medical products regulatory activities of States Parties and other partners.
6. **Good governance and stewardship:** AMA will observe practices of good governance in creating an enabling environment for sustained regulatory systems, partnership and coordination of activities in an integrated manner.

7. **Competency:** AMA shall fulfil its functions by deploying and maintaining the best competencies available.
8. **Confidentiality:** The AMA shall adhere to the principles of confidentiality in all its operations.
9. **Commitment to sound quality management:** In all its functions the AMA shall adhere to international standards of quality management and create the conditions for continuous improvement of its regulatory practices and those of NMRAs of Member States of the African Union.
10. **Partnerships and collaboration:** The AMA shall build and strengthen partnerships and promote collaboration and information sharing with all relevant stakeholders.
11. **Support for innovation:** The AMA shall support innovations to enhance access to new medical products in order to address the public health priorities of Africa.

PART TWO
STATUS OF THE AFRICAN MEDICINES AGENCY AND ITS STAFF

ARTICLE 6
Legal Personality

1. The AMA shall have legal personality, in the territory of each State Party, necessary for the fulfilment of its objectives and the exercise of its functions in accordance with this Treaty.
2. For the smooth fulfilment of its objectives, the AMA shall, in particular, have the legal capacity to:
 - a) enter into agreements;
 - b) acquire and dispose of movable and immovable property; and
 - c) institute and defend legal proceedings.

ARTICLE 7

Privileges and immunities

1. The States Parties undertake to accord to the AMA and all its personnel, AUC staff, its premises, property and assets, and experts on mission providing advice or assistance to the AMA, the privileges and immunities as stipulated in the 1965 General Convention on Privileges and Immunities of the Organization of African Unity and the Additional Protocol to the OAU General Convention on Privileges and Immunities, and such facilities and courtesies as are necessary for the exercise of their functions in connection with the AMA.

ARTICLE 8

Headquarters of the AMA

1. The Headquarters of AMA shall be determined by the Assembly of the Union upon the Conference of State Parties recommendation in accordance with the AU criteria adopted in 2005.
2. The AUC shall enter into a host agreement with the government of the host country in which the AMA Headquarters will be situated with regard to the provision of the premises, facilities, services, and privileges and immunities for the purposes of the efficient operation of the AMA.

PART THREE

ADMINISTRATION AND INSTITUTIONAL FRAMEWORK

ARTICLE 9

Organs of the AMA

The AMA shall have the following organs:

- a) The Conference of the Parties;
- b) Governing Board;
- c) The Secretariat; and

- d) Technical Committees

ARTICLE 10

Establishment of the Conference of the State Parties

1. The Conference of the State Parties is hereby established as the highest organ of the AMA and shall have the power to undertake such functions as are provided for in this Treaty and as may otherwise be necessary to achieve the objectives of this Treaty.

ARTICLE 11

Composition of Conference of the State Parties

1. The Conference of State Parties shall be composed of all Parties to this Treaty and shall function as the policy organ of the AMA.
2. The State Parties shall be represented by ministers responsible for health or their duly authorised representatives.

ARTICLE 12

Session of the Conference of the State Parties

1. The Conference of the State Parties shall meet at least once every two years in ordinary session and in an extraordinary session at the request of the Chairperson, the Bureau, the Governing Board or two-thirds of the State Parties.
2. The quorum of the Conference of the Parties shall be a simple majority of the State Parties to the AMA.

Decisions of the Conference of Parties shall be taken by consensus failing which by a two-thirds majority of the State Parties present and voting.

ARTICLE 13

Functions of the Conference of the State Parties

1. The Conference of the Parties shall be responsible for the following functions:
 - a) Set the amount of the annual contribution and special contribution by Parties, to the budget of the AMA;
 - b) Appoint and dissolve, for cause, the Governing Board;
 - c) Adopt regulations setting out the powers, duties and conditions of service of the Director General.

- d) Approve the structure and administrative guidelines of the Secretariat, as well as adopt its governing rules and regulations;
 - e) Provide policy direction to the AMA;
 - f) Recommend the location for the headquarters of the AMA in accordance with the AU criteria adopted by in 2005.
 - g) Adopt a scheme to alternate the terms of members of the Board, to ensure that the Board at all times comprises a mix of new and old members;
 - h) Adopt rules of procedure for itself and for any subsidiary organs of the AMA, as well as rules to determine, in particular, the financial contribution of the Parties to AMA.
 - i) Recommend any amendments to this Treaty to the Assembly for consideration.
 - j) The Conference of State Parties shall, on the basis of rotation and geographical distribution, elect, after due consultation and on the basis of rotation and geographical distribution, elect a Chairperson and other members of the Bureau, namely, three (3) Vice-Chairpersons and a Rapporteur.
3. The Members of the Bureau shall hold office for a period of two (2) years.
 4. The Bureau will meet at least once every year.
 5. In the absence of the Chairperson or in case of a vacancy, the Vice-Chairpersons or the Rapporteur in order of their election shall act as the Chairperson
 6. The Conference of Parties shall have the right to invite observers to attend its meetings, and such observers shall not have the right to vote.

ARTICLE 14

Establishment of the Governing Board

1. There is hereby established a Governing Board of the AMA appointed by and answerable to the Conference of the Parties.

ARTICLE 15

Composition of the Governing Board

1. The Board shall consist of eleven (11) members, composed as follows:
 - a) Five (5) Heads of NMRAs, one (1) drawn from each of the AU-recognized regions;
 - b) Three (3) Representatives of RECs responsible for regulatory affairs, on rotational basis and appointed by the RECs;
 - c) One (1) Representative of Regional Health Organizations responsible for regulatory affairs, on rotational basis appointed by the RHOs;

- d) One (1) Representative of National Committees Responsible for Bioethics, on a rotational basis and appointed by the RECs;
 - e) The Commissioner for Social Affairs, AUC;
2. The Board shall elect its own Chairperson and Vice Chairperson from amongst the Heads of NMRAs.
 3. The Legal Counsel of the AU or his/her representative shall be an ex-officio member of the Board and shall attend meetings to provide legal advice.
 4. Remuneration for Members of the Board shall be determined by the Conference of the State Parties.
 5. The Director General of the AMA, shall serve as the Secretary of the Board.

ARTICLE 16

Sessions of the Governing Board

1. The Board shall meet in regular session at least once a year, and may convene an extraordinary session at the request of the Chairperson or Vice Chairperson of the Board or of the chairperson or the Bureau of the Conference of the State Parties.
2. The quorum for meetings of the Board shall be two-thirds of the membership of the Board.
3. The decision of the Board shall be taken by consensus and failing that, by a simple majority vote by the Members present.
4. In the event the Members are not in a position to attend personally, duly accredited representatives shall represent them.
5. The Board shall consider and recommend its Rules of Procedure and those of the Technical Working Groups to the Conference of State parties for adoption.
6. All members of the Board shall be subject to the rules of confidentiality, declaration of interest and conflict of interest.
7. The Board may invite such experts as may be required, to its meetings.

ARTICLE 17

Functions of the Governing Board

1. The Board is responsible for providing strategic direction, technical decision-making, guidance and monitoring the performance of the AMA.
2. The functions of the Board shall be to:
 - a) approve the Strategic Plan, Programme of Work, budgets, activity and reports submitted by the Director General;
 - b) set up an independent panel to review complaints against the AMA decisions or opinions in line with agreed procedures;
 - c) recommend for endorsement by the Conference of the Parties, the appointment and dismissal of the Director General of AMA;
 - d) appoint and dismiss, if necessary, the independent auditor of the AMA;
 - e) recommend regulations setting out conditions of service of the staff of the Secretariat.
 - f) assist the Secretariat with resource mobilization;
 - g) establish technical committees (TCs) to provide technical guidance on the functions of the AMA.
 - h) establish rules governing the issuance of scientific opinions and guidance to Parties, including expedited approval of products during health outbreaks;
 - i) approve recommendations submitted by the TCs;
 - j) provide scientific guidance to State Parties on: complex molecules and substances, and on priority and emerging issues and pandemics; as well as on ethics clearance of and regulatory oversight over clinical trials, and facilitate the conduct of multicentre trials;
 - k) designate the Regional Centres of Regulatory Excellence (RCOREs); after consultation with the Bureau of Conference of State Parties.
 - l) carry out any other functions as it may deem necessary or referred to it by the Conference of the Parties or the Bureau.

ARTICLE 18

Term of Office of the Governing Board

1. The term of office of the members of the Board, unless otherwise specified below, shall be a non-renewable period of three (3) years.
2. The term of office of Board members representing the RECs, RHOs shall be a non-renewable period of two (2) years.
3. The Commissioner of Social Affairs shall hold a permanent seat.

4. The Board shall elect, by a simple majority and for a three (3) year non-renewable term a Chairperson and Vice Chairperson of the Board from among the heads of NMRAs², taking into account the Union's principle of regional rotation and gender equity.

ARTICLE 19

Establishment of Technical Committees of the AMA

1. There shall be established technical committees to provide technical guidance on specific areas of regulatory expertise that will be assigned to them by the Board and Secretariat accordingly.
2. The areas to be considered may include but not be 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 of active pharmaceutical ingredients (API) and finished pharmaceutical products, quality control laboratories; bioavailability and bioequivalence studies; pharmacovigilance risk assessment; and African traditional medicines.

ARTICLE 20

Functions of the Technical Committees

1. The technical committees shall be responsible for carrying out scientific assessments and conducting scientific reviews of dossiers, including quality aspects, and clinical trial applications; inspection of manufacturing facilities; and providing scientific opinion to facilitate the proper functioning of the AMA. These may be either permanent or ad hoc structures.
2. The technical committees shall:
 - a) conduct scientific reviews and provide guidelines and opinions relevant to the work of the AMA at the request of the Board and Secretariat, in a timely manner;

² At the second stakeholders meeting, ministers were replaced by NMRA's.

- b) identify and advise the AMA on relevant scientific, regulatory, medical and public health issues;
- c) develop harmonized medical products regulatory policies and standards, and scientific guidelines for consideration and approval by the Board and Conference of State Parties ;
- d) contribute to capacity development programmes for the AMA in their areas of expertise.
- e) carry out any other functions as may be assigned to it by the Board or the Director General.

ARTICLE 21

Composition of the Technical Committees (TCs)

1. The TCs shall be composed of not more than nine (9) experts representing a wide range of competencies and experiences.
2. Members of the TCs shall be drawn from State Party NMRAs as appointed by the Board and, shall reflect geographic representation.
3. The technical experts in relevant fields may be drawn from across and outside the continent, when necessary.
4. Each TC shall be headed by a Chair and Vice Chair as specified in its terms of reference adopted by the Board.
5. All members of the TCs shall be subjected to the rules of confidentiality, declaration of interest and conflict of interest.

ARTICLE 22

The Secretariat of the AMA

1. The Secretariat of the AMA shall be responsible for the implementation of the decisions of the Conference of the Parties, the Policy organs of the African Union, and the Board of the AMA.
2. The Secretariat shall:
 - a) coordinate implementation of activities and ensure effective performance of the AMA in fulfilment of its objectives and functions;
 - 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 programmes and work of all technical committees and the Board.
- e) establish and maintain capacity building and regulatory systems strengthening programmes for the benefit of Member States;³
- f) 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;
- g) 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.

ARTICLE 23
The Director General of the AMA

1. The Director General shall be the Head of the Secretariat and shall be responsible for the day-to-day management of the AMA.
2. The Director-General shall be appointed by the Conference of State Parties upon recommendation of the Board recommendation.
3. The Director General, shall serve as the Chief Executive Officer of the AMA and shall report to the Board, the Conference of State Parties and the African Union, as appropriate.
4. The Director General shall be appointed for a term of four (4) years, renewable once.
5. The Director General shall appoint staff of the Secretariat in line with the approved structure and procedures by the Conference of State Parties.
6. The Director General shall be a person of demonstrated competence, leadership ability and integrity, expertise and experience in the subject matter of this Treaty or related issues.
7. The Director General shall be a national of a State Party.
8. The Director General shall be responsible for monitoring the code of conduct of AMA staff and experts.
9. 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.

ARTICLE 22
Subsidiary or Affiliated Entities of the AMA

³ There was a debate on whether this should be only State Parties or all Member States. The conclusion was that there can be no weak link in the chain of regulation, i.e. hence as much as possible even Non-State Parties should benefit from capacity building and regulatory strengthening programs.

There may be such subsidiary or affiliated entities of the AMA as the Board may decide to designate for the purposes of carrying out functions of AMA.

ARTICLE 23
Objections to Scientific Opinions

1. In the event that a person duly objects to a scientific opinion, advice and decisions issued by AMA, he/she may refer or appeal to the Board.
2. The Board shall set up an independent panel to review the complaint in line with agreed procedures.
3. The Board shall develop procedures for appeals.

PART FOUR
FINANCIAL PROVISIONS

ARTICLE 24
Financial Resources

1. The annual assessed contribution to be paid by the State Parties to defray the costs of the AMA shall be set by the Conference of Parties and adopted concurrently with the budget of the AMA.
2. The AMA shall devise ways of resource mobilization.
3. The AMA may also receive grants, donations and proceeds for its activities from international organizations, governments, private sector, foundations and other entities in accordance with guidelines set by the Board and approved by the Conference of State Parties , provided there is no conflict of interest.
4. The Conference of the State Parties shall determine the appropriate sanctions to be imposed on any Party that defaults in the payment of its contributions to the budget of the AMA for a period of two years from the date the payment is due.
5. Pending the adoption of the AMA Financial Rules by the Conference of State Parties, it shall abide by the AU Financial Rules and Regulations where appropriate.

ARTICLE 25
Expenses

1. The Secretariat may incur expenses for administrative, operational and investment purposes in accordance with the approved programme of work, budget and financial rules

and regulations of the AMA as approved by the Governing Board and adopted by the Conference of the State Parties.

2. The finances and accounts of the AMA shall be audited by an independent auditor appointed by the Board in terms of Article 17 of this Treaty.

PART FIVE EXTERNAL RELATIONS OF THE AMA

ARTICLE 26 *Relationship with the African Union*

1. The AMA shall maintain a close working relationship with the AU whose assistance will be required in the achievement of its objectives.
2. The AMA shall present a written annual report on its activities to the AU Assembly through the relevant STC and Executive Council.

ARTICLE 27 *Relationship with States*

1. The AMA may establish and maintain active cooperation with AU Member States and Non-AU Member States.
2. The State Parties shall appoint focal points to coordinate country level activities of AMA.

ARTICLE 28 *Relationship with Other Organizations and Institutions*

1. The AMA shall establish and maintain a close working relationship and collaboration with the following :
 - a) World Health Organization (WHO).
 - b) Africa Centres for Disease Control and Prevention (Africa CDC).
 - c) Regional Economic Communities (RECs).
 - d) Any other UN agencies, inter-governmental organizations and non-governmental organizations or other institutions, including specialized agencies other than specifically provided for in this Treaty, that AMA considers necessary to assist in achieving its objectives.

PART SIX FINAL PROVISIONS

ARTICLE 29 *Working Languages*

The working languages of the AMA shall be those of the AU, namely Arabic, English, French and Portuguese.

ARTICLE 30
Amendment of the Treaty

1. Any State Party may propose an amendment to this Treaty and submit it to the Chairperson of the AU Commission through the Director General of the AMA.
2. No amendments to the Treaty shall be considered by the Conference of the State Parties unless notice has been given by the Chairperson of the AU Commission to all Parties at least three months prior to such consideration.
3. An amendment shall be approved by a two-thirds majority vote of the State Parties of the AMA.
4. An amendment shall come into force after its adoption by the Assembly and in respect of each Party that accepts same three months after the deposit of the instrument of acceptance.
5. Instruments of acceptance of an amendment shall be deposited with the Chairperson of the AU Commission.

ARTICLE 31
Settlement of Disputes

1. Any dispute that may rise concerning the interpretation and/or application of any of the provisions of this Treaty, which cannot be settled by the parties to the dispute, shall be submitted to the Conference of the State Parties.
2. If the Conference of State Parties does not reach a decision on the dispute, or if the decision of the Conference of State Parties is not accepted by the parties to the dispute concerned, either party to the dispute may request that the matter be submitted for arbitration by an Arbitration Tribunal composed of three members selected in the following manner:
 - a) Each party shall nominate an arbitrator;
 - b) The third arbitrator, who shall be the Chairperson of the Arbitration Tribunal, shall be chosen by common agreement between the arbitrators nominated by the parties to the dispute.

- c) If there are more than two (2) parties to the dispute, then each of the parties shall be entitled to select one arbitrator, and these arbitrators shall nominate another arbitrator who shall be the Chairperson of the Arbitration Tribunal.
3. If the Arbitration Tribunal is not formed within a period of three months from the date of the request for the arbitration, either of the parties to the dispute may request the Chairperson of the Conference of the State Parties to make the necessary nominations for the Arbitration Tribunal, except when the AMA itself is a party to the dispute, in which case nominations shall be made by the Chairperson of the AU Commission.
4. The award of the Arbitration Tribunal shall be binding on the parties to the dispute.

ARTICLE 32 ***Dissolution***

1. The AMA may be dissolved by the agreement of two-thirds of the State Parties to this Treaty at a meeting of the Conference of the State Parties in accordance with Article 32 and upon endorsement by the AU Assembly.
2. At least six (6) months' notice shall be given of any meeting of the Conference of the State Parties at which the dissolution of the AMA is to be discussed.
3. Once agreement has been reached on the dissolution of the AMA, the Conference of the State Parties shall establish the modalities for the liquidation of the assets of the AMA.

ARTICLE 33 ***Signature, Ratification and Accession and entry into Force***

1. This Treaty, in the Arabic, English, French and Portuguese texts, shall be deposited with the Chairperson of the AU Commission.
2. This Treaty shall be open for signature and ratification by all the Member States of the African Union.
3. This Treaty shall be applied provisionally, once it has been signed by at least fifteen (15) Member States of the AU, and to each signatory state to the extent that provisional application is consistent with that State's own constitution, laws or regulations, pending ratification by the State concerned or the definitive entry into force of this Treaty.
4. This Treaty shall be subject to ratification, acceptance or accession.
5. This Treaty shall enter into force definitively thirty (30) days from the date of the deposit of the fifteenth (15th) instrument of ratification or accession.

6. Any AU Member State desirous of becoming a member of the AMA after the entry into force of this Treaty, may do so by depositing with the Chairperson of the AU Commission its instrument of accession to this Treaty.
7. The Instruments of ratification or accession shall be deposited with the Chairperson of the AU Commission.
8. The Chairperson of the AU Commission shall transmit certified copies of this Treaty and information relating to the ratification or accession of this Treaty to all AU Member States.

ARTICLE 34
Reservations

No reservation shall be made to this Treaty if the reservation is incompatible with the objects of this Treaty.

ARTICLE 35
Withdrawal

1. Any Party may withdraw from this Treaty by written notification to the Chairperson of the AU Commission who, within thirty (30) days of receipt of such notification, shall inform the AMA and the State Parties.
2. The notification of withdrawal shall become effective one year following receipt by the Chairperson of the AU Commission of the notification of withdrawal.
3. The obligations incurred by the withdrawing Party under this Treaty, prior to its withdrawal taking effect, shall continue in force.

IN WITNESS WHEREOF, the undersigned, duly authorized Plenipotentiaries representing the Governments of their respective States, have signed the Treaty.

Done at....., the Republic of.....,
on the day of, year, in Arabic,
English, French and Portuguese, all texts being equally authentic.
