



THE NATIONAL ASSEMBLY

MINISTRY OF FOREIGN AFFAIRS JUN 2022

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MEMORANDUM

ON THE

RATIFICATION OF AFRICAN UNION TREATY

FOR THE ESTABLISHMENT OF THE

AFRICAN MEDICINES AGENCY (AMA)

**MEMORANDUM ON THE RATIFICATION OF AFRICAN UNION TREATY  
FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY  
(AMA)**

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**1.0 OBJECTIVE OF THE MEMORANDUM**

- 1.1 The objective of this Memorandum is to seek approval for Kenya's ratification of the Ratification of African Union Treaty for the Establishment of the African Medicines Agency (AMA)
- 1.2 The ratification process was approved by the Cabinet during its meeting held on **12<sup>th</sup> May, 2022.**

**2.0 BACKGROUND**

- 2.1 Africa's public and private sector actors are increasingly recognizing that real region-wide progress and transformation is only attainable through improved connectivity, competitive logistics and production value chain integration in targeted strategic sectors including pharmaceuticals and agriculture. This, together with the establishment of regulatory policy convergence, is vital for the continent's trade and regional integration agenda.
- 2.2 The pharmaceutical sector, under the guidance of the African Union, has developed and launched initiatives under the Pharmaceutical Manufacturing Plan for Africa (PMPA) framework of the AU endorsed by the Assembly in 2005.
- 2.3 In 2019, due to the fact that, weak regulatory systems have resulted in the circulation of substandard and falsified (SF) medical products in many African Union Member States; posing risk to public health, harming patients and undermining confidence in healthcare delivery systems; the Assembly of Heads of State and Government, at its 32nd

ordinary session decision Assembly/AU/Dec.735(XXXII) reaffirmed the Executive Council 34th ordinary session decision EX.CL/1141(XXXIV) to establish the African Medicines Agency placing an emphasis on investment in regulatory capacity strengthening.

- 2.5 The Treaty seeks to establish the African Medicines Agency (AMA) to enhance the capacity of State Parties and Regional Economic Communities (RECs) to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent.
- 2.6 Twenty-six (26) member states (Algeria, Benin, Burundi, Cameroon, Chad, Cote d'Ivoire, Egypt, Gabon, Ghana, Guinea, Madagascar, Mali, Mauritius, Morocco, Niger, Rwanda, Republic of Congo, Saharawi Arab Democratic Republic, Senegal, Seychelles, Sierra Leone, Tanzania, Togo, Tunisia, Uganda and Zimbabwe) have signed the treaty
- 2.7 Seventeen (17) member states (Algeria, Benin, Burkina Faso, Cameroon, Chad, Gabon, Ghana, Guinea, Mali, Mauritius, Namibia, Niger, Rwanda, Seychelles, Sierra Leone, Tunisia and Zimbabwe) have ratified the Treaty for the Establishment of the African Medicines Agency and deposited the legal instrument of ratification to the Commission.
- 2.8 The Treaty for the Establishment of the African Medicines Agency (AMA) entered into force on **5<sup>th</sup> November 2021**.

### **3.0 OBJECT AND SUBJECT MATTER OF THE CONVENTION**

- 3.1 The African Medicines Agency is a Specialized Agency of the African Union with its own rules, membership and resources to enhance the capacity of State Parties and Regional Economic Communities (RECs), to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent.

- 3.2 The AMA intends to provide a platform for coordination and strengthening of on-going regional and continental harmonization initiatives, serving to pool expertise and capacities for optimal use of the limited resources. The AMA will not replace existing national and regional regulatory bodies or harmonization initiatives at RECs level.
- 3.3 AMA will complement their efforts and contribute to their capacity building towards improving access to quality assured medical products ~~within the agenda of Universal Health Coverage and the Sustainable~~ Development Goals.
- 3.4 AMA defines acceptable standards in the regulation of medical products in the continent. The establishment of a Continental Agency that contributes to the improved regulation of medicines, medical products and technologies is therefore timely and critical.

#### **4.0 OBLIGATIONS IMPOSED BY THE PROTOCOL**

- 4.1 The AMA's vision is to ensure that all Africans have access to quality-assured, safe, efficacious and affordable medical products, that meet internationally recognised standards, for priority diseases or conditions
- 4.2 The obligations of the AMA Treaty are forward looking. States parties are obligated to *inter alia*:-
- a. To coordinate national and sub-regional medicines regulatory systems;
  - b. To conduct regulatory oversight of selected medical products including traditional medicines;
  - c. To promote cooperation, harmonisation and the mutual recognition of regulatory decision;
  - d. To strength and harmonize efforts of the African Union-recognized RECs, RHOs and Member States; and

- e. To complement and enhance collaboration and contribute to improving patients' access to quality, safe and efficacious medical products and health technologies on the continent.

## **5.0 PROBLEM ANALYSIS**

- 5.1 An assessment performed by the World Health Organisation (WHO) of 26 African National Medicines Regulatory Authorities (NMRAs) between 2002 and 2009 found that only 15% of these NMRAs were mandated to carry out functions of marketing authorization, licensing, inspection, quality control and pharmacovigilance of medical products.
- 5.2 In many cases, not all of these functions were operational, including having access to a functional national regulatory quality control laboratory. It is important to note that not all NMRAs are expected to perform all the regulatory functions on their own, but could rely on other NMRAs' decisions such as for Good Manufacturing Practice inspection of foreign manufacturing sites and marketing authorisations.
- 5.3 The assessment found that even where local manufacturing occurred, good distribution practices (GDP) were poorly enforced thereby increasing the risk of substandard, spurious, falsely labelled, falsified and counterfeit medical products in the market. In addition to the above matters, common challenges within the continental regulatory space include lack of published standards and operating procedures, and shortage of qualified personnel.
- 5.4 Although the assessment was based on information obtained over twelve years ago, for the most part, this reflection is still valid in the current pharmaceutical regulation situation in the continent.
- 5.5 Access to quality health products and technologies, especially for low- and middle-income countries, during the COVID-19 pandemic continues to be a challenge due to disruptions in the global supply

chain systems. If established in the coming years, AMA will help African nations to fight pandemics and support national and regional responses by ensuring that only high-quality drugs, vaccines, and other health-related supplies reach African populations.

## **6.0 JUSTIFICATION FOR RATIFICATION**

6.1 The signing and ratification of the Treaty by Kenya will demonstrate ~~Kenya's commitment to the Continents' collective action to the~~ improved regulation of medicines, medical products and technologies. Ratification will bring about positive consequences both to the country and States Members which include:

### **i) Ease of Doing Business**

The AMA will provide guidance, streamline and enhance efforts of the RECs towards harmonization of medical products regulation. This will ensure efficient resource utilization by reducing duplication of investments by Member states and expediting introduction of registered medicines in the regional market through harmonized procedures.

The AMA will lead to reduction of operational costs as Kenya will employ mutual recognition of the regulatory decisions of other countries; thereby offering incentives for manufacturers to set up factories within the region thus attracting investments.

### **ii) Access to Safe, Quality and Efficacious Medical Products**

The AMA will serve as a catalyst for stronger regulatory oversight to counteract proliferation of Substandard and Falsified medical products and enable competitiveness of locally produced medicines, particularly those used to treat diseases and conditions disproportionately affecting the African continent. This will be achieved through cross-border enforcement based on

enhanced collaboration amongst stakeholders including customs, police and judiciary.

**iii) Capacity Building**

Expertise built as a result of interaction by professionals from the various countries, and routine assessment of regulatory systems encourages regulatory agencies to improve processes. This translates to enhanced quality assurance systems for medical products.

**iv) Access to the African Continental Free Trade Area**

The African Continental Free Trade Area (AfCFTA), makes Africa the largest geographically integrated trading area in the world, allowing access without tariffs to a market of over 1.2 billion potential consumers and by extension creating an African Economic Community by 2028. This therefore will have significant implications to public health and safety, hence regulation of health products and technologies shall be critical to guaranteeing the protection of this market from fake, substandard, and counterfeit products and services.

**v) African Industrialisation**

The progressive industrialization of Africa, and the possibility of transforming raw materials into products, including into medicines, medical devices and technologies; requires Kenya to strategically position herself as a leader under the AU recognized RECs. This will be in line to advance the implementation of the Pharmaceutical Manufacturing Plan of Africa.

**7.0 CONSTITUTIONAL AND LEGISLATIVE IMPLICATIONS**

7.1 The Convention is consistent with the Constitution and promotes constitutional values and objectives, it does not allude to an amendment of the Constitution.

7.2 The Treaty advocates for the adoption of the African Union Model Law on Regulation of Medical products. This will require Kenya to amend existing relevant legislation and policies to adapt to this model law in

the spirit of harmonization to enable implementation of the Convention. Some of which may include, the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya, Health Products and Technologies Bill.

7.3 Kenya may also need to generate guidelines for the periodic reporting obligations generated from joint assessment exercises to establish the capacity of member states in health products and technologies and technical capacities, in line with the proposed logical framework for AMA.

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7.4 Other non-legislative, yet practical measures that Kenya may need to undertake include: the review of existing policies and develop regionally cohesive protocols to enable participation in harmonization activities.

## **8.0 IMPLICATIONS RELATING TO COUNTIES**

8.1 The obligations imposed under the Protocols are under the purview of the National Government.

## **9.0 FINANCIAL IMPLICATIONS**

9.1 At the onset, the AMA will be supported by donor funding. Thereafter, States Parties will be required to contribute the amounts to be assessed by the Conference of States Parties towards the AMA budget upon the lapse of donor support funding.

9.2 The financial requirements during implementation will be catered for during the normal budgetary estimates of the relevant Ministries, Departments and Agencies.

## **10. MINISTERIAL RESPONSIBILITY**

10.1 The Ministry that will be responsible for the implementation and any activity in regard to the Convention is the Ministry of Health.



10.2 The Office of the Attorney General and Department of Justice and the Ministry of Foreign Affairs will coordinate the reporting process on State obligations pursuant to the Treaty Making and Ratification Act No 45 of 2012.

**11. RESERVATIONS**

11.1 Article 35, permits member States to submit reservations when ratifying the Treaty on condition that it is compatible with the objects and purpose of the Treaty. Presently, the Ministry of Health has no reservations.

**12. PUBLIC PARTICIPATION**

12.1 Public participation has been undertaken via various fora including and virtual meetings.

**13. RECOMMENDATION TO THE NATIONAL ASSEMBLY**

13.1 In consideration of the aforementioned facts, the National Assembly is invited to:

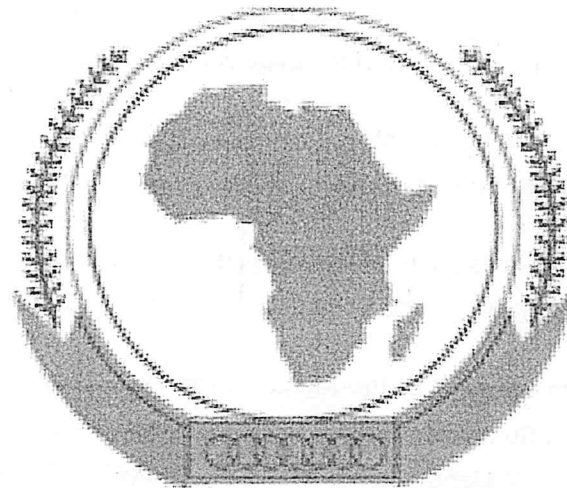
1. Note the contents of the Memorandum;
2. Consider and approve Kenya's Ratification of African Union Treaty for the Establishment of the African Medicines Agency; and
3. Direct the Cabinet Secretary of Foreign Affairs to prepare and deposit the relevant instruments to the Depository, the Chairperson of the African Union Commission.

SIGNED.....

DATED.....<sup>30<sup>th</sup></sup>..... MAY, 2022

**AMB. RAYCHELLE OMAMO, SC, EGH  
CABINET SECRETARY  
MINISTRY OF FOREIGN AFFAIRS**





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

## TREATY OF THE AFRICAN MEDICINES AGENCY (AMA)

**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 1<sup>st</sup> 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”** 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 biosimilar 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. 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 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.

**ADOPTED BY THE THIRTY-SECOND ORDINARY SESSION OF  
THE ASSEMBLY, HELD IN ADDIS-ABABA, ETHIOPIA**

**11<sup>TH</sup> FEBRUARY 2019**

