



FREQUENTLY ASKED QUESTIONS (FAQs) ON THE AFRICAN MEDICINES AGENCY (AMA)

Q. What is African Medicines Agency (AMA)?

A. The African Medicines Agency will be the second specialised health agency of the African Union after the Africa Centres for Disease Control and Prevention (Africa CDC) that will enhance capacity of State Parties and AU recognised Regional Economic Communities (RECs) to regulate medical products to improve access to quality, safe and efficacious medicines, medical products and technologies on the continent.

Q. How was AMA Treaty established?

A. The AMA Treaty was adopted by Heads of States and Government during their 32nd Ordinary Session of the Assembly on 11 February 2019 in Addis Ababa, Ethiopia Assembly/AU/Dec.735 (XXXII). The Treaty establishing the African Medicines Agency (AMA) entered into Force on 5th November 2021, following the deposit of the 15th instrument of ratification, on the 5th of October 2021, by the Republic of Cameroon at the African Union Commission (Article 38; AMA Treaty).

Q. What will be the main functions of AMA?

A. AMA aims to provide support for the improvement of weak regulatory systems. AMA shall build on the efforts of the African Medicines Regulatory Harmonization (AMRH) initiative (2009),

which is led by the Africa Union Development Agency - the New Partnership for Africa's Development (AUDA-NEPAD). The AMRH initiative provides guidance to AU recognised Regional Economic Communities (RECs) and Regional Health Organizations (RHOs), to facilitate harmonisation of regulatory requirements and practice.

Q. How many countries have deposited the AMA instruments of ratification at the Commission?

A. As of 5th November 2021, 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 AMA and deposited the legal instrument of ratification to the Commission. One (1) member state, namely Morocco, has ratified the Treaty but is yet to deposit the instrument of ratification to the Commission.

Q. How many countries have signed the AMA Treaty so far?

A. As of 5th November 2021, 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) had signed.

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Q. Where will the Headquarters of AMA be?

A. The assessment missions report to review and evaluate the proposals submitted by member states to host AMA shall be presented to the Conference of State Parties who will recommend the location for the headquarters of the AMA in accordance with the AU criteria adopted in 2005. The Headquarters of AMA shall be determined by the Assembly of the Union upon the recommendations of the State Parties.

Q. What next after the Treaty enters into force?

A. The Commission shall convene the first meeting of the Conference of State Parties, which is the highest policy-making organ of the AMA composed of all member states of the African Union who have ratified or acceded to AMA Treaty, once the AMA Treaty comes into Force. The Conference of State Parties will establish and determine the composition, sessions, function and term of office of the AMA Governing Board. The Governing Board will include 5 Heads of National Medicines Regulatory Authority (NMRAs) from each region, one (1) Regional Economic Community (REC) representative, one (1) representative of Regional Health Organization (RHOs), 1 representative of National Committees Responsible for bioethics on rotational basis and the Commissioner for Commissioner for Health, Humanitarian Affairs and Social Development (HHS) at the African Union Commission (AUC).

Q. Who will Head the African Medicines Agency?

A. The Director General of AMA will serve as the Head of AMA Secretariat and will be responsible for the day-to-day management of the AMA. The Director General will be appointed by the Conference of the State Parties upon the recommendations of the Governing Board.

Q. What role will AMA play in the fight against future pandemics and infectious disease outbreaks?

A. The efforts to coordinate the regulatory systems strengthening and harmonisation initiative under the leadership of the 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 the use of substandard and falsified medical products. AMA will facilitate expeditious approval of products that address the health needs of the African populace, especially for diseases that disproportionately affect Africa.

In addition, AMA will promote the adoption and harmonisation of medical products regulatory policies

and standards, as well as scientific guidelines, and coordinate existing regulatory harmonisation efforts in the Regional Economic Communities (RECs) and Regional Health Organizations (RHOs).

Q. Who are the main partners in the establishment of the African Medicines Agency?

A. The African Union Commission has been working with the African Union Development Agency (AUDA-NEPAD) and the World Health Organization (WHO) in supporting the advocacy activities to sign and ratify the AMA Treaty.

Q. How will the African Medicines Agency be financed?

A. AMA will be financed by the State Parties as per the financial rules and regulations approved by the Governing Board and adopted by the Conference of the State Parties.

Q. What is the state of the African pharmaceutical industry?

A. African Union's Pharmaceutical Manufacturing Plan for Africa (PMPA) was established to develop the African pharmaceutical industry (Assembly/AU/Dec.55(IV), a sector with considerable potential for reducing the burden of disease in Africa. With a projected value of over US\$40 billion by the next decade, the sector will also contribute significantly to economic growth.

A business plan for implementing the plan was developed and considerable progress has been recorded including the establishment of initiatives to harmonise medicine regulation on the continent [Assembly/AU/DEC-413(XVIII)], addressing human capacity and skills shortages, and promoting cooperation and advocacy in the industry. The optimism in the sector has also galvanised countries and regions with manufacturing capacity to harness support for the development of the sector despite the funding challenges.

Q. How will AMA leverage on the opportunities brought about by the African Continental Free Trade Area (AfCFTA)?

A. AMA will gain a great deal from the African Continental Free Trade Area (AfCFTA) as it allows access of goods and services without tariffs to a market of over 1.2 billion potential consumers. Through this mechanism Africa has created a single continental market for goods and services across the continent as well as accelerated the establishment of a customs union which now leads to the creation of an African Economic Community by 2028. Through the coming into a force of the AfCFTA, Africa becomes the largest integrated trading area in the world. This has huge implications for the pharmaceutical industry and in particular for the movement of goods and services associated with medicines, medical products and technologies. Regulation shall be critical to guaranteeing the protection of the 1.2 billion African market from fake, substandard, and counterfeit products and services.

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