TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY

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(AMA)

PREAMBLE

THE PARTIES,

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

COGNISANT THAT existence of SF products pose a risk to public health, harm patients and undermine 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 **e**ndorsed 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 COGNISANT 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 efforts of 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 24th Ordinary Session of the NEPAD Heads of State and Government Orientation Committee of January 2015 Decision {Assembly/AU/Dec.563(XXIV) Para 11} as part of the implementation of the African Medicines Regulatory Harmonization (AMRH) Initiative;

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 regional economic communities (RECs) and regional health organizations (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 local production and trade in pharmaceuticals 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 Executive Council Decision, {EX.CL/Dec.857 (XXVI))} in January 2015 which 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) Initiative, and as part of PMPA framework; and the request to the AUC, NEPAD Agency and WHO to compose a joint Secretariat for the establishment of AMA and to coordinate the work of the AMA Task Team;

FURTHER RECOGNIZING the AU Assembly Decision Assembly/AU/Dec.1-17(XXVI) and Declaration Assembly/AU/Decl.1-2(XXVI) of January 2016 taken during its 26th Ordinary Session 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 them enter 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 and health technologies 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 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
Definitions and Acronyms

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

"AMRH" means the African Medicines Regulatory Harmonization Initiative of the African Union;

"Africa CDC" means the Africa Centres for Disease Control and Prevention;

"Assembly" means the Assembly of Heads of State and Government of the African Union;

"AMA" means the African Medicines Agency;

"AMRC" means the African Medicines Regulators Conference;

"AU" means the African Union as established by the Constitutive Act;

"Board" means the Governing Board of the AMA;

"Commission" means the African Union Commission;

"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;

''**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" include medicines, vaccines, 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;

"NEPAD" means New Partnership for Africa's Development;

"NMRA" means National Medicines Regulatory Authority;

"other regulated products" may include complementary medicines, traditional medical products, cosmetics, food and related products;

"Party" means an AU Member State that is a Party to this Treaty;

"REC" means Regional Economic Community recognized by the African Union;

"RCOREs" means Regional Centres of Regulatory Excellence;

"RHOs" means the Regional Health Organizations;

"Secretariat" means the Secretariat of the AMA;

"Treaty" means a Treaty to establish the African Medicines Agency

"TWGs" means the Technical Working Group comprised of experts constituted under this Treaty;

"WHO" means the World Health Organization.

ARTICLE 2
Establishment of the AMA

AMA is hereby established as a Specialized Agency of the AU to assist Member States of the African Union to improve their capacities to regulate medical products.

ARTICLE 3
Objectives of the AMA

The objectives of the AMA are to:

a) ensure the coordination and strengthening of continental initiatives to harmonize medical products regulation;
b) provide guidance and technical support to, and complement and enhance the efforts of, the regional economic communities (RECs), regional health organizations (RHOs) and Member States,
c) contribute to improving access to quality, safe and efficacious medical products and health technologies on the continent.

ARTICLE 4
Functions of the AMA

1. The AMA shall undertake such functions as may be necessary to achieve its objectives.

2. 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, and 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, Regional Economic Communities, or Member States;
   d. Provide technical assistance, where possible, on regulatory matters to countries 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 and health technologies;
   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 for the use of the AU Model Law on medical products regulation in member states 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 Member State 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.

ARTICLE 5
Guiding Principles

1. **Leadership:** The AMA is an institution that provides strategic direction and promotes good public health practice within Member States through capacity building, and the promotion of continuous quality improvement in the delivery of medical products and health technology 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. Member States will maintain national-level ownership of the AMA simultaneously through an advisory role in the shaping of AMA priorities and through direct programmatic engagement.

4. **Timely dissemination of Information:** The AMA leadership will regularly update RECs and Member State NMRAs on on-going programs and activities through strong partnerships and networking.

5. **Transparency and Accountability:** The AMA will operate in accordance with generally accepted international standards of governance, transparency and accountability.

    a. In the interest of the public, 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 will be accountable to Member States in all its operations.

6. **Value-addition:** In every strategic aim, objective or activity, the AMA will demonstrate how its initiative adds value to the medical products and health technologies regulatory activities of Member States and other partners.

PART TWO
STATUS OF THE AFRICAN MEDICINES AGENCY AND ITS STAFF

ARTICLE 6
Legal Capacity

1. The AMA shall have full legal personality in the territory of each Party, necessary for the fulfilment of its objectives and the exercise of its functions in accordance with this Treaty.

2. For the 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 of the AMA

The Parties undertake to accord to the AMA and all its personnel, 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 will be situated in such a location as the Conference of Parties shall determine, based on criteria agreed upon by the Conference of Parties.

2. The AU shall, as soon as practicable, enter into an agreement with the government of the country in which its 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) Technical Working Groups; and
d) The Secretariat.

ARTICLE 10
The Establishment, Composition and Session of the Conference of the Parties

1. The Conference of the Parties is hereby established as the supreme 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.

2. The Conference of Parties shall be composed of all Parties to this Treaty and shall function as the policy organ of the AMA.

3. The Parties shall be represented by Ministers responsible for Health or their duly authorised representatives.

4. The Conference of the Parties shall meet at least once every two years in ordinary session and at such other times as may be requested in writing by at least two-thirds of the Parties, or by the Governing Board of the AMA.

5. The quorum of the Conference of the Parties shall be a simple majority of the Parties to the AMA.

6. Decisions of the Conference of Parties shall be taken by a two-thirds majority of the Parties present and voting.

7. The Conference of Parties shall 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.

8. The Conference of Parties shall have right to invite observers to attend its meetings, and such observers shall not have the right to vote.

ARTICLE 11
Functions of the Conference of the 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 in accordance with Article 12;
    c) Approve the structure and administrative guidelines of the Secretariat, as well as adopt its governing rules and regulations;
    d) Provide policy direction to the AMA and address policy matters relating to the Agency;
    e) Determine the location for the headquarters of the AMA in accordance with the criteria for hosting the AMA and its organs, as adopted by the Conference of the Parties;
    f) 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;
    g) Amend this Treaty in accordance with Article 31;
    h) Settle disputes regarding the interpretation and/or application of the Treaty, in accordance with Article 32.
    i) Dissolve the AMA, if deemed necessary, in accordance with Article 33;
    j) Delegate any of its functions to any organ of the AMA, and
    Endorse the appointment of the Director General by the Board.

ARTICLE 12
Establishment of the Governing Board

There shall be a Governing Board of the AMA appointed by and answerable to the Conference of the Parties.

ARTICLE 13
Composition of the Governing Board

1. The Board shall consist of (17) members, composed as follows:

a) Ten (10) Heads of NMRAs, two (2) drawn from each of the AU-recognised regions;
b) Two (2) 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 Ethics Committees (NECs), on a rotational basis and appointed by the RECs;
e) The Commissioner for Social Affairs, AUC;
f) One (1) representative of the Civil Society Organizations in Health nominated by an AU-recognised regional CSO forum.

2. The Board shall elect its own Chairperson and Vice Chairperson from amongst 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. The Board may invite such experts as may be required, to its meetings.

5. Remuneration for Members of the Board shall be determined by the Conference of the Parties.

6. The Director General of the AMA, shall serve as the Secretary of the Board.

ARTICLE 14
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) Assist the Secretariat with resource mobilization;

f) Establish Technical Working Groups (TWGs) to provide technical guidance on the functions of the AMA.
g) Establish rules governing the issuance of scientific opinions and guidance to Parties, including expedited approval of products during health outbreaks;
h) Approve recommendations submitted by the TWGs;
i) Provide scientific guidance to 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;
j) Approve the designation and re-designation of the RCOREs;
k) Carry out any other functions as it may deem necessary or referred to it by the Conference of the Parties.

ARTICLE 15
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 and representative of civil society shall be a non-renewable period of two (2) years.
   a) The Commissioner of Social Affairs shall hold a permanent seat.
3. 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 16
Meetings of the Governing Board

1. The Board shall meet in regular session at least twice a year, and may convene an extraordinary session at the request of the Chairperson of the Board or of the Conference of the Parties.
2. The quorum for meetings of the Board shall be two-thirds of the members of the Board.
3. The decision of the Board shall, as far as possible, be taken by consensus and failing that, by a simple majority vote.
4. Alternate members, identified by the nominating structures, will deputise for the members of the Board in case of their unavailability.
5. The Board shall adopt its own Rules of Procedure and those of the Technical Working Groups.

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

ARTICLE 17
Establishment of Technical Working Groups of the AMA

1. There shall be established Technical Working Groups 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 18

Functions of the Technical Working Groups

1. The TWGs 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 TWG 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;
    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;
    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.

ARTICLE 19

Composition of the Technical Working Groups

1. The TWGs shall be composed of not more than nine (9) experts representing a wide range of competencies and experiences.
2. Members of the TWGs shall be drawn from Parties NMRAs as appointed by the Board and, as far as possible reflect equity between geographic regions.
3. The Board may also appoint, as consultants, additional experts from academia, research community, industry, and consumer and patient groups, with due regard to avoiding conflicts of interest..
4. The technical experts in relevant fields may be drawn from across and outside the continent, when necessary.
5. Each TWG shall be headed by a Chair and Vice Chair as specified in its terms of reference.
6. All members of the TWGs shall be subject to the rules of confidentiality, declaration of interest and conflict of interest.

ARTICLE 20
The Secretariat of the AMA

1. The Secretariat 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 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, which term shall be renewable once.

4. The Director General shall appoint staff of the Secretariat in line with the approved structure and procedures.

5. The Board shall adopt regulations setting out conditions of service of the staff of the Secretariat.

6. 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 Working Groups and the Board.
e) Establish and maintain capacity building and regulatory systems strengthening programs for the benefit of Member States;
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 21
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 a person of demonstrated competence, leadership ability and integrity, expertise and experience in the subject matter of this Treaty or related issues.

3. The Director General shall be a national of the Party to this Treaty, appointed for a term of four (4) years, which term may be renewed once.

4. The Conference of the Parties shall adopt regulations setting out the powers, duties and conditions of service of the Director General.

5. 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

There shall 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 objects to a scientific opinion or advice issued by AMA, he/she may appeal to the Board.

2. The Board shall set up a panel to review the complaint in line with agreed procedures.

PART FOUR

FINANCIAL PROVISIONS

ARTICLE 24
Financial Resources

1. The annual assessed contribution to be paid by the 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 Conference of the 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.

3. The AMA shall devise innovative ways of resource mobilization.

4. 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, provided there is no conflict of interest.

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 adopted by the Conference of the Parties.

2. Expenses incurred by representatives of the Parties and by their alternates in attending meetings of the Conference of the Parties shall be borne by their respective governments.

3. The finances and accounts of the AMA shall be audited by an independent auditor appointed by the Board in terms of Article 14 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 Executive Council.

ARTICLE 27
Relationship with States

1. The AMA may establish and maintain active co-operation with AU Member States, other UN agencies, inter-governmental organizations and non-governmental organizations or other institutions, including specialised agencies other than specifically provided for in this Treaty, that AMA considers necessary to assist in achieving its objectives.

2. The 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 World Health Organization (WHO).
2. The AMA shall establish and maintain a close working relationship and collaboration with the Africa Centres for Disease Control and Prevention (Africa CDC).
3. The AMA shall establish and maintain a close working relationship and collaboration with Collaboration with Regional Economic Communities (RECs).

ARTICLE 29
Transitional Provisions

Pending the entry into force of this Treaty and during the transitional period, interim structures shall be constituted:

1. The African Medicines Regulatory Harmonization (AMRH) Initiative shall serve as a foundation for establishment of the AMA in accordance with the AU Executive Council Decision, {EX.CL/Dec.857 (XXVI))} of January 2015.

2. A minimum of fifteen (15) signatories to this Treaty shall be required in order to function as the interim Conference of the Parties.

3. Upon constitution of the Interim Conference of the Parties, the AMRH Secretariat shall be designated as an “Interim AMA Secretariat”

4. The Interim AMA Secretariat shall continue with the work of harmonization, capacity building and all functions of the former AMRH until ratification of the signed treaty.

5. Upon ratification of the treaty by all 15 signatories, the designated Interim Conference of Parties and the Interim AMA Secretariat shall be transformed into “Conference of the Parties” and “The AMA Secretariat” respectively. The work of the existing Steering Committee and Technical Working Groups, under the AMRH Initiative, shall be absorbed by the relevant AMA Governance Structures.

6. Legal liability will vest, during the transitional period, in the Interim Secretariat and in the AU in the final instance.

PART SIX
FINAL PROVISIONS

ARTICLE 30
Working Language

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

ARTICLE 31
Amendment of the Treaty

1. Any 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 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 adopted by a two-thirds majority vote of the Parties of the AMA.

4. An amendment shall come into force 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 32
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 Parties.

2. If the Conference of the Parties does not reach a decision on the dispute, or if the decision of the Conference of the 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 the 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 Parties to make the necessary nominations, 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 33
Dissolution

1. The AMA may be dissolved by the agreement of two-thirds of the Parties to this Treaty at a meeting of the Conference of the Parties in accordance with the Article 11(i) 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 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 Parties shall establish the modalities for the liquidation of the assets of the AMA.

ARTICLE 34
Signature, Ratification and Accession

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 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 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 approval

5. This Treaty shall enter into force definitively thirty (30) day from the date of the deposit of the 15th instrument of ratification, acceptance or approval.

6. Financial obligations shall not be imposed on a Party until it has ratified this Treaty.

7. 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.

8. The Instruments of ratification, acceptance or approval shall be deposited with the Chairperson of the AU Commission.

9. Chairperson of the AU Commission shall transmit certified copies of this Treaty and information relating to the ratification, acceptance or approval of this Treaty to all Member States of the AU.

ARTICLE 35
Reservations

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

ARTICLE 36
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 Parties to this Treaty.

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 authorised 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.

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