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**EXECUTIVE COUNCIL
Thirty-Fourth Ordinary Session
7 - 8 February 2019
Addis Ababa, ETHIOPIA**

EX.CL/1141(XXXIV)
Original : English

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



African Union
a United and Strong Africa

DRAFT
TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES
AGENCY

DRAFT
TREATY OF THE AFRICAN MEDICINES AGENCY

We, Member States of the African Union,

AFFIRMING THAT quality-assured, safe and efficacious medical products are fundamental to the health and safety of the population of Africa;

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 Assembly of the Union, Assembly/AU/Dec.553(XXIV) on Ebola Virus Disease (EVD) Outbreak, of January 2015);

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 July 2012 AU Assembly Declaration, Assembly/AU/Decl.2(XIX) on the report of AIDS Watch Africa (AWA) Action Committee of Heads of State and Government in which the Council decided that the African Medicine Regulatory Harmonization (AMRH) Initiative shall serve as a foundation for the establishment of AMA.

FURTHER RECALLING the AU Assembly Decision, Assembly/AU/Dec.589(XXVI) of January 2016 on the 1st STC on Legal and Justice Affairs, doc.EX.CL/935(XXVIII) in which the Assembly adopted the AU Model Law on Medical Products 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

“**AU**” refers to the African Union;
“**Africa CDC**” refers to the Africa Centres for Disease Control and Prevention;
“**AMA**” refers to the African Medicines Agency;
“**AMRC**” refers to the African Medicines Regulators Conference;
“**AMRH**” refers to the African Medicines Regulatory Harmonization Initiative of the African Union;
“**API**” refers to Active Pharmaceutical Ingredient;
“**GMP**” refers to Good Manufacturing Practices;
“**NEPAD**” refers to New Partnership for Africa’s Development;
“**NMRA**” refers to National Medicines Regulatory Authority;
“**OAU**” refers to Organization of African Unity;
“**PMPA**” refers to refers to Pharmaceutical Manufacturing Plan for Africa;
“**RCOREs**” refers to Regional Centres of Regulatory Excellence;
“**RECs**” refers to Regional Economic Communities recognized by the African Union;
“**RHOs**” refers to the regional health organizations;
“**TC**” refers to Technical Committee;
“**TWGs**” refers to the Technical Working Group comprised of experts constituted under this Treaty;
“**WHO**” refers to the World Health Organization.

ARTICLE 2

Definitions

In this Statute, unless the context requires otherwise:

"Agency" means the Agency established under Article 3;

"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 States 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.

"Conference of States Parties" means the Conference of the Parties to this Treaty;

"Constitutive Act" means the Constitutive Act of the African Union;

"Diagnostic" means a medicine or medical device or substance used for the analysis or detection of diseases or other medical conditions.

"Director General" means the Director General of the AMA;

"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 means 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**” means complementary medicines, traditional medical products, cosmetics, food supplements and related products;

“**Secretariat**” means the Secretariat of the AMA;

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

“**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 3 Establishment of the AMA

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

ARTICLE 4 Objectives of the AMA

The main objective of AMA is to enhance capacity of States Parties and RECs, to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent.

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 States 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;
 - b. Accountability to States Parties in all its operations;
 - c. Independent decisions, 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. **Confidentiality:** The AMA shall adhere to the principles of confidentiality in all its operations;
7. **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.

ARTICLE 6

Functions

The AMA shall perform the following functions:

- a) Coordinate and strengthen ongoing initiatives to harmonize medical products regulation and enhance the competence of GMP inspectors to do so;
- b) Coordinate the collection, management, storage and sharing of information on all medical products including SF medical products, with all its States Parties and globally;

- c) coordinate joint reviews of applications for the conducting of clinical trials and 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;
- d) 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;
- e) Designate, promote, strengthen, coordinate and monitor RCOREs with a view to developing the capacity of medical products regulatory professionals;
- f) Coordinate and collaborate, where required and on a regular basis, the inspection of drug manufacturing sites, including the regulatory oversight and safety monitoring of medical products, as determined by State Parties and/or the AMA, and make reports available to States Parties;
- g) Promote cooperation, partnership and recognition of regulatory decisions, in support of regional structures and NMRAs, that takes into account mobilization of financial and technical resources to ensure sustainability of the AMA;
- h) Convene, in collaboration with the WHO, the AMRC and other bodies, meetings related to medical products regulation in Africa;
- i) Provide regulatory guidance, scientific opinions and a common framework for regulatory actions on medical products, as well as priority and emerging issues and pandemics 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;
- j) 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 States Parties;
- k) Provide guidance on regulation of traditional medical products;
- l) Provide advice on the marketing authorization application process for the priority drugs described by the States Parties or on the products proposed by the pharmaceutical laboratories;
- m) Monitor the medicines market through the collection of samples in every State Party to ensure the quality of selected drugs, have them analysed and provide the results to States Parties and other interested parties, who will thus have reliable information on the quality of the drugs circulating in their countries and, where necessary, will take appropriate measures;
- n) Develop systems to monitor, evaluate and assess the comprehensiveness of national medical products regulatory systems with the view to recommend measures that will improve efficiency and effectiveness;
- o) Evaluate and decide on selected medical products, including complex molecules, for treatment of priority diseases/conditions as determined by the African Union, and WHO.
- p) Provide technical assistance and resources, where possible, on regulatory matters to States Parties that seek assistance and pool expertise and capacities to strengthen networking for optimal use of the limited resources available;

- q) coordinate access to and network the services available in quality control laboratory services within national and regional regulatory authorities; and
- r) Promote and advocate for the adoption of the AU Model Law on medical products regulation in States Parties and RECs to facilitate regulatory and legal reforms at continental, regional and national levels.

PART TWO
STATUS OF THE AFRICAN MEDICINES AGENCY AND ITS STAFF

ARTICLE 7
Legal Personality

1. The AMA shall have legal personality that is 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 8
Privileges and immunities

The General Convention on the Privileges and Immunities of the OAU and the Additional Protocol to the OAU General Convention on Privileges and Immunities, shall apply to AMA, its members, its international personnel, premises, property and assets.

ARTICLE 9
Headquarters of the AMA

1. The Headquarters of AMA shall be determined by the Assembly of the Union.
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, privileges and immunities for the purposes of the efficient operation of the AMA.

PART THREE
ADMINISTRATION AND INSTITUTIONAL FRAMEWORK

ARTICLE 10
Organs of the AMA

The AMA shall have the following organs:

- a) The Conference of the States Parties;
- b) Governing Board;
- c) The Secretariat; and
- d) Technical Committees.

ARTICLE 11
Establishment of the Conference of the States Parties

The Conference of the States Parties is hereby established as the highest policy-making organ of the AMA. It 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 12
Composition of Conference of the States Parties

1. The Conference of the States Parties shall be composed of all Member States of the African Union who ratify or accede to this Treaty.
2. The States Parties shall be represented by Ministers responsible for health or their duly authorised representatives.
3. The Conference of States Parties shall, 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.
4. The Members of the Bureau shall hold office for a period of two (2) years.
5. The Bureau will meet at least once every year.
6. 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
7. The Conference of States Parties shall have the right to invite observers to attend its meetings, and such observers shall not have the right to vote.

ARTICLE 13
Session of the Conference of the States Parties

1. The Conference of the States 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 States Parties shall be a simple majority of the States Parties to the AMA.
3. Decisions of the Conference of the States Parties shall be taken by consensus, failing which by a two-thirds majority of the State Parties.

ARTICLE 14
Functions of the Conference of the States Parties

The Conference of the States Parties shall be responsible for the following functions:

- a) Set the amount of the annual contribution and special contribution by States Parties, to the budget of the AMA;
- b) Appoint and dissolve, on good 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) Approve Regional Centres of Regulatory Excellence (RCORES), on the recommendation of the Governing Board which makes such recommendation after consultation with the Bureau;
- h) 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;
- i) Adopt its rules of procedure and for any subsidiary organs
- j) Recommend any amendments to this Treaty to the Assembly for consideration.

ARTICLE 15
Establishment of the Governing Board

The Governing Board of the AMA is hereby established by this Treaty. It shall be appointed by and answerable to the Conference of the State Parties.

ARTICLE 16
Composition of the Governing Board

1. The Board shall consist of Nine (9) members, composed as follows:
 - a) Five (5) Heads of NMRAs, one (1) drawn from each of the AU-recognized regions;
 - b) One (1) Representative of RECs responsible for regulatory affairs, to be appointed by the RECs on rotational basis;
 - 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 AMA 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 States Parties.
5. The Director General of the AMA, shall serve as the Secretary of the Board.

ARTICLE 17
Sessions of the Governing Board

1. The Board shall meet:
 - (a) in regular session at least once a year;
 - (b) in extraordinary session at the request of the Chairperson of the Board, the Bureau of the Conference of States Parties or a simple majority of the members of the Board.
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 which, by a simple majority vote of the Members present.

4. In the event the Members are not in a position to attend personally, duly accredited representatives shall represent them in accordance with the rules of the governing board
5. The Board shall consider and recommend its Rules of Procedure and those of the Technical Committees to the Conference of States 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 18

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) recommend for endorsement by the Conference of the States Parties, the appointment and dismissal of the Director General of AMA;
 - c) appoint and dismiss, if necessary, the independent auditor of the AMA;
 - d) recommend regulations setting out conditions of service of the staff of the Secretariat.
 - e) assist the Secretariat with resource mobilization;
 - f) establish technical committees (TCs) to provide technical guidance on the functions of the AMA.
 - g) establish rules governing the issuance of scientific opinions and guidance to States Parties, including expedited approval of products during health outbreaks;
 - h) approve recommendations submitted by the TCs;
 - i) establish such subsidiary or affiliated entities for purposes of carrying out the functions of AMA as it considers necessary.
 - j) carry out any other functions referred to it by the Conference of the States Parties or the Bureau as mandated by the Conference of States Parties.

ARTICLE 19

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 (which will become Commissioner for Health, Humanitarian Affairs and Social Development) 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 NMRAs, taking into account the Union's principle of regional rotation and gender equity.

ARTICLE 20
Establishment of Technical Committees of the AMA

1. The Board shall establish permanent or ad hoc technical committees to provide technical guidance on specific areas of regulatory expertise.
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 21
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.
2. The technical committees shall carry out any other functions as may be assigned to it by the Board.

ARTICLE 22
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. Other 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 23
The Secretariat of the AMA

1. The Secretariat of the AMA, located at the headquarters shall be responsible for coordinating the implementation of the decisions of the Conference of the States 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 States Parties;
 - c) coordinate the programmes and work of all technical committees and the Board.
 - d) establish and maintain capacity building and regulatory systems strengthening programmes for the benefit of Member States;
 - e) 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 States Parties;
 - f) perform any other duties as may be assigned by the Board and the Conference of the States Parties and other relevant structures of the African Union.

ARTICLE 24
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 the States Parties upon the recommendation of the Governing Board.

3. The Director General, shall serve as the Chief Executive Officer and shall represent the AMA in all matters, and shall report to the Board, the Conference of the States Parties and the African Union, as appropriate.
4. The Director General shall be appointed for a term of four (4) years, renewable once, in accordance with regional rotations.
5. The Director General shall recruit staff of the Secretariat in line with the structure and procedure approved by the Conference of States 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 States 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 25
Objections to Scientific Opinions

1. In the event that a person or entity duly objects to a scientific opinion, advice or decisions issued by AMA, he/she may lodge their objection with the Board.
2. The Board shall set up an independent panel to consider the objection in line with the agreed procedures.
3. The Board shall develop procedures for objection.

PART FOUR
FINANCIAL PROVISIONS

ARTICLE 26
Financial Resources

1. The Conference of States Parties shall:
 - (a) set the annual assessed contribution to be paid by the States Parties;

- (b) adopt the annual the budget of the AMA;
 - (c) determine the appropriate sanctions to be imposed on any Party that defaults in the payment of its contributions to the budget of the AMA in line with the sanctions regime as adopted by the Assembly.
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 States Parties, provided there is no conflict of interest.
 4. Pending the adoption of the AMA Financial Rules by the Conference of States Parties, it shall abide by the AU Financial Rules and Regulations where appropriate.

ARTICLE 27

Expenses

1. The Secretariat expenses for administrative, operational and investment purposes shall be 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 States Parties.
2. The finances and accounts of the AMA shall be audited by an independent auditor appointed by the Board.

PART FIVE RELATIONS WITH THE AU, MEMBER STATES AND OTHER PARTNER INSTITUTIONS

ARTICLE 28 Relationship with the African Union

1. The AMA shall maintain a close working relationship with the AU.
2. The AMA shall present a written annual report on its activities to the AU Assembly through the relevant STC and Executive Council.

ARTICLE 29
Relationship with States

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

ARTICLE 30
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 31
Working Languages

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

ARTICLE 32
Settlement of Disputes

1. Any dispute that may arise between State Parties with regard to the interpretation, application and implementation of this Statute shall be settled by mutual consent between the States concerned, including through negotiations, mediation, conciliation or other peaceful means.
2. In the event of failure to settle the dispute, the Parties may, by mutual consent, refer the dispute to:

- a) To an Arbitration Panel of three (3) Arbitrators whose appointment shall be as follows:
- i. Each Party to the dispute shall appoint one (1) Arbitrator;
 - ii. The third arbitrator, who shall be the Chairperson of the Arbitration Tribunal, shall be chosen by common agreement between the arbitrators appointed by the parties to the dispute; and
 - iii. The decision of the Panel of Arbitrators shall be binding.

Or

- b) The African Court of Justice Human and Peoples' Rights.

ARTICLE 33 Reservations

1. A State Party may, when ratifying or acceding to this statute submit in writing a reservation, with respect to any of the provisions of this treaty.
2. Reservations shall not be incompatible with the objects and purpose of this treaty.
3. Unless otherwise provided, a reservation may be withdrawn at any time.
4. The withdrawal of a reservation must be submitted in writing to the Chairperson of the Commission who shall notify other States Parties of the withdrawal accordingly.

ARTICLE 34 Withdrawal

1. At any time after three years from the date of entry into force of this treaty, a State Party may withdraw by giving written notification to the depositary.
2. Withdrawal shall be effective one year after receipt of notification by the depositary, or on such a later date as may be specified in the notification.
3. Withdrawal shall not affect any obligations of the withdrawing State Party prior to the withdrawal.

ARTICLE 35 Dissolution

1. The AMA may be dissolved by the agreement of two-thirds of the States Parties to this Treaty at a meeting of the Conference of the States Parties and upon endorsement by the AU Assembly.
- 2.

3. 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.
4. Once agreement has been reached on the dissolution of the AMA, the Conference of the States Parties shall establish the modalities for the liquidation of the assets of the AMA.

ARTICLE 36 **Amendment and Revision**

1. Any State Party may submit proposals for the amendment or revision of this Treaty. Such proposal shall be adopted at a meeting of a Conference of States Parties.
2. Proposals for amendment or revision shall be submitted to the Chairperson of the Commission who shall transmit the amendment or revision to the Chairperson of the Governing Board within thirty days (30) of receipt thereof.
3. The Conference of States Parties, upon the advice of the Governing Board shall examine these proposals within a period of one year from the date of receipt of such proposals.
4. Amendment or revision shall be adopted by the conference of States Parties by consensus or, failing which, by two thirds majority.
5. The Amendment or revision shall enter into force in accordance with the procedures outlined in Article 38 of this Treaty.

ARTICLE 37 **Signature, Ratification and Accession**

1. This Treaty shall be open to Member States of the Union for signature and ratification or accession.
2. The instrument of ratification or accession to the present Treaty shall be deposited with the Chairperson of the Commission who shall notify member states of the union of the deposit of the instrument of ratification or accession.

ARTICLE 38 **Entry into Force**

1. This Treaty shall enter into force thirty days (30) after the deposit of the fifteenth (15) instrument of ratification and accession.

2. The Chairperson of the Commission shall inform all Member States of the Union of the entry into force of the present treaty.
3. For any member state of the Union acceding to the present treaty, the treaty shall come into force in respect of that State on the date of the deposit of its instrument of accession.

ARTICLE 39
Depository

This Treaty shall be deposited with the Chairperson of the AU Commission, who shall transmit a certified true copy of the Statute to the Government of each signatory State.

ARTICLE 40
Registration

The Chairperson of the Commission upon the entry into force of this Treaty shall register this Treaty with the United Nations Secretary General in conformity with Article 102 of the Charter of the United Nations.

ARTICLE 41
Authentic Texts

This Treaty is drawn up in four (4) original texts in the Arabic, English, French and Portuguese languages, all of which are equally authentic.

IN WITNESS WHEREOF, WE the Heads of State and Government or duly authorised representatives of the Member States of the African Union have signed and sealed this Treaty in four original texts in Arabic, English, French, and Portuguese languages, all texts being equally authentic.

SIGNED at, on this day of in the year 2018.

2019-02-07

Draft treaty for the establishment of the African Medicines Agency

Africa Union

African Union

<https://archives.au.int/handle/123456789/6512>

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