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**EXECUTIVE COUNCIL**  
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**PROGRESS REPORT ON THE ESTABLISHMENT AND  
OPERATIONALIZATION OF THE AFRICAN MEDICINES AGENCY**

**PROGRESS REPORT ON THE ESTABLISHMENT AND OPERATIONALIZATION  
OF THE AFRICAN MEDICINES AGENCY  
1<sup>st</sup> January 2023 – 31<sup>st</sup> December 2023**

This report is organized into four sections:

- i. Section 1: Progress Report on the Establishment and Operationalization of the African Medicines Agency
- ii. Section 2: Draft Decision on the 2023 African Medicines Agency (AMA) Progress Report

**Section 1. Progress Report on the Establishment and Operationalization of the African Medicines Agency**

**I. Introduction**

1. The Treaty for the Establishment of the African Medicines Agency (AMA Treaty) was adopted on 11 February 2019 during the 32<sup>nd</sup> Ordinary Session of the African Union (AU) Assembly, in Addis Ababa, Ethiopia (Assembly/AU/Dec.735(XXXII)). The AMA Treaty came into force on 5 November 2021 following the deposit of the 15<sup>th</sup> instrument of ratification. The expeditious entry into force (2 years and 9 months) has remained to be a record in the annals of the African Union Commission. Moreover, the urgent need for and importance of having the continent's medicine regulatory agency has not only been reflected in the number of ratifications of the AMA Treaty, but also in the progress made in the operationalization of the AMA. Established as a specialized agency of the African Union, the AMA will enhance the capacity of State Parties and Regional Economic Communities (RECs), to regulate and improve access to quality, safe and efficacious medicines, medical products and technologies in Africa. Additionally, it will coordinate the ongoing regulatory initiatives and systems in the continent.

**II. Background**

2. The health and well-being of Africans is highlighted as a fundamental building block to achieving the socio-economic and structural transformation as envisaged in the Africa Agenda 2063. In addition, it has been underscored as the main goal of the Africa Health Strategy 2016-2030(AHS) through which *Essential medicines, Commodity Security and Supply Systems is defined as the strategic approach of AHS*. At the centre of the continent's healthy and productive population, is access to safe, effective, quality and affordable medicines, medical products and technologies - a core pillar of Universal Health Coverage.

3. In Africa, access to safe, effective, quality medicines, medical products and technologies remain limited. This is largely due to the weak and inefficient as well as the overall fragmented regulatory systems and processes. The fragmented regulatory systems and processes have contributed to delaying researchers and manufacturers of pharmaceutical products, who must navigate multiple regulatory systems to register the same health product across multiple member states.

4. On the other hand, weak and inefficient regulatory systems have resulted in the widespread circulation of substandard and falsified (SF) as well as harmful medicines, medical products and health technologies in many AU member states. The sale and consumption of SF medicines have posed a serious threat to securing the continent's public health. Its brunt's has been felt both socially and economically. For instance, several reported deaths from consumption of SF medicines, clinical consequences such as masking of clinical symptoms of ailments and drug resistance, and loss of public trust in the healthcare service delivery system. Furthermore, it has also increased out-of-pocket healthcare spending on diseases that arise from the consumption of SF medicines, forfeited government revenues from unpaid taxes and huge government spending to combat the menace.

5. Against this backdrop, the AU Executive Council in January 2015, recognized the need to strengthen the capacity of medical products regulation and the harmonization of regulatory systems in Africa, as a foundation for the establishment of a single medicine regulatory agency in Africa, within the context of the African Medicines Regulatory Harmonization (AMRH) Initiative, and part of the Pharmaceutical Manufacturing Plan for Africa (PMPA) (EX.CL/Dec.857 (XXVI)). Noteworthy, the Africa Health Strategy 2016-2030 also highlights as one of its strategic approaches, the building of a strong regulatory environment to support the provision of safe and quality medicines and technologies including nurturing African Traditional Medicine.

6. Consequently, the Executive Council endorsed the AMA milestones and requested the Commission, the African Union Development Agency-NEPAD and World Health Organization in collaboration with other stakeholders to define the scope of the medicines, medical products and technologies that would be covered by the work of the AMA, and to work out detailed modalities, institutional framework, legal and financial implications, of the establishment of the AMA. It is in this context that the AMA Treaty was then adopted by African Heads of State in February 2019 (Assembly/AU/Dec.735 (XXXII)) and entered into force on 5 November 2022 following the deposit of the 15<sup>th</sup> instrument of ratification.

### III. Status of Signing and Ratification of the AMA Treaty

7. As of 24 November 2023, thirty-three (33) member states have signed the AMA Treaty while twenty-six (26) member states have ratified and deposited the legal instrument of ratification at the Commission. Table 1 shows the number and member states that have signed and ratified the AMA Treaty as of 31<sup>st</sup> December 2022.

**Table 1: Signing and Ratification Status of the AMA Treaty as of 24 November 2023**

<b>Member States that have signed: 33</b>	<b>Member States that have ratified: 26</b>
1. Algeria	1. Algeria
2. Benin	2. Benin
3. Burundi,	3. Burkina Faso*
4. Cabo-Verde	4. Cabo-Verde
5. Cameroon	5. Cameroon
6. Chad	6. Chad
7. Comoros	7. Congo

8. Egypt	8. Egypt
9. Republic of Congo	9. Gabon
10. Cote d'Ivoire	10. Ghana
11. Equatorial Guinea	11. Guinea
12. Ethiopia	12. Kenya
13. Gabon	13. Lesotho*
14. Ghana	14. Mali
15. Guinea	15. Mauritius
16. Kenya	16. Morocco
17. Mali	17. Namibia*
18. Mauritius	18. Niger
19. Morocco	19. Rwanda
20. Madagascar	20. Saharawi
21. Mozambique	21. Senegal
22. Niger	22. Seychelles
23. Rwanda	23. Sierra Leone
24. Saharawi	24. Tunisia
25. Sao Tome and Principe	25. Uganda
26. Senegal	26. Zimbabwe
27. Seychelles	(* Ratification without signing)
28. Sierra Leone	
29. Tanzania	
30. Tunisia	
31. Togo	
32. Uganda	
33. Zimbabwe	

#### IV. Operationalization of the AMA

8. The AU Commission has made progress in fast-tracking the operationalization of the AMA. Major milestones achieved include;

- **Presentation of the 2022 AMA Progress Report to the Assembly of the Union in February 2023 and adoption of the AMA Governing Board Nomination Modalities;**
- **Signing of the AMA Headquarters Host Country Agreement on 10 June 2023;**
- **Second Extraordinary Session of the Conference of the State Parties to the AMA Treaty: 19-20 June 2023;**
- **Establishment of the AMA Governing Board;**
- **RECs and RHOs Sensitization Workshop on AMA Operationalisation, 10 July 2023;**
- **AMA Advocacy for Increased ratifications.**

a) **Presentation of the 2022 AMA Progress Report to the Assembly of the Union in February 2023**

9. The 37<sup>th</sup> Ordinary Assembly of the African Union Heads of State and Government in February 2023 adopted the AMA establishment and operationalisation Progress Report along with the AMA Governing Board Nomination modalities and key steps on way forward.

**b) Signing of the AMA Headquarters Host Country Agreement on 10 June 2023**

**10.** Further to the Decision of 41<sup>st</sup> Ordinary Session of the Executive Council EX.CL/Dec.1179(XLI) in accordance with the Assembly decision Assembly/AU/Dec. 830(XXXV), authorizing the Executive Council to take a decision *on behalf of the Assembly on the host of the AMA Headquarters*, the AMA Headquarters was decided to be in Rwanda. Therefore, the Commission, through its office of legal counsel has engaged with the Government of Rwanda to finalise the draft AMA Headquarters Host Agreement. Once finalised, the Commission and the Government of Rwanda signed the draft AMA Headquarters Host Agreement on 10 June 2023, a host agreement that was later ratified by the Rwandan Parliament in October 2023.

**c) Second Extraordinary Session of the Conference of State Parties to the AMA: 19-20 June 2023**

**11.** In accordance with the recommendations by the First Extraordinary Session of the Conference of the State Parties to the AMA Treaty held from 3-4 November 2022 decided that the second extraordinary session shall focus on the: a) Appointment of the members of the AMA Governing Board and Consideration and adoption of the Terms of Reference of the Director General, the Commission organised the Second Extraordinary Session of the Conference of State Parties to the AMA (CoSP) from 19 - 20 June 2023. During this Session, the CoSP was briefed on the status of Progress on AMA establishment and operationalisation including but not limited to the establishment of AMA Governing Board. Further, the CoSP adopted the AMA Director General Job Description.

**12.** However, the establishment of the AMA Governing Board was postponed by the CoSP because out of the 7 nominations received of the AMA Governing Board members, 3 of which conform to the criterion and 4 of them do not conform to the AMA Board criterion. In this regard, replacement with adequate profiles and relevant experience are required to strengthen the capacity of AMA to operate with competency and achieve its goals. Furthermore, the Central and Northern Regions were encouraged to finalise consultations and send their nominees latest by 3<sup>rd</sup> of August 2023.

**13.** Against this backdrop, the CoSP proposed establishing an ad-hoc committee to work with the AU Commission to consult with the regions to assess the submitted profiles. Accordingly, the CoSP requested the AMA bureau Members (see table below) to oversee this process with the support of AUC, NEPAD and Africa CDC.

Table 2: The Representation of the AMA Bureau

<b>Region</b>	<b>Member State</b>	<b>Position</b>
<b>Western Africa</b>	Republic of Ghana	<b>Chair</b>
<b>Central Africa</b>	Republic of Chad	<b>First Vice Chair</b>
<b>Eastern Africa</b>	Republic of Uganda	<b>Second Vice Chair</b>

<b>Northern Africa</b>	To be Confirmed	<b>Third Vice Chair</b>
<b>Southern Africa</b>	Republic of Namibia	<b>Rapporteur</b>

14. The Second Extraordinary Session of AMA CoSP proposed the following as agenda items for its third extraordinary session:

- i) Adoption of AMA Governing Board;
- ii) Selection Modalities of AMA Director General and;
- iii) Adoption and AMA essential Structure.

**d) Establishment of the AMA Governing Board**

<b>Names</b>	<b>Profiles</b>	<b>Country/Institution</b>	<b>Contact Details</b>
1. Col. Dr Yossounon Chabi,	Director General, Benin Pharmaceutical Regulatory Agency	Benin for Western Region	<a href="mailto:chabivoss@yahoo.fr">chabivoss@yahoo.fr</a>
2. Germina Mamoeti Mphoso	Head of Pharmacy & Regulatory Authority of the Ministry of Health (MOH)	Lesotho for Southern region	<a href="mailto:germina.mphoso@gov.ls">germina.mphoso@gov.ls</a> , <a href="mailto:gmpphoso@yahoo.com">gmpphoso@yahoo.com</a>
3. Dr Emile Bienvenu	Director General for Rwanda Food and Drug Authority (FDA)	Rwanda for Eastern region	<a href="mailto:dg@rwandafda.gov.rw">dg@rwandafda.gov.rw</a>
4. Dr Haoua Haroun Saker	Deputy Director for Pharmacy and Drugs	Tchad, for Central Region	<a href="mailto:haouasaker@yahoo.fr">haouasaker@yahoo.fr</a>
5. H.E. Amb. Minata Samate Cessouma	Commissioner for Health, Humanitarian Affairs and Social Development	AUC	
<b>Pending</b>			
TB	Northern Africa Region	Reminder sent	
TB	CEN-SAD	Letter in process  CEN-SAD reported to the Commission through an official letter that it does not have the requested capacity, but it delegated the Egyptian Drugs Authority to represent them. Then after, Morocco	

		sent a Note Verbale to the Commission claiming that they are representing CEN-SAD. The Commission requested CENSAD to conduct consultations and communicate the name of the person representing CENSAD as soon as possible.	
TB	ECCAS	ECCAS and WAHO are in the process of appointing their representative.	
TB	West African Health Organization (WAHO)		

15. In accordance with the conclusions and recommendations of the 2<sup>nd</sup> CoSP to the AMA Treaty, the Commission engaged in sending further communications (Note Verbales and Letters) to Member States, RECs and RHOs within the indicated one month deadline to respond. The deadline has expired, and the Commission has sent reminders but to date, there are only two additional nominations which make the current status of membership to 5 including the Commission. See table below

**e) RECs and RHOs Sensitization Workshop on AMA Operationalization, 10 July 2023**

16. Further to the encountered challenges with the AMA Governing Board Nomination and the expected roles to be played by RECS and RHOS, the Commission organized a virtual sensitization workshop with all the AU recognized RECs and RHOs on 10 July 2023. The workshop was an opportunity for the AUC to brief RECs and RHOs on the status of progress on AMA operationalization but to also discuss how RECs and RHOs could FastTrack the AMA Governing Board processes.

**f) AMA Advocacy for Increased ratifications**

17. Further to the Decision of 41<sup>st</sup> Ordinary Session of the Executive Council EX.CL/Dec.1179(XLI) “**ENCOURAGES** Member States that have signed the AMA Treaty to ratify it and **CALLS ON** other Member States to sign and ratify the said treaty to safeguard public health, safety and security and to improve access to quality, safe and efficacious medicines and medical products on the continent” the Commission has proposed Terms of Reference and a high-level advocacy plan for Hon. Michel Sidibe AMA Special Envoy. The objective is to revive advocacy efforts around increased signing and ratifications of AMA treaty. The plan is under review for high level missions to start during the first quarter of 2024 with an initial visit to 7 countries in addition to RECs as per the recommendation from the RECs and RHOs sensitization workshop.

**V. Expression of Interest in Hosting the Regional Centres for Regulatory Excellence of the AMA (RCOREs)**

**18.** Two (2) State Parties have expressed interest to host the RCOREs. The first expression of interest was made by the Republic of Zimbabwe during the First Ordinary Session of the Conference of State Parties in June 2022. The Commission received the second expression of interest from the Republic of Mauritius.

**19.** The Commission just takes note of the expressions of interest. As the Commission is now in the process of the operationalization of AMA, the candidatures for the RCOREs has not yet launched. In due course these expressions of interest will be submitted to the Conference of the State Parties to decide, in conformity with AMA treaty and rules of procedure.

### **Support for the Operationalization of the AMA**

#### **a. AUDA-NEPAD and Africa CDC**

**20.** Africa CDC and AUDA- NEPAD provided technical and financial support to the commission as part of the coordination effort during AMA operationalization process.

#### **b. Support from the World Health Organization**

**21.** In line with the AUC/WHO Memorandum of Understanding dated 18 November 2019, World Health Organization agreed to continue supporting the Commission Advocacy agenda towards increased ratification of the African Medicines Agency (AMA) in the amount of USD 200,000.

#### **c. The Bill and Melinda Gates Foundation**

**22.** The Bill and Melinda Gates Foundation – expressed interest in supporting the operationalization of the AMA and has committed financial support for 2023. Modalities of support and areas of collaboration have been agreed and outlined in a Draft Memorandum of Understanding to be signed. Part of the financial support was used to cover the cost of organising two major events:

- i) the Second Extraordinary Conference of State Parties to the AMA Treaty and;
- ii) and advocacy event in the side-lines of the 73rd UNGA titled " Advancing Pandemic Prevention, Preparedness and Response (PPPR) Local manufacturing of health products and technologies in Africa, Leveraging the role of public-private partnerships".

#### **d) Challenges**

**23.** The Commission has experienced three major challenges in advancing AMA operationalization:

- i. The first challenge pertains to the very slow and delayed reactions from AU Member States, RECs and RHOs regarding the establishment of the AMA Governing Board. This has resulted in the delay to finalize the board;
- ii. The Second challenge is related to budget for AMA activities. The Commission has relied fully on external partner support to conduct 2023 AMA related

activities. The Commission has therefore enjoyed less flexibility and often had to rely on partner processes.

- iii. The third challenge is related to the lack of capacity. The Health and Humanitarian Affairs Directorate has no dedicated full staff for AMA operationalization, which contributed to the delay of AMA activities implementation.

**e) Next steps and way forward**

- i. Continuation of advocacy for the signing and ratification of the AMA Treaty by AU member states;
- ii. Finalisation of the AMA Governing Board nomination processes with CENSAD, ECCAS and WAHO. For CENSAD, the Commission has also requested a legal opinion and has been accordingly advised. The next step will be for CEN-SAD to send a name to the Commission;
- iii. Finalisation of the AMA Structure and modalities for Financial Contribution;
- iv. Organization of the 3rd Extraordinary Session of the Conference of State Parties;
- v. Organization of the First Ordinary Session of AMA Governing Board during the first quarter of 2024 to adopt their rules of procedures and further discuss relevant processes on AMA Structure and DG Recruitment Modalities;
- vi. Remain engaged with the Governemnt of Rwanda to ensure smooth implementation of the AMA Host Agreement;
- vii. Secondment of the AUC set-up team from the key and relevant operational departments to AMA HQ to support establishment process of the office.

## SECTION 2. DRAFT DECISION ON THE 2023 AFRICAN MEDICINES AGENCY (AMA) PROGRESS REPORT

The Assembly,

1. **TAKES NOTE** of the 2023 African Medicines Agency (AMA) Progress Report and the recommendations contained therein.
2. **TAKES NOTE ALSO** of the challenges related to the feedback from Member States, RECs and RHOs encountered by the Commission in the establishment of the AMA Governing Board;
3. **CALLS** the RECs and RHOs that not yet designate candidate to finalize the consultations and send to the Commission for consideration on the AMA Governing Board.
4. **WELCOMES** the signing and the ratification of the AMA Treaty Headquarters between the Commission and the Government of Rwanda as well as the adoption of the AMA Director General Job Description by the Conference of State Parties to the AMA Treaty
5. **COMMENDS** the Commission, AUDA-NEPAD, Africa CDC, the AMA Bureau and the Conference of State Parties to the AMA Treaty for the status of progress achieved despite numerous challenges in the establishment and operationalization of AMA;
6. **COMMENDS ALSO** the 26 countries that have ratified the AMA Treaty and urges the remaining countries for those that that signed the treaty to ratify and the remaining to sign and ratify.

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