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REPUBLIC OF ZAMBIA

REPORT

OF THE

COMMITTEE ON HEALTH, COMMUNITY DEVELOPMENT AND SOCIAL SERVICES ON THE RATIFICATION OF THE TREATY FOR THE ESTABLISHMENT OF THE AFRICAN MEDICINES AGENCY

FOR THE

THIRD SESSION OF THE THIRTEENTH NATIONAL ASSEMBLY

Printed by the National Assembly of Zambia

FOREWORD

Hon Madam Speaker, pursuant to Standing Order 198(f), of the National Assembly of Zambia Standing Orders, 2021, the Committee on Health, Community Development and Social Services is vested with the power to consider International Agreements, Conventions and Treaties in accordance with Article 63 of the Constitution. Thus, the Committee was mandated to consider the Ratification of the Treaty to Establish the African Medicines Agency.

In order to acquaint itself with the ramifications of acceding to Establishment of the African Medicines Agency, the Committee held four meetings and sought both written and oral submissions from stakeholders. The stakeholders, who appeared before the Committee, are listed at Appendix II.

The Committee is grateful to all the stakeholders who tendered both written and oral submissions. The Committee further wishes to thank you, Madam Speaker, for affording it an opportunity to carry out its work. It also appreciates the services rendered by the Office of the Clerk of the National Assembly and his staff throughout the Committee's deliberations.

Ms Marjorie Nakaponda, MP
VICE - CHAIRPERSON

February, 2024
LUSAKA

LIST OF ACRONYMS

AMA	African Medicines Agency
RECs	Regional Economic Communities
AU	African Union
OAU	Organisation of African Union
ZAMRA	Zambia Medicines and Regulatory Authority

TABLE OF CONTENTS

1.0 MEMBERSHIP OF THE COMMITTEE

The Committee consisted of: Dr Christopher K Kalila, MP (Chairperson); Mrs Marjorie Nakaponda, MP (Vice Chairperson); Mr Masautso Tembo, MP; Mr Miles Sampa, MP; Mr Joseph S Munsanje, MP; Mr Leevan Chibombwe, MP; Mr Monty Chinkuli, MP; Mr Paul Chala, MP; Mr Heartson Mabeta, MP; and Mr Alex Katakwe, MP.

2.0 BACKGROUND

The African Union (AU) Treaty for the Establishment of the African Medicines Agency (AMA) is a Treaty establishing a specialised agency of the AU for the enhancement of the capacity of State parties and Regional Economic Communities (RECs) to regulate medical products so as to improve access to quality, safe and efficacious medical products on the African continent. It was adopted by the 32nd Ordinary Session Decision of the Assembly of Heads of State and Government of the AU on 11th February, 2019. It came into effect on 5th November, 2021, after ratification by the 15th AU Member State.

The AMA was established by AU and regional African bodies in an effort to improve medical capacity in the continent. The outbreaks of the Ebola virus disease and the COVID-19 pandemic highlighted the need for such a body. It was hoped that ratification of the AMA Treaty would allow the AMA to play a role in distributing relevant drugs and vaccines throughout Africa in the coming years. Thus, it was intended to address a deficiency in drug production and challenges posed by counterfeit and substandard products.

3.0 OBJECTIVES OF THE AMA

The main objectives of the AMA were as follows:

i. provide a platform for coordination and strengthening of on-going regional and continental harmonisation initiatives in the field of medicine;
ii. complement efforts of RECs and contribute to capacity building towards improving access to quality assured medical products with the agenda of Universal Health Coverage and Sustainable Development Goals; and
iii. define acceptable standards in the regulation of medical products in the continent.

4.0 SUMMARY OF THE PROVISIONS OF THE AGREEMENT

The summarised provisions of the Treaty were as set out below.

PART ONE

THE AFRICAN MEDICINES AGENCY AND ITS OBJECTIVES

Article 1- Acronyms
This Article provided for the acronyms used in the Treaty, alongside their full meanings.

Article 2 - Definitions
This Article defined key terms used in the Treaty.

Article 3 – Establishment of the AMA
This Article provided for the establishment of the African Medicines Agency as a Specialised Agency of the AU.

Article 4 – Objectives of AMA
This Article provided for the main objectives of the AMA which included enhancing capacity of State Parties and regional economic communities, to regulate medical products in order to improve access to quality, safe and efficacious medical products on the continent.

Article 5 – Guiding Principles
This Article set out the guiding principles of the AMA which included among others the following: leadership, credibility, ownership, transparency and accountability, value-addition, confidentiality and commitment to sound and quality management.

Article 6 – Functions
Article 6 provided for the functions of the AMA.

PART TWO
STATUS OF THE AFRICAN MEDICINES AGENCY AND ITS STAFF

Article 7 – Legal Personality
This Article provided for the legal personality of the AMA which would have the legal capacity to enter into agreements, acquire and dispose of movable and immovable property; and institute and defend legal proceedings in its own name.

Article 8 – Privileges and Immunities
This Article provided for the Privileges and Immunities of the AMA, its members, its international personnel, premises, property and assets as provided for in the General Convention on the Privileges and Immunities of the Organisation of African Union (OAU) and the Additional Protocol to the OAU General Convention on Privileges and Immunities.

Article 9 – The Headquarters of the AMA
This Article provided that the Headquarters for AMA should be determined by the Assembly of the Union. It further provided for the procedure in which the African Union Commission shall undertake with the government of the host country in which the AMA Headquarters would be situated for purposes of the efficient operation of the AMA.

PART THREE
ADMINISTRATION AND INSTITUTIONAL FRAMEWORK

Article 10 – Organs of the AMA
Article 10 provided the list of the organs of the AMA as follows: the Conference of the States Parties, Governing Board, Secretariat and Technical Committees.

Article 11 - Establishment of the Conference of the State Parties
Article 11 provided for the establishment of the Conference of the States Parties, as the highest policy-making organ of the AMA.

Article 12- Composition of Conference of the State Parties
Article 12 provided for the composition of the Conference of the States Parties, the tenure of office of the bureau members and criteria for election of the bureau and the rights to vote.

Article 13- Session of the Conference of the States Parties
Article 13 set out the timings of the Meetings of the Conference of State Parties, the quorum and the threshold necessary in decision-making.

Article 14 – Functions of the Conference of the States Parties
Article 14 provided for the functions of the Conference of the States Parties.

Article 15- Establishment of the Governing Board
Article 15 established the Governing Board of AMA which should be answerable to the Conference of the State Parties.

Article 16 - Composition of the Governing Board
This Article provided for the composition of the Governing Board which should consist of nine Members.

Article 17 – Sessions of the Governing Board
Article 17 sets out the timings of the Meetings of the Governing Board, the quorum and the threshold necessary in decision - making.

Article 18 – Functions of the Governing Board
This Article outlined the functions of the Governing Board which included approving the strategic plan, programme of work, budgets, activity and reports submitted by the Director-General.

Article 19 – Term of Office of the Governing Board
Article 19 provided the tenure of office for members of the Board, which was a non-renewable period of three years, and the manner of electing the Chairperson and Vice-Chairperson of the Board.

Article 20 – Establishment of Technical Committees of the AMA
This Article provided for the Board to establish permanent or *ad hoc* technical committees to provide guidance on specific areas of regulatory expertise. The areas to be considered by the technical committees included, among others, dossier assessment for advanced therapies, biological (including bio-similar and vaccines), pharmacovigilance risk assessment and African traditional medicines.

Article 21 - Functions of Technical Committees
Article 21 provided for the functions of the technical committees to facilitate the proper functioning of AMA.

Article 22- Composition of the Technical Committees
This Article provided for the composition of the technical committees, where they would be drawn from and what they would be subjected to.

Article 23 – The Secretariat of AMA
Article 23 provided for the Secretariat of AMA and its primary role in coordinating the implementation of the decisions of the Conference of the States Parties, the Policy organs of the AU and the Board of AMA.

Article 24 – The Director-General of AMA
Article 24 of the Treaty provided for the position of Director-General as Head of the Secretariat, responsible for the day-to-day management of the AMA. It further provided for the tenure of office of the Director-General, competences and the functions of the Director-General.

Article 25 – Objections to Scientific Opinions
Article 25 provided for individuals or entities the right to object to a specific opinion, advice, or decision issued by AMA by lodging their objection with the Board.

PART FOUR

FINANCIAL PROVISIONS

Article 26 – Financial Resources
This Article provided for the financial resources of the AMA which included the contributions to be made by the States Parties, grants, donations and proceeds for its activities from international organisations, governments, private sector,

foundations and other entities. The Article also stipulated that the AMA was yet to adopt its financial rules.

Article 27- Expenses
This Article provided for the manner in which the expenses for administrative, operational and investment purposes should be disbursed.

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

Article 28 – Relationship with the AU
Article 28 provided for the AMA to maintain a close working relationship with the AU and present a written annual report on its activities to the AU Assembly through the relevant specialised technical committee and Executive Council.

Article 29 - Relationship with States
This Article provided the AMA to establish and maintain active cooperation with both AU member States and non- AU Member States.

Article 30 – Relationship with Other Organisations and Institutions
Article 30 provided for the AMA to establish and maintain a close working relationship and collaborate with organisations and institutions like the World Health Organisation and other UN agencies, inter-governmental organisations and non-governmental organisations including specialised agencies not mentioned in the Treaty, that the AMA considered necessary in achieving its objectives.

PART SIX
FINAL PROVISIONS
Article 31 - Working Languages
Article 31 provided for the AMA working languages to be those used in the AU namely; Arabic, English, French and Portuguese.

Article 32 - Settlement of Disputes
This Article provided for the mechanism for resolving disputes arising out of the Treaty between States Parties.

Article 33 – Reservations
Article 33 provided for the State sovereignty.

Article 34 - Withdrawal
This Article provided for the State Parties to withdraw from the Treaty.

Article 35 – Dissolution
This Article provided for the procedure to be followed in dissolving the AMA.

Article 36 – Amendment and Revision
Article 36, provided for the amendment or revision of the Treaty.

Article 37 - Signature, Ratification and Accession
Article 37 provided for the procedure to follow for a country seeking to be a party to the Treaty.

Article 38 – Entry into Force
This Article provided for the period the Treaty should enter into force after depositing the instrument of ratification and accession.

Article 39 -Depository
Article 39 provided for the deposit of the Treaty with the Chairperson of the AU Commission, who should transmit a certified true copy of the Statute to the Government of each signatory State.

Article 40 – Registration
Article 40 provided for the registration of the Treaty with the United Nations Secretary-General in conformity with Article 102 of the Charter of the United Nations.

Article 41- Authentic Texts
The Article provided for the languages that would be used in drawing the Treaty.

5.0 SUMMARY OF SUBMISSIONS FROM STAKEHOLDERS

The Committee was informed that the Treaty for the establishment of the African Medicines Agency was progressive as it established a board that would oversee regulation of medicines of member States in Africa especially that Africa has been trying to reduce regulatory bureaucracies across borders, with regards to certification of medicines. In this regard, Zambia would benefit from the expertise and experience that other States Parties possessed and do not have in the area of medicine regulation. The Committee was further informed that Zambia was a beneficiary of organisations such as ZAZIBONA, which was a collaboration between national medicines regulatory authorities in Zambia, Zimbabwe, Botswana, Namibia, South Africa, Tanzania, Democratic Republic of Congo, Mozambique and Malawi, Eswatini, Angola, Seychelles and Madagascar. These countries were working together across borders on medicine regulation had assisted in ensuring that the Zambia Medicines Regulatory Authority (ZAMRA) dealt with issues of substandard and falsified pharmaceutical products. Additionally, collective decision making by

States Parties had resulted in a partial reduction of the backlog of product registration at ZAMRA and belonging to this treaty would reduce the backlog further.

5.1 Expected Benefits of Ratifying the AMA Treaty

The Committee was informed that the ratification of the AMA Treaty would demonstrate Zambia's commitment to the continent's collective action to the improved regulation of medicines, medical products, and health technologies. Stakeholders submitted that some of the benefits Zambia would enjoy by ratifying the Treaty included but were not limited to the following:

(a) Improved Access to Quality Medicines

Zambia would benefit from being a part of an all-encompassing institution that ensured that State Parties that did not have strong pharmaceutical regulatory systems and could easily be used as conduits of substandard and falsified pharmaceutical products were assisted. It was further, submitted that the AMA with its leadership clearly outlined that Zambia would also benefit on the aspect of trade, as it would open up the market for pharmaceutical products manufactured in Zambia. The burden of registration in different African jurisdictions would be removed.

(b) Regulatory Harmonisation

The harmonisation of regulatory requirements for registration of medicines entailed that manufacturers would submit the same dossier to different regulatory agencies without making major changes to the information. This would then facilitate information sharing by national medicines regulatory agencies and promote reliance on decisions made by other regulators. It would also contribute to expedited access to quality, safe and efficacious medicines by Member States.

(c) Reliance and Mutual Recognition:

The AMA Treaty under Article 6 provided that decisions made by other regulatory agencies within the continent who were Members would be standardised, thereby facilitating expedited decision making in respect to product registration and related matters. This would also facilitate regulatory information sharing and enhanced relationships with other regulatory agencies as envisaged under Article 30 of the Treaty.

(d) Collaboration and Knowledge Sharing

The Committee was informed that considering the prevalence of substandard and falsified medical products in the region, information sharing would be used as a tool for reducing and preventing the circulation of unwanted medical products. This would serve as a valuable

platform for sharing knowledge and fostering engagement in pharmaceutical manufacturing across Africa.

(e) Capacity Building

Stakeholders submitted that signing of the AMA Treaty and subsequent membership to the AMA would present opportunities for capacity building of the local experts in various regulatory functions.

It was further submitted that although Zambia had not officially ratified the Treaty, the Zambia Medicines and Regulatory Authority was co-opted to participate in the technical committees, as created under Article 22 of the Treaty. Therefore, once the Treaty was ratified, it would enhance the Zambia's participation in the technical committees. This would in turn help to build capacity for experts who were expected to be drawn from the Authority in line with Article 22(2) of the Treaty.

(f) Promoting Economic Integration

The Treaty would actively contribute to the enhanced economic integration of the African continent. The implementation of the African Continental Free Trade Area (AfCFTA) since June, 2020 had significantly bolstered economic integration efforts. The Treaty would further facilitate increased trade and investment by streamlining and simplifying pharmaceutical product registration processes, resulting in reduced fragmentation and shorter timelines.

5.2 Perceived Disadvantages of Ratifying the AMA Treaty

In addition to the expected benefits of ratifying the AMA Treaty, stakeholders also identified some downsides such as the ones below.

(a) Implementing the requirements of the Treaty, such as aligning with harmonised regulatory standards and enhancing regulatory capacity, may require significant financial and human resources. Zambia may face challenges in allocating sufficient resources to meet these obligations, particularly if its healthcare budget was already over-stretched.

(b) While the Treaty aimed to improve access to medicines, there was a possibility that Zambia's local pharmaceutical industry could face increased competition from manufacturers in other African countries. This could potentially negatively impact the competitiveness of domestic drug producers and pose challenges for their sustainability.

(c) Adhering to the regulatory requirements set forth, the AMA Treaty may impose a compliance burden on Zambia's pharmaceutical industry and

regulatory agencies. Meeting these standards could require additional time, effort, and resources, potentially slowing down the approval process for new medicines and increasing administrative overhead.

(d) There could also be adaptation challenges, thus, Zambia's existing medicines regulatory framework may need to undergo significant adjustments and reforms to align it with the provisions of the Treaty. Implementing these changes could pose logistical challenges and required careful coordination among various Government agencies and stakeholders.

(e) There could also be a potential for regulatory capture in that there was a risk that the AMA's regulatory processes could be influenced by powerful pharmaceutical interests. This could lead to regulatory capture or bias towards certain industry players. This could undermine the Agency's independence and effectiveness in safeguarding public health interests.

6.0 CONCERNS BY STAKEHOLDERS

Some stakeholders despite supporting the ratification of the Treaty, raised concerns as outlined below.

i. The preamble of the Treaty stated as follows:

> "*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 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"*

Despite this, it did not address how the pharmaceutical manufacturing would be achieved. Furthermore, the Treaty did not demonstrate how it would protect or aid the already established pharmaceutical manufacturing industries in respective jurisdictions among States Parties.

ii. Stakeholders also expressed concern on whether or not Zambia was in a position to comply with the provision of the Treaty under Article 26 which required Member States to make annual contributions as determined by the Conference of the State Parties as provided in Article 14(a), considering that the health care budget may already be over-stretched.

7.0 COMMITTEE'S OBSERVATIONS AND RECOMMENDATIONS

From the outset, the Committee agrees and supports the ratification of the Treaty to establish the African Medicines Agency. This is tandem with all the stakeholders who appeared before it. This is on account that the AMA Treaty is progressive and aims at improving access to essential medicines and health products that are safe, effective, affordable, and quality assured.

The Committee observes that the Treaty does not demonstrate how it intends to incorporate the African traditional medicines in respective jurisdictions among States Parties. The Committee, therefore, recommends that the AMA should take interest in the use and development of African traditional medicines.

The Committee also observes that the ratification of the Treaty will have financial implications in terms of membership contribution fees and resources that will be required in the implementation of the measures for compliance to the Treaty. In this regard, the Committee recommends that a budgetary allocation should be provided, to ensure that Zambia fulfils the financial obligation to the Treaty.

The Committee further observes that there was a potential regulatory capture considering that the AMA in its initial stage will receive financial support from the European Union. This may result in the AMA's regulatory processes being influenced by powerful pharmaceutical interests and potentially leading to regulatory capture or bias towards certain industry players. This could in turn undermine the Agency's independence and effectiveness in safeguarding public health interests. The Committee therefore, recommends that the AMA should work to being financially self sustainable.

The Committee observes with concern that countries with big pharmaceutical companies have not ratified the Treaty. Further, the Committee observes that Article 31 of the AMA Treaty which provided for the languages to be used by the AMA were not indigenous African languages.

In addition, the Committee observes that while the perceived disadvantages are worth considering, they should be weighed against the potential long-term benefits of enhanced access to medicines, improved public health outcomes, and strengthened regional collaboration that the AMA Treaty aims to facilitate.

7.0 CONCLUSION

The Committee is in support of the ratification of Treaty for the Establishment of the AMA as it is in line with the Constitutional obligation of ensuring that proper medical standards are enforced for the protection and benefit of the citizens. By

ratifying the Treaty, Zambia will benefit from a network of States parties among which there is international cooperation, assistance and exchange of experiences.

The Committee is further of the view that the impact of implementing the AMA Treaty will foster cooperation and coordination in the fields of health within the AU members that will ratify the Treaty and that once the AMA is up and running, Member States will be better equipped to achieve the issues outlined below.

(a) Increase access to medicines and health products that are safe, effective and of good quality, thereby improving health and consequently, economic growth.
(b) Combat substandard and falsified medical products.
(c) Improve efficiency.
(d) Lower overheads on medical products.
(e) Expedite market entry of life saving products; Enhance regulatory services, research, and innovation.
(f) Take a further step towards local production of medicines and medical products including vaccines.

(g) Contribute to the attainment of Universal Health Coverage of the population.
(h) Foster cooperation and coordination in health among African countries.

Mrs Marjorie Nakaponda, MP
VICE - CHAIRPERSON

February, 2024
LUSAKA

APPENDIX I - List of National Assembly Officials

Mrs Doreen N C Mukwanka, Director – Social Committees
Mrs Chitalu K Mumba, Deputy Director – Social Committees
Ms Christabel Malowa, Senior Committee Clerk (SC1)
Mrs Media Hachombwa Mweele, Committee Clerk
Ms Catherine Chibuye, Administrative Assistant
Mr Muyembi Kantumoya, Parliamentary Messenger

APPENDIX II - List of Witnesses

i. Ministry of Health
ii. Ministry of Justice
iii. Zambia Medicines and Regulatory Authority
iv. Pharmaceutical Business Forum
v. Pharmaceutical Society of Zambia
vi. Medicines Research Access Platform
vii. Zambia Medicines and Medical Supplies Agency