REPUBLIC OF KENYA
THE NATIONAL ASSEMBLY
THIRTEENTH PARLIAMENT – SECOND SESSION – 2023
DIRECTORATE OF DEPARTMENTAL COMMITTEES
DEPARTMENTAL COMMITTEE ON HEALTH

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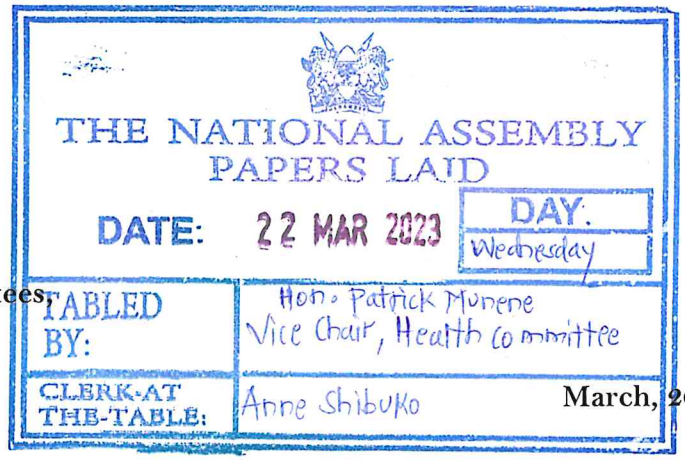
REPORT OF THE DEPARTMENTAL COMMITTEE ON HEALTH ON THE RATIFICATION OF AFRICAN UNION TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)



Directorate of Departmental Committees,
Clerk's Chambers,
Parliament Buildings,
NAIROBI.

March, 2023

Table of Contents

LIST OF ANNEXURES

CHAIRPERSON'S FOREWORD

The Cabinet Secretary, Ministry of Foreign Affairs, submitted a memorandum to the National Assembly dated 18th May, 2022 regarding the ratification of the African Union Treaty for the establishment of the African Medicines Agency (AMA). The memorandum and text of the Protocols were committed to the Departmental Committee on Health for processing. Considering that, the House proceeded to *Sine die* recess immediately thereafter, marking the end of the 12th Parliament, the paper could not be considered. The aid treaty was re-tabled before the House on Thursday. December 1, 2022 in the 13th Parliament.

The African Union treaty on establishment of the African Medicines Agency (AMA) was approved on 12th May, 2022 by Cabinet during its meeting. Considering the protocols, the Committee held a total of five sittings.

Pursuant to the provisions of Article 118 (1)(b) of the Constitution on public participation and section 8(3) of the Treaty Making and Ratification Act of 2012, the Committee placed advertisements in two local dailies of nationwide circulation, on 26th January 2023 requesting for submissions of memoranda on the subject. The Committee received a memorandum in support of the African Medicines Agency (AMA).

Further, the Committee deliberated on the treaty with the agencies involved, in recognition of the crosscutting nature of the treaty.

The Committee is thankful to the Office of the Speaker and the Clerk of the National Assembly for the logistical and technical support accorded to it during its Sittings.

Pursuant to Section 8(4) of the Treaty Making and Ratification Act, 2012 and Standing Order 199, it is my pleasant duty to present the Report of the Departmental Committee on Health on its consideration of the treaty on the establishment of the African Medicines Agency (AMA).

HON. DR. ROBERT PUKOSE, MP- CHAIRPERSON
DEPARTMENTAL COMMITTEE ON HEALTH

1.0 PREFACE

1.1 Establishment of the Committee

The Departmental Committee on Health is established pursuant to Standing Order 216.

1.2 Mandate of the Committee

The Committee is mandated under Standing Order 216 (4) and (5) to inter alia-

a) *investigate, inquire into, and report on all matters relating to the mandate, management, activities, administration, operations and estimates of the assigned ministries and departments;*

b) *study the programme and policy objectives of ministries and departments and the effectiveness of the implementation and effectiveness of the implementation;*

c) *study and review all legislation referred to it;*

d) *study, assess and analyze the relative success of the ministries and departments as measured by the results obtained as compared with their stated objectives;*

e) *investigate and inquire into all matters relating to the assigned ministries and departments as they may deem necessary, and as may be referred to them by the House;*

f) *vet and report on all appointments where the Constitution or any law requires the National Assembly to approve, except those under Standing Order 204 (Committee on Appointments);*

g) examine treaties, agreements and conventions;

h) *make reports and recommendations to the House as often as possible, including recommendation of proposed legislation;*

i) *consider reports of Commissions and independent offices submitted to the house pursuant to the provisions of Article 254 of the Constitution; and*

j) *examine any questions raised by Members on a matter within its mandate.*

In executing its mandate, the Committee oversights the Ministry of Health;

According to second Schedule of the Standing Orders, the Committee is mandated to consider the following subjects:

i. Health;

ii. Medical care and Health insurance including universal health coverage.

1.3 Committee Membership

The Committee comprises the following fifteen (15) Members;

4. The Committee was constituted by the House on 27th October 2022 and comprises the following Members;

Chairperson
Hon. (Dr.) Robert Pukose, MP
Endebes Constituency
UDA Party

Vice-Chairperson
Hon. Ntwiga, Patrick Munene MP
Chuka/Igambang'ombe Constituency
UDA Party

Members

Hon. Owino Martin Peters, MP
Ndthiwa Constituency
ODM Party

Hon. Julius Ole Sunkuli Lekakeny, MP
Kilgoris Constituency
KANU

Hon. Muge Cynthia Jepkosgei, MP
Nandi (CWR)
UDA Party

Hon. MaingiMary, MP
Mwea Constituency
UDA Party

Hon. Wanyonyi Martin Pepela, MP
Webuye East Constituency
Ford Kenya Party

Hon. Mathenge Duncan Maina, MP
Nyeri Town Constituency
UDA Party

Hon. Kipngok Reuben Kiborek, MP
Mogotio Constituency
UDA Party

Hon. LengurisPauline, MP
Samburu (CWR)
UDA Party

Hon. Nyikal James Wambura, MP
Seme Constituency
ODM Party

Hon. Oron Joshua Odongo, MP
Kisumu Central Constituency
ODM Party

Hon. Kibagendi Antoney, MP
Kitutu Chache South Constituency
ODM Party

Hon. (Prof.) JaldesaGuyo Waqo
Moyale Constituency
UPIA Party

Hon. Mukhwana Titus Khamala, MP
Lurambi Constituency
ANC Party

1.4 Committee Secretariat

1. The following are the Secretariat who support the Committee;

Mr. Hassan Abdullahi Arale
Clerk Assistant II/Head of Secretariat

Mr. Gladys Jepkoech Kiprotich
Clerk Assistant III

Ms. Marlene Ayiro
Principal Legal Counsel II

Ms. Salat Abdi Ali
Senior Serjeant-At-Arms

Ms. Faith Chepkemoi
Legal Counsel II

Mr. Yakub Ahmed
Media Relations Officer II

Mr. Rahab Chepkilim
Audio Recording Officer II

Ms. Abigel Muendi
Research Officer III

Mr. Hiram Kimuhu
Fiscal Analyst III

Mr. Benson Kimanzi
Serjeant-At-Arms III

2.0 ANALYSIS OF THE AGREEMENT

INTRODUCTION

1. Article 2(5) of the Constitution of Kenya, 2010 provides that the general rules of international law while Article 2(6) of the Constitution provides that any treaty or convention ratified by Kenya shall form part of the law of Kenya under this Constitution.

2. The Treaty Making and Ratification Act, No. 45 of 2012 (hereinafter referred to as "the Act") was enacted by Parliament to give effect to Article 2(6) of the Constitution. The Act governs the making and ratification of treaties in Kenya.

3. Section 2 of the Act defines a treaty as an "international agreement concluded between States in written form and governed by international law, whether embodied in a single instrument or in two or more related instruments and whatever its particular designation and includes a convention".

4. Under the Constitution and the Act, the responsibility of initiating the treaty making process, negotiating and ratifying a Treaty lies with the Executive. In making this decision, the Executive ought to be guided by Section 5(2) of the Act which provides considerations that must be followed including:

    a) the need that the new treaty is to meet;
    b) the existing legal regime, including the extent of its applicability to the perceived problem;
    c) the probability of reaching the required measure of agreement on the solution aimed for;
    d) any relevant legislative efforts related to the perceived problem;
    e) the optimal form for the proposed treaty;
    f) the likelihood that the proposed treaty shall be accepted by a sufficient number of states, where the treaty is multilateral;
    g) the anticipated time schedule for completing the treaty-making process;
    h) the expected costs of formulating and adopting the treaty to Kenya; and
    i) in formulating treaties relating to technical or scientific problems; whether extensive scientific studies or research have been carried out to determine the parameters of the problem and the lines of potential solutions.

ROLE OF THE NATIONAL ASSEMBLY IN TREATY MAKING AND RATIFICATION

5. Although initiation of the treaty making process is the role of the Executive, Parliament as the legislative arm decides whether a Treaty shall form part of the law of Kenya upon which the treaty comes into force. This flows from Article 94(5) of the Constitution which provides that "no person or body, other than Parliament, has the power to make provision having the force of law in Kenya except under authority conferred by this Constitution or by legislation".

6. After the Treaty has been approved by the National Assembly, it therefore becomes binding upon Kenya and Kenya cannot invoke the provisions of its domestic law to justify any failure to perform its obligations under a treaty ratified by it.

7. According to the Vienna Convention on the Law of Treaties, 1969 which governs the making and ratification of treaties internationally, a treaty becomes binding on a state upon ratification.

8. Section 2 of the Treaty Making and Ratification Act defines ratification as the "the international act by which the State signifies its consent to be bound by a treaty and includes acceptance, approval and accession where the treaty so provides".

9. Under section 7 of the Act, where the Government intends to ratify a treaty, the Cabinet Secretary of the relevant State department shall, in consultation with the Attorney-General, submit to the Cabinet the treaty, together with a memorandum outlining—

    a) the objects and subject matter of the treaty;
    b) any constitutional implications including—
        i. any proposed amendment to the Constitution; and
        ii. that the treaty is consistent with the Constitution and promotes constitutional values and objectives;
    c) the national interests which may be affected by the ratification of the treaty;
    d) obligations imposed on Kenya by the treaty;
    e) requirements for implementation of the treaty;
    f) policy and legislative considerations;
    g) financial implications;
    h) ministerial responsibility;
    i) implications on matters relating to counties;
    j) the summary of the process leading to the adoption of the treaty:
    k) the date of signature;
    l) the number of states that are party to the treaty;
    m) the views of the public on the ratification of the treaty;
    n) whether the treaty sought to be ratified permits reservations and any recommendations on reservations and declarations;
    o) the proposed text of any reservations that should be entered when ratifying the treaty in order to protect or advance national interests or ensure conformity with the Constitution; and
    p) whether expenditure of public funds will be incurred in implementing the treaty and an estimate, where possible, of the expenditure.

Consideration by the National Assembly

The Treaty Making and Ratification Act, No. 45 of 2012

10. Section 8 of the Treaty Making and Ratification Act, No. 45 of 2012 provides for the consideration of Treaties by Parliament. Upon approval of a Treaty by Cabinet, the relevant Cabinet Secretary shall submit the Treaty together with a memorandum on the Treaty to the Speaker of the National Assembly for tabling pursuant to the Standing Orders.

11. Section 8(3) of the Treaty Making and Ratification Act, No. 45 of 2012 provides that the relevant parliamentary Committee in the National Assembly is tasked with consideration of the Treaty and shall ensure public participation in the ratification process in accordance with the laid down parliamentary procedures. (Section 8(3) of the Act).

Decision on Ratification by the National Assembly

12. The National Assembly may:

a) **refuse to approve the ratification of a Treaty**-where the National Assembly refuses to approve the ratification of a treaty, the Clerk of the National Assembly shall submit the resolution of the House to the relevant Cabinet Secretary within fourteen (14) days of such resolution (Section 8(7) of the Act) and the Government shall not ratify the said Treaty;

b) **approve the ratification of a Treaty without reservations to specific provisions of the treaty** (Section 8(4) of the Act)-where the ratification of a treaty is approved by National Assembly without any reservations to the treaty, the relevant Cabinet Secretary (the Cabinet Secretary for the time being responsible the subject matter of the treaty) shall, within thirty (30) days from the date of the approval of the ratification of treaty request the Cabinet Secretary to prepare the instrument of ratification of the treaty;

c) **approve the ratification of a Treaty with reservations to specific provisions of the treaty**-where a treaty is approved for ratification with reservations to some provisions of the treaty, the treaty shall be ratified with those reservations to the corresponding article in the treaty.

13. Proposed reservations made by the National Assembly are introduced as a provision into the Treaty in line with the procedure set out in the Standing Orders (Section 8(5) of the Act).

14. In making the decision on the approval for ratification of a Treaty, Section 8(9) of the Act provides that the National Assembly shall not approve:

a) the ratification of a treaty or part of it if its provisions are contrary to Constitution; and

b) a reservation to a treaty or part of it if that reservation negates any of the provisions of the Constitution even if the reservation is permitted under the relevant treaty.

15. Section 12 of the Act provides that a Treaty cannot be ratified unless the same has been considered and approved by the Cabinet and Parliament. A person who ratifies a Treaty without following this process commits an offence and shall be liable to imprisonment for a term not exceeding fifteen (15) years or to a fine not exceeding twenty (20) million shillings or to both such fine or imprisonment.

1. The National Assembly Standing Orders

16. One of the functions of Departmental Committees under Standing Order 216(5)(fa) is to *"examine treaties, agreements and conventions".*

17. The procedure of ratification of treaties is guided by Part XXI and in particular Standing Order 170A of the National Assembly Standing Orders. Standing Order 170A provides:

"(1) A treaty submitted to the National Assembly for ratification shall be laid on the Table of the House and stand committed to the relevant Committee for consideration.

(2) The committee shall undertake public participation before submitting its report to the House.

(3) In addition to the information required to be submitted to the National Assembly under written law, the committee may require the relevant Cabinet Secretary to submit further information, including—

a) the social and environmental impact of the treaty in the short-term, medium term and long-term; and,
b) the nature and evidence of any public participation conducted on the treaty.

(4) The report of the committee to the House shall include—

a) information on the views of the people on the ratification of the treaty emanating from public participation conducted by the committee;
b) the findings of the committee on the treaty and any other information the committee may deem necessary; and
c) a recommendation that the House—

(i)approves the ratification of the treaty, or
(ii) approves the ratification of the treaty with reservations, or
(iii) rejects the ratification of the treaty.

(5) In approving ratification of a Treaty with reservations, the House shall specify the affected provisions of the Treaty and the proposed text of each reservation, which may include prescription of timelines within which an obligation is to be fulfilled before implementation of the Treaty.

(6) Upon decision of the House on a Treaty, the Clerk shall, within seven (7) days, notify the relevant Cabinet Secretary and enter the information in the register of treaties."

A. OBJECTIVE OF THE TREATY

18. The African Union (AU) Treaty for the Establishment of the African Medicines Agency (hereinafter "the Treaty") was adopted by the 32nd ordinary session decision of the Assembly of Heads of State and Government on 11th February 2019.

19. The Treaty establishes the African Medicines Agency (AMA) under Article 3. AMA is a specialized agency of the AU with its own rules, membership and resources, intended 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 African continent.

20. Weak regulatory systems have resulted in the circulation of substandard and falsified medical products in many African Union member states causing risk to public health, harm to patients and undermining confidence in healthcare delivery systems. The AMA therefore intends to:

a) Provide a platform for coordination and strengthening of on-going regional and continental harmonization initiatives
b) Complement efforts of RECs and contribute to their capacity building towards improving access to quality assured medical products with the agenda of Universal Health Coverage and Sustainable Development Goals

c) Define acceptable standards in the regulation of medical products in the continent

21. The Organs of the AMA are:
    (a) The Conference of the State Parties-the highest policy-making organ of the Agency. It is composed of all member states of the African Union (AU) who ratify the Treaty and which will be represented by their Ministers responsible for health or their representatives. The conference shall meet once every two (2) years.
    (b) Governing Board-it shall be composed of the heads of National Medicines Regulatory Authorities (NMRAs), RECs, Regional Health Organizations responsible for regulatory affairs among others.
    (c) The Secretariat-responsible for coordinating the implementation of the decisions of the Conference of State Parties and Policy organs of the AU and the Board of the AMA. The secretariat shall be headed by the Director General who shall be responsible for the day-to-day management of the AMA.
    (d) The Technical Committees-The Board shall permanent and ad hoc technical committee to provide technical guidance on specific areas of regulatory expertise.

22. The obligations of State Parties under the Treaty include:

    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, harmonization and mutual recognition of regulatory decision;
    d) To strength and harmonize efforts of the AU-recognized RECs, Regional Health Organizations (RHOs) and Member states; and
    e) To complement and enhance collaboration and contribute to improving patient's access to quality, safe and efficacious medical products and health technologies on the continent.

23. The AMA is supposed to work closely with the AU, World Health Organization (WHO), African Centres for Disease Control and Prevention (Africa CDC), and any other UN agencies. It shall further maintain active cooperation with AU member states and other countries as well.

24. Article 33 allows a State Party when ratifying the Treaty to submit reservations to any provisions of the Treaty in writing. The reservation should not contravene the objects and purpose of the Treaty. The reservation may be withdrawn at any time in writing.

25. Article 34 allows a State Party to withdraw from the Treaty three (3) years from the date of entry into force of the Treaty provided that the obligations of such a party prior to the withdrawal shall still subsist.
26. The Treaty may be dissolved by an agreement of two-thirds of the State Parties to the Treaty and may be amended or revised pursuant to Article 35 and 36 of the Treaty.

27. Under Article 37, the Treaty is open for signature and ratification by Member Sates of the AU.

28. Under Article 39 of the Treaty, the Treaty shall enter into force thirty (30) days after deposit of the fifteenth (15th) instrument of ratification. For countries such as Kenya that are ratifying the Treaty after it has come into force, the Treaty shall come into force on the date of deposit of instrument of accession or ratification.

B. PUBLIC PARTICIPATION ON THE TREATY

a) Legal Provision on Public Participation

29. Article 118 (1) (b) of the Constitution of Kenya provides as follows
"Parliament shall facilitate public participation and involvement in the legislative and other business of Parliament and its Committees."

30. Section 8 of the Treaty Making and Ratification Act, No. 45 of 2012 provides for the consideration of Treaties by Parliament. Upon approval of a Treaty by Cabinet, the relevant Cabinet Secretary shall submit the Treaty together with a memorandum on the Treaty to the Speaker of the National Assembly for tabling pursuant to the Standing Orders.

31. Section 8(3) of the Treaty Making and Ratification Act, No. 45 of 2012 provides that:
"the relevant parliamentary Committee shall, during its consideration of the Treaty, ensure ***public participation*** *in the ratification process in accordance with laid down parliamentary procedures".*

32. Standing Order 170A provides:
"(2) The committee shall undertake public participation before submitting its report to the House.

(4) The report of the committee to the House shall include—

d) information on the views of the people on the ratification of the treaty emanating from public participation conducted by the committee;

(b) Methodology used by the Committee in Public Participation

33. The Memorandum by the Ministry of Foreign Affairs on the Ratification of the African Union Treaty for the Establishment of the African Medicines Agency (AMA) was laid on the Table of the House on Tuesday, 7th June 2022. The Treaty was however not considered as the House in the 12th Parliament proceeded to *Sine die recess* immediately thereafter.

34. The Treaty was re-tabled before the House on Thursday, 1st December 2022 in the 13th Parliament and committed to the Departmental Committee on Health for consideration.

35. Pursuant to the aforementioned provisions of the Constitution, the Treaty Making and Ratification Act, 2012 and Standing Orders, the Committee through local daily newspapers of 26th January, 2023 published an advertisement inviting the public to submit memoranda. Further, in a letter dated 25th January, 2023, the Committee wrote to various stakeholders including the Ministry of Foreign Affairs, National Treasury, Ministry of Health, Ministry of Trade, Investment and Industry, Ministry of East African

Community, Office of the Attorney General and Department of Justice, Kenya Revenue Authority, Kenya Law Reform Commission to submit memorandum on the Treaty which they all supported the treaty *(responses attached)*.

36. The Committee also held a stakeholder engagement forum on 27th February 2023 with various non-state actors and non-governmental organizations at Mercure Hotel, Nairobi. The stakeholders who attended the forum were:
    (a) ROCHE
    (b) Coalition for Health Research and Development (CHREAD)
    (c) PATH
    (d) Kenya Pharmaceutical Association
    (e) International AIDS Vaccine Initiative (IAVI)
    (f) DNDI
    (g) Generic Specialities
    (h) Federation of Kenya Pharmaceutical Manufacturers
    (i) Pharmaceutical Society of Kenya
    (j) Renal Patients Society of Kenya
    (k) NCD Alliance of Kenya
    (l) Kenya Medical Laboratory Technicians and Technologist Board
    (m) Mission for Essential Drugs and Supplies (MEDS)
    (n) Ministry of Health, Directorate of Health Product and Technologies
    (o) United States Pharmacopeia (USP)
    (p) Pharmacy and Poisons Board
    (q) National Quality Control Laboratory
    (r) African Medical and Research Foundation (AMREF)
    (s) MI-PH

37. The report is divided into two parts as follows:

    Part I of the Report contains the analysis of the public submissions on the ratification of the Treaty, written and oral submissions received from the public and various stakeholders noting general comments in support or against the ratification of the Treaty and the list of institutions that submitted their memoranda.

38. Part II of the Report contains a copy of the newspaper advertisements of Wednesday, 26th January, 2023 inviting the public to submit memoranda on the ratification of the Treaty and a letter inviting the relevant stakeholders for memoranda and the minutes of the Committee sittings during the consideration of the ratification of the Treaty.

3.0 STAKEHOLDER VIEWS ON THE AFRICAN UNION TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY

39. The table below highlights the stakeholder comments on the ratification of the Treaty—

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
1.	State Department for East African Community Ministry of East African Community and Regional Development	After consultations with the Ministry of Heath, supports ratification of the Treaty vide letter dated 2nd February 2023.	• AMA flows from the African Medicines Regulatory Harmonization (AMRH) Initiative that has been advanced by the AU Development Agency and regional economic communities (RECs) in collaboration with development partners. • Kenya supported AMRH initiatives- set up of EAC-MRH Programme and implementation-helped Kenya realize its health sector development goals • AMA to complement efforts of existing national and regional regulatory bodies or harmonization initiatives at RECs level which will continue with their work • Kenya to benefit when the treaty comes into force as follows: a) AMA provides platform for coordination and strengthening on-going regional and continental harmonization initiatives, pool expertise and capacities for optimal use of the limited resources and combat of substandard and falsified medical products b) Will strengthen Kenya's clinical trials ecosystem including Covid-19, manufacturing industry, and ability to regulate and monitor safety of health products
2.	Ministry of Foreign and Diaspora Affairs Office of the Attorney General Ministry of Health	Jointly supports the ratification of the Treaty vide letter dated 3rd February 2023. No reservations raised.	• MOH through the Pharmacy and Poisons Board (PPB) ensures quality, safety and efficacy of health products and technologies through capacity building, WHO collaborative procedures, harmonization initiatives, collaboration with development partners • Kenya through PPB has been contributing technically to the AMRH initiatives that has facilitated the realization of Kenya's health

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
			sector development goals; Two (2) officers of PPB are Chairpersons of Technical Committees under the AUDA-NEPAD AMRH Initiative, the precursor of the AMA • AMA headquarters in EAC (Rwanda) • 23-member states have ratified Treaty (Rwanda and Uganda have fully ratified and deposited instruments to the AU Commission) • Covid-19 triggered the interest of African countries to develop their manufacturing capacities to remedy challenge of access to essential health products such as vaccines when global supply chains deprioritize Africa's needs • Depicts Kenya's commitment to Africa's collective action for improved regulation of medicines, medical products and technologies as a Member of AU and RECs such as EAC and IGAD • Ratification facilitates the achievement of Kenya Vision 20230 and supports the achievement of objectives under the Kenya National Health Policy, Kenya Health Sector Strategic Plan and Kenya National Pharmaceutical Policy. • Kenya has the largest pharmaceutical industry in the common market for the Eastern and Southern African Regions- over 30 manufacturing plants • AMA will open up market for Kenyan pharmaceutical products from USD 160 Million (EAC) to USD 1.2 Billion (African Continent) *Legal Implication* • Treaty in line with/ not amending the Constitution • May require amendment of Kenyan laws for compliance with and implementation of the Treaty obligations-Treaty advocates for adoption of the AU model law on regulation of medical products • Kenya may need to develop guidelines for periodic reporting obligations

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
			arising from joint capacity assessments for Member States
3.	Pharmaceutical Society of Kenya (PSK)-Professional Body of Pharmacists in Kenya)	Support the ratification of the Treaty vide letter dated 8th February 2023.	• Given that the objectives of the Treaty on Medicines entail ensuring public safety, promoting innovation, streamlining product registration, harmonizing healthcare education systems among others, Pharmacists are important stakeholders in this and their role and contribution should be given more prominence in the entire process of establishing the AMA. Their expertise can be applied to several areas such as innovation of new therapeutic products and systems technologies and management of non-communicable diseases. They can form a think tank funded by AU or AMA to collect data and offer policy direction and guidance on effective use of medicines. They can also work with higher learning regulators in developing a harmonized curriculum for pharmacists in the continent. • The Treaty encourages local manufacturing. • In relation to resourcing, the Treaty is presently being funded by donors, what will happen later when donors pull out? • The role of pharmacists and the pharmaceutical profession needs to be leveraged upon in the implementation of the Treaty.
4.	Kenya AIDS NGOs Consortium (KANCO)	Supports the expedited ratification of the Treaty vide letter dated 9th February 2023.	• The Treaty provides: ✓ Support for growth of local pharmaceutical production ✓ Mechanism for evaluating medical products for treatment of priority diseases ✓ Coordination of joint reviews of clinical trial applications for vaccines ✓ Information sharing and collaboration with RECs and National Medicines Regulatory Authorities in identification of

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	POSITION	JUSTIFICATION
			substandard and falsified medical products • Kenya is a major player in the field of global health should be in the forefront in ratifying the Treaty which will promote Article 43 of Constitution on the right to access the highest attainable standard of health including reproductive health care. • The Treaty has been ratified by 33 out of 55 AU Member States. • 20 nations have ratified and deposited the Treaty; 3 have ratified but not deposited, 22 not ratified or signed, 10 including Kenya have signed but not ratified. • There is need to establish an African Digital Platform that lists the approved medical products and technologies in the Continent. • The Association applauded the Kenyan Parliament for undertaking public participation on Treaty.
5.	Coalition for Health Research and Development Note: KANCO is part of this coalition.	Supports the expedited ratification of the Treaty vide letter dated 9th February 2023	• Ratification of the Treaty will catalyze realization of Universal Health Coverage through faster access to the highest quality of medical products thereby facilitating the realization of Article 43 of the Constitution. • The Coalition supports harmonization of regulatory systems for medical products in the country. • The Treaty is in line with the Constitution and will contribute to achievement of government health policies such as Kenya Health Policy, Kenya National Pharmaceutical Policy etc. • Ratification will lead to job creation, economic growth, reduced over reliance in imported expensive medicines and medical products and increased local manufacturing capabilities.

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
			• AMA will provide capacity building upon request, to national regulatory authorities such as the Pharmacy and Poisons Board. • After ratification, there is need to identify gaps and strengthen the existing legislation. • There is need to assess elements of patient safety so as to reduce harm to consumers and ensure the intended therapeutic outcomes of the Treaty.
6.	Kenya Revenue Authority	Supports the ratification of the Treaty vide letter dated 13th February 2023.	KRA does not have additional input on the Treaty and Memorandum from the Ministry of Foreign Affairs.
7.	Office of the Attorney General and Department of Justice	Supports the ratification of the Treaty vide letter dated 2nd February 2023.	The Treaty and Memorandum from the Ministry of Foreign Affairs are in order from a legal perspective.
8.	Federation of Kenya Pharmaceutical Manufacturers	Supports the ratification of the Treaty vide letter dated 1st March 2023.	• How will all African pharmaceutical companies have a level playing field in protected countries such as Ghana, and Algeria and Morocco which restricts the list of products that can be imported into the country and support sale of locally manufactured products? • What mechanisms have been put in place to ensure that AMA will work with individual state parties and RECs in regulation of medical products in the continent? • Kenya should be represented in the AMA Secretariat. • What is the situation with regard to the EAC Harmonization policy? Will money be earned from registration and authorization of medicines? • Involvement of pharmacists in research on medicines- There is need to have a harmonized way of training pharmacists

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
			• There is need to ensure proper disposal of medication • There is fear that the pharmaceutical market might be swamped • There is need to reduce the cost of production so as to improve productivity and cost effectiveness • The Treaty is aligned to the Constitution and policy framework. It makes economic sense and strengthens regulatory expertise and ensures harmonized processes • There is need to ensure Kenya can manufacture and benefit from the sale of Active Pharmaceutical Ingredients (APIs)?
9.	PATH.	Supports the ratification of the Treaty.	• Treaty ratified on 11th January 2019 and came into force on 5th November 2022. • 23 member countries have fully ratified the Treaty; 10 member countries have signed the Treaty but not completed the ratification process. Kenya part of the 10 countries. • The main objective of Treaty is to enhance capacity of state parties and Regional Economic Communities (RECs). • The Treaty facilitates the implementation of the AU Model Law on Regulation of Medical Products. • AMA will be an advisory institution and a platform for collaboration between national medicines regulatory authorities/ RECs steered by state parties. • The AMA Governing Council to be formed in two weeks' time. Kenya lost the opportunity to host AMA and therefore needs to position its people for the positions of influence in the AMA Governing Council. • The AU Model Law on the Regulation of Medicines is being implemented through the Kenya Drugs Authority Bill

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
			sponsored by the Chairperson of the Committee. The Bill also anchors the AMA. The Bill ought to be enacted to guarantee the safety of drugs in Kenya.
10	African Medical and Research Foundation (AMREF)	Supports the ratification of the Treaty.	• The Treaty ensures access to medicine. • Kenya is the lead in Africa in the pharmaceutical manufacturing sector as it currently manufactures both for the local and external markets. 70% of Kenyan pharmaceutical products are exported • The Treaty encourages capacity building through knowledge transfer and training.
11	Mission for Essential Drugs and Supplies (MEDS)	Supports the ratification of the Treaty.	• MEDS supports ratification of the Treaty as it will reduce bureaucracy in manufacturing of health products and technologies due to improvement in regulatory requirements • Kenya needs to leverage on the local capacity to ensure quality control • There is need to do post medical surveillance • There is need to fast-track the Kenya Development Authority Bill • There is need to revive the Traditional Practice Bill that was done during the previous Parliament.
12	Renal Patients Society of Kenya and Non-Communicable Diseases (NCD) Alliance of Kenya	Supports the ratification of the Treaty.	• The Treaty will help in reduction in the cost of drugs and ensure availability of drugs. There is need to ensure local or regional production of drugs using locally available materials and expertise so that drugs can be sold at a cheapest price. This will solve the problem of expensive drugs while ensuring safety and quality. The AMA to provide for a means of capacity building within the continent • Africa was considered last in the supply of vaccines during the covid-19 period.

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
13	Drugs for Neglected Diseases	Supports the ratification of the Treaty.	• Accelerated access to treatment should focus on policy adoption- will there be reliance on WHO for recommendation before adoption of medicines in the continent? • In relation to the regulatory aspect, does establishment of AMA eliminate the WHO? • What is the effect on customs within the respective jurisdictions? Each and every jurisdiction has to inspect a drug manufacturer's factory to check quality and standards?
14	ROCHE	Supports the ratification of the Treaty.	• The Treaty will ensure regulatory harmonization and convergence and tackle the following challenges (a) Delay in product registration which affects market authorization certification as well as product retention in the market- The EAC takes 90 to 180 days to authorize the sale of drugs within the EAC Member States. (b) Lengthy WHO pre-qualification processes which lengthens the provision of approvals-it takes at least four (4) years to get such pre-qualification. (c) Trade barriers- The Treaty incorporates best practices by providing mechanisms for inspection and audit of drugs. It also links trade and regulation by removing the multiplicity of regulation for instance Kenya has Kenyan Bureau of Standards (KEBS) and Anti-Counterfeit Authority.
15	Kenya Pharmaceutical Association	Supports the ratification of the Treaty.	• The Association supports the treaty and memorandum by the Ministry of Foreign Affairs. • The focus of Treaty is on governance structure. There is little on practice and the access to health care. How will HRH/healthcare workers benefit from the Treaty? Is there provision for Cross-border practice? Will there be standardization of HRH? What are the norms for HRH that will ensure

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
			harmonization of training and certification of health care professionals within the continent? • Some countries have zero regulations. What will be the effect of the lack of domestic regulations particularly with border entry points restrictions? How does the Treaty guarantee the authenticity of health products? • How are middle level practitioners taken care of under the Treaty?
16	Pharmacy and Poisons Board	Supports the ratification of the Treaty.	• The Board supports the Treaty and was part of its development process. • The Treaty will deal with the high cost of manufacturing of medicines and particularly APIs. South Africa and DRC have been extracting quinine. China is the biggest producer of APIs in the country. • There is need to do capacity building within the country for buy in within and outside the country. • There is a huge market for the country as AMA is continental. Manufacturers can distribute drugs within the whole continent and manufacturers can come and set up their businesses in the country. There is therefore need to look at the cost of electricity and taxation so as to encourage the influx of pharmaceutical manufacturers. • There is need to critically assess the therapeutic outcome of the Treaty and tap into it as a country. • There is multiplicity of Regulations on drugs within the country. There is need to avoid duplicity for instance the country has inspectors from PPB and the Anti-Counterfeit Authority have the same responsibilities? The lack of harmonization of laws is the main reason why Kenya is at the maturity level 1. This issue to be addressed in the Kenya

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	POSITION	JUSTIFICATION
			Drugs Authority Bill sponsored by the Chairperson of the Committee. • The Treaty ensures short marketing timelines and will lead to revenue generation as the country can sell drugs across the continent. • There is a big challenge of capacity in the regulatory entities. The number of people in regulatory authorities is currently less than 15 in number when optimal ought to be 100. • The implementation of the Treaty requires digitization of processes and systems. • The WHO prequalification process only assesses a class of drugs namely malaria, ARVs, Reproductive health, diarrhea in children, Covid-19 and other emergency issues. The Treaty will not replace the WHO but will work alongside WHO for strengthening of capacity within the country and the region. There are assessors working for WHO in Tanzania, Ghana and Kenya. Kenya has two WHO qualified assessors. • There is need to check the ingress of substandard and falsified medicines while checking market control in line with the Head of Public Service circular on border management. • Cross border trading will benefit from the Treaty as there is harmonized regulation. There is however need to build an alert system. • The EAC is working on regulation of pharmacists which will ensure access to quality products • The list of OTC poisons in part I and Part II of the Schedule to the Pharmacy and Poisons Act, Cap. 244. The list needs to be revised. The law also needs to amended to provide for scheduling and rescheduling of medicines. • There are three categories of drugs namely OTC, prescription only and

THE AFRICAN UNION (AU) TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)			
	STAKEHOLDER	**POSITION**	**JUSTIFICATION**
			pharmacy only. The prescription category has more categories and the PPB has developed some guidelines on the same.
17	Kenya Medical Laboratory Technicians and Technologist Board	Supports the ratification of the Treaty.	• The Treaty will ensure access to safe and quality health products and technologies in the continent.
18	National Quality Control Lab	Supports the ratification of the Treaty.	• There is need to develop an alert system for substandard and falsified medicines in the continent. • The Treaty should provide for the regulation of herbal products as the Treaty currently only provides for dietary supplements and traditional medicine.
19	Cabinet Secretary, Ministry of Health	Supports the ratification of the Treaty.	• The African continent was the last to receive the covid-19 vaccines. These vaccines arrived late and many of them expired because of low intake by members of the Public. • The Cabinet Secretary requested the Committee to support the Treaty/ World Health Organization (WHO) Logistics Centre in Kenyatta University and the Africa Centre for Disease Control (CDC).

4.0 COMMITTEE OBSERVATIONS

39. The Committee having considered the ratification of the African Union Treaty for the Establishment of the African Medicines Agency and submissions from stakeholders makes the following observations:

(i) The Cabinet Secretary, Ministry of Foreign and Diaspora Affairs, Dr. Alfred Mutua signed the Treaty on 16th February, 2023;
(ii) The Treaty is in line with the Constitution of Kenya, 2010 and complies with the provisions of the Treaty Making and Ratification Act, No. 45 of 2012;
(iii) The Treaty may require amendment of Kenyan laws for compliance with and implementation of the Treaty obligations as the Treaty advocates for the adoption of the African Union Model Law on Regulation of Medical products;
(iv) Ratification of the Treaty will catalyze realization of Universal Health Coverage through faster access to the highest quality of medical products thereby facilitating the realization of Article 43 of the Constitution;
(v) The Treaty will contribute to achievement of government health policies such as Kenya Health Policy, Kenya National Pharmaceutical Policy among others; and
(vi) The Treaty will benefit Kenya as it supports local pharmaceutical production and strengthens the country's ability to regulate and monitor safety of health products.

5.0 FINDINGS

40. Pursuant to the analysis of the submissions and documents tabled, the Committee finds that the African Union Treaty on the establishment of the African Medicines Agency is consistent with constitution and do not propose any amendment to the Constitution.

6.0 COMMITTEE RECOMMENDATION

41. The Committee recommends: -

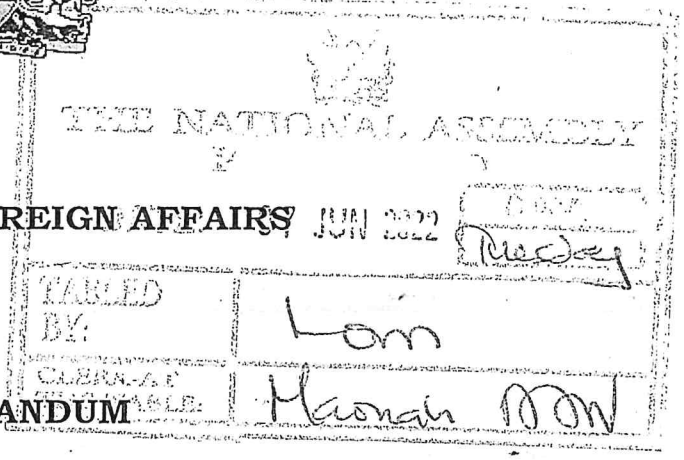
THAT, Pursuant to Section 8 of the Treaty Making and Ratification Act, the House **APPROVES the Ratification** of the African Union Treaty for the Establishment of the **African Medicines Agency**.

Justification
The African Union Treaty for the Establishment of the African Medicines Agency facilitates the realization of Universal Health Coverage through improved regulation of medical products.

for **Signed**..... **Date:** 16/3/2023

HON. DR. ROBERT PUKOSE, MP – CHAIRPERSON
DEPARTMENTAL COMMITTEE ON HEALTH

THE NATIONAL ASSEMBLY
PAPERS LAID
DATE: 22 MAR 2023
DAY: Wednesday
TABLED BY: Hon. Patrick Munene Vice Chair, Health Committee
CLERK-AT THE-TABLE:



MINISTRY OF FOREIGN AFFAIRS

MEMORANDUM

ON THE

RATIFICATION OF AFRICAN UNION TREATY

FOR THE ESTABLISHMENT OF THE

AFRICAN MEDICINES AGENCY (AMA)

TREATY MEMO NO: ...../2022

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

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 **12th 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 **5th 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.

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.

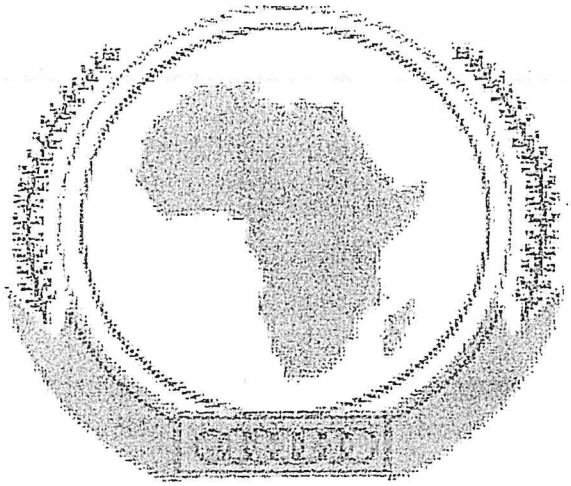
13. RECOMMENDATION TO THE NATIONAL ASSEMBLY

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**.....30th..... **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 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" 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

11TH FEBRUARY 2019

Directorate of Legislative & Procedural Services
The Table Office

MEMO

TO : DIRECTOR, AUDIT, APPROPRIATION AND OTHER SELECT COMMITTEES' SERVICES (NA)

FROM : PRINCIPAL CLERK ASSISTANT I

DATE : DECEMBER 5, 2022

SUBJECT : PAPERS LAID

The following **Papers** were laid on the Table of the House on **Thursday, December 1, 2022 (Afternoon Sitting): -**

i.) Memorandum on the Ratification of African Union Treaty for the establishment of the African Medicines Agency (AMA);

ii.) Annual Report for the Financial Year 2020/2021 from the Parliamentary Service Commission;

iii.) Reports of the Auditor – General and financial Statements of the following Institutions for the year ended 30th June, 2021 and the certificates therein:

1. Kitale National Polytechnic;
2. Bungoma North Technical and Vocational College;
3. Lugari Diploma Teachers Training College;
4. Mathioya Technical and Vocational College;
5. Kenya School of Government;
6. Institute of human Resource Management;
7. National Housing Corporation;
8. Kenya Urban Roads Authority;
9. Kenya National Highways Authority; and
10. Lake Basin Development Authority.

iv.) Reports of the Auditor – General and financial Statements of the following constituencies for the year ended 30th June, 2021 and the certificates therein:

1. Rangwe;
2. Suba South;
3. Likoni;
4. Kitutu Chache;
5. South Murirango;
6. Bobasi;
7. Mvita;
8. Malindi;
9. Magarini;
10. Awendo;
11. Nyaribari Chache;
12. Bonchari;
13. Taveta; and
14. Kilifi NORTH

Enclosed herewith, please find the said papers for your necessary action.

RACHEL KAIRU

Copy: Clerk of the National Assembly
Deputy Clerks
Director, Legislative & Procedural Services

(*Encls*)

NATIONAL ASSEMBLY
RECEIVED
05 DEC 2022
DIRECTOR
AUDIT/APPROPRIATIONS/SELECT COMMITTEES
Time:..... Sign:.....

REPUBLIC OF KENYA
THE NATIONAL TREASURY AND ECONOMIC PLANNING

MEMORANDUM BY THE CABINET SECRETARY FOR THE NATIONAL TREASURY AND ECONOMIC PLANNING ON THE CONSIDERATION OF THE RATIFICATION OF THE AFRICAN UNION TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY BY THE GOVERNMENT OF KENYA

1. This Memorandum on the consideration of the ratification of the Treaty for the establishment of African Medicines Agency (AMA) by the Government of Kenya; is submitted to the Clerk of the National Assembly by the Cabinet Secretary for the National Treasury and Economic Planning. The Memorandum gives the overview, highlights of the Treaty, and the conclusion.

A. Overview

2. The Treaty seeks to establish the AMA whose main objective will be to enhance 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. This is based on the premise that access to quality health products and technologies, especially for low and middle-income countries, during the Ebola and COVID-19 pandemics continues to be a challenge due to disruptions in the global supply chain systems. If established, 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.

B. Highlights of the Treaty

3. The Treaty provides that the functions of the AMA will include but not limited to: providing a platform for coordination and strengthening of on-going regional and continental harmonization of medical products; management of information on all medical products; joint review of clinical trials; adoption and harmonization of medical products regulatory policies and standards; designate promote, strengthen, coordinate and monitor Regional Centers of Regulatory Excellence (RCOREs); coordinate inspection of drugs manufacturing sites; promote partnership of regulatory decisions; convene meetings in collaboration with World Health Organization (WHO); provide regulatory guidance on medical products in Africa; monitor medicines market; promote the adoption of African Union (AU) model law on medical products among others.

4. In relation to the financial implications, the Treaty provides that the Conference of State Parties shall: (a) set the annual assessed contribution to be paid by the States Parties; (b) adopt the annual budget of the AMA; and (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. In addition, the AMA shall devise ways of resource mobilization.

5. Further, the AMA may also receive grants, donations and proceeds for its activities from international organizations, governments, private sector, foundations and other entities in accordance with guidelines set by the Board and approved by the Conference of State Parties, provided there is no conflict of interest. It is further noted that 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.

6. In relation to the expenses, the Treaty provides that 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 State Parties. In addition, the finances and accounts of the AMA shall be audited by an independent auditor appointed by the Board.

C. CONCLUSION

7. The National Treasury supports the ratification of the Treaty for the establishment of the African Medicines Agencies. The Agency, if established will provide for an African platform for the coordination of regulatory systems regarding medical products. This will ensure that the African population receives quality-assured, safe and efficacious medical products which are fundamental to health and safety for all.

NJUGUNA NDUNG'U, EGH
CABINET SECRETARY

REPUBLIC OF KENYA

MINISTRY OF HEALTH

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

1.0. OBJECTIVE OF THE MEMORANDUM

I.1. This Memorandum seeks to support Kenya's ratification of the Treaty for the Establishment of the African Medicines Agency (AMA).

2.0. BACKGROUND

2.1. The Treaty seeks to establish the AMA to enhance the capacity of State Parties and Regional Economic Communities (RECs) to regulate medical products to improve access to quality, safe and efficacious medical products on the continent.

2.2. AMA is intended to provide a platform for coordination and strengthening ongoing regional and continental harmonization initiatives, serving to pool expertise and capacities for optimal use of the limited resources.

2.3. The Ministry of Health (MOH), through the Kenya Pharmacy and Poisons Board (KPPB), ensures the **quality**, **safety** and **efficacy** of health products and technologies. This has been done through various strategic interventions including building technical capacity, World Health Organisation (WHO) collaborative procedures, reliance mechanisms, harmonisation initiatives and strong collaboration with development partners.

2.4. Since 2009, the Africa Union Development Agency (AUDA-NEPAD), working with regional economic communities (RECs)

and collaborating with development partners, has been advancing the African Medicines Regulatory Harmonization (AMRH) Initiative which has now culminated into the Africa Medicines Agency (AMA).

2.5. Kenya, led by the Pharmacy and Poisons Board, has been contributing technically to the AMRH initiatives including in the set-up of the EAC-MRH Programme and implementation. These initiatives at the regional and continental levels have to a great extent aided Kenya's realization of its Health Sector development goals and targets while strengthening the national capacity for effective health service delivery.

3.0. CURRENT STATUS OF AMA

3.1. As of January 2023, twenty-three (23) member states have fully ratified and deposited their instruments of ratification of the AMA treaty. In **East Africa**, **Rwanda** and **Uganda** have **fully ratified** and deposited instruments to the African Union Commission (AUC) while **Tanzania, Burundi** and **DRC have signed** but are yet to ratify and deposit instruments of ratification to AUC.

3.2. The AUC is responsible for the administrative and governance setup while AUDA-NEPAD is in charge of the technical set-up of AMA. Currently, **two (2) Kenyans,** officers of the Pharmacy and Poisons Board, are Chairpersons of technical committees under the AUDA-NEPAD AMRH initiative which will be a key precursor of the AMA. i.e. Evaluation of Medicinal Products Technical Committee (EMP-TC) and the Africa Medical Devices Forum (AMDF).

3.3. There have been 2 meetings of the Conference of Parties thus far. The Governing Board of the AMA should soon be appointed to enable the appointment of a Director General for the AMA and set up of the Secretariat.

3.4. The East African Community is privileged to host AMA headquarters in the Republic of Rwanda.

4.0. OBLIGATIONS IMPOSED ON KENYA BY AMA

4.1. Coordinate national and sub-regional medicines regulatory systems;

4.2. To conduct regulatory oversight of selected medical products including traditional medicines;

4.3. To promote cooperation, harmonisation and the mutual recognition of regulatory decisions;

4.4. To strengthen and harmonise efforts of the African Union – recognised RECs, Regional Health Organizations (RHOs) and Member States; and

4.5. 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. African countries have over-relied on health products manufactured elsewhere despite contributing to 20% of the global burden of disease. Ensuring quality, safe and efficacious health products for the African population remains a core goal of the continent's health products regulators.

5.2. The African Pharmaceutical sector is one of the fastest growing in the world and is expected to grow from $19 billion in 2012 to $66 billion by 2022. It is estimated that the health and wellness sector in Africa will be worth about $259 billion by 2030, with the potential to create over 16 million jobs.

5.3. Africa has substantively seen a reduction in the number of sub-standard and falsified health products (SFs) circulating in its markets as a result of various joint efforts including in setting up of vibrant Regional Economic Communities (RECs) that work together to review and evaluate applications/dossiers, conduct pharmacovigilance and post-market surveillance across the regions.

5.4. Presently, Africa has lagged in regulating complex and specialized molecules, growing its pharmaceutical manufacturing industry and lacks an Active Pharmaceutical Ingredient database that would help enable reliability and trust among its member states.

5.5. The COVID-19 pandemic has further triggered the interest of African countries, Kenya included, to develop their manufacturing capacities to remedy the challenges of access to essential health products including vaccines when global supply chains deprioritize Africa's needs.

6.0. JUSTIFICATION FOR RATIFICATION

6.1. In the spirit of regionalism and integration, Kenya's role in continental and regional initiatives and being a member of the AU and RECs such as EAC, and IGAD, in signing and ratifying AMA Treaty will demonstrate Kenya's commitment to the Continent's collective action to improved regulation of medicines, medical products and technologies.

6.2. **Access to safe, quality and efficacious medical products;**

(i) AMA will provide a platform for a multi-faceted approach to combating Substandard and Falsified medical products by strengthening medicine regulatory systems including the capacity for conducting pre-marketing authorizations and routine post-marketing surveillance.

(ii) AMA will complement the National Regulatory Authority's efforts and contribute to capacity building towards improving access to quality-assured medical products within the agenda of Universal Health Coverage and Sustainable Development Goals.

6.3. AMA is in line with the Constitution of Kenya, 2010 and will contribute to the achievement of the Kenya Vision 2030 while supporting the achievement of objectives under the Kenya National Health Policy (2018 – 2030), the Kenya Health Sector

Strategic Plan 2018–2023 and the Kenya National Pharmaceutical Policy (KNPP).

6.4. **Ease of doing business;**

(i) AMA will provide guidance, and streamline and enhance the efforts of REC towards harmonisation of medical products regulation.

(ii) With over 30 pharmaceutical manufacturing plants, Kenya's pharmaceutical industry is the largest in the common market for the Eastern and Southern African regions. AMA is central in ensuring the thriving and development of Africa's Pharma Industry, reducing over-reliance on imported and often expensive medicines and health products.

(iii) AMA will promote local pharmaceutical manufacturing as AMA will reduce duplication of regulatory efforts and ensure efficient use of resources, towards improving access to safe and efficient health products.

6.5. **Access to the African Continental Free Trade Area;**

(i) In terms of Trade and Economic development, it is anticipated that Kenyan products will have greater access, including reduced time to place products in the markets to a bigger market of all 55 countries in Africa thus benefiting from economies of scale. Additionally, AMA will open up the market for Kenya's local production and manufacturing industry to the USD 1.2 billion markets in Africa, which would go beyond the current USD 160 million at the EAC level.

(ii) AMA will harmonize the regulatory landscape and move Africa towards a truly single integrated block especially when it comes to highly regulated health products. Similarly, AMA will enhance standards, improve the ease of movement of health products that meet accepted international standards, promote local production,

encourage innovation, and ensure efficiency and ease of innovation introduced into the African market.

7.0. CONSTITUTIONAL AND LEGISLATIVE IMPLICATIONS

7.1. AMA promotes constitutional values and objectives and does not allude to an amendment to the Constitution.

7.2. The Treaty requires AMA to develop, monitor, evaluate and assess the comprehensiveness of National Medical Products Regulatory Systems to recommend measures that will improve efficiency and effectiveness.

7.3. The Treaty advocates for the adoption of the African Union Model Law on Regulation of Medical Products to facilitate legal reforms. This may require Kenya to amend its domestic laws to harmonise them with the provisions of the Treaty to facilitate its implementation and to accommodate the work of the AMA.

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

8.0. RESERVATIONS

8.1. Article 33 of the AMA Treaty allows ratification with reservations as long as the same is compatible with the objects of the Treaty. There is however no issue in the Treaty that may warrant reservations by Kenya.

9.0. CONCLUSION

9.1. All the above-mentioned gains will align with the attainment of Kenya's health priorities for implementation of the Kenya Health Plan (2014-2030), implementation of the Kenya Vision 2030, Sustainable Development Goals (SDGs), Africa Union Agenda 2063 by facilitating access by all citizens to high-quality, safe and efficacious medicines.

9.2. Kenya's growing economy and its comparative advantage across the continent, coupled with its strong pharmaceutical industry, puts the country at a better standpoint to benefit more once AMA comes into force. It is therefore in the national interest that Kenya ratifies the Treaty for the Establishment of AMA.

MEMORANDA ON RATIFICATION OF THE TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY (AMA)

JUSTIFICATION FOR RATIFICATION

1. Since 2009, the Africa Union Development Agency (AUDA-NEPAD), working with regional economic communities (RECs) and collaborating with development partners, has been advancing the African Medicines Regulatory Harmonization (AMRH) Initiative that has now culminated into the African Medicines Agency (AMA).

2. The AMA is intended to provide a platform for coordination and strengthening on-going regional and continental harmonization initiatives, serving to pool expertise and capacities for optimal use of the limited resources. This memorandum therefore seeks to support Kenya's ratification.

3. AMA will enable Kenya strengthen its Clinical Trials ecosystem including that of COVID-19, strengthen its manufacturing industry, enable it conform to the best practices and standard for health products, strengthen Kenya's capacity to regulate and monitor safety of health products.

4. AMA will provide a platform for a multi-faceted approach for combating Substandard and Falsified medical products by strengthening medicine regulatory systems including the capacity for conducting pre-marketing authorizations and routine post marketing surveillance.

5. The existing national and regional regulatory bodies or harmonization initiatives at RECs level will continue with their mandate but AMA will complement their efforts and contribute to capacity building towards improving access to quality-assured medical products within the agenda of Universal Health Coverage and the Sustainable Development Goals.

6. Kenya supported the AMRH initiatives including in the set-up of the EAC-MRH Programme and implementation. These initiatives at the regional and continental levels have largely aided Kenya's realization of its Health Sector development goals and targets while strengthening the national capacities for effective health service delivery.

7. The establishment of AMA puts Kenya at a better standpoint to benefit more once AMA comes into force. It is therefore in the national interest that Kenya ratifies the Treaty for the Establishment of AMA