



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

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.


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

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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 oversees 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. Maingi Mary, 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. Lenguris Pauline, 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.) Jaldesa Guyo 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.