

The United Republic of Tanzania signs the Treaty for the establishment of the African Medicines Agency (AMA)

10 August 2021. The United Republic of Tanzania becomes the twenty second (22nd) African Union (AU) Member State to sign the Treaty for the establishment of the African Medicines Agency (AMA) on 10 August 2021, at the AU Commission in Addis Ababa, Ethiopia. H.E. Dr Monique Nsanzabaganwa, Deputy Chairperson, African Union Commission, received H.E. Liberata Mulamula, Minister of Foreign Affairs of the United Republic Tanzania.

H.E. Dr Monique Nsanzabaganwa noted that Tanzania has been a key leader in supporting the efforts of the Commission and the East African Community, in the harmonization of regulatory policies, under the African Medicines Harmonization Initiative, being led by the African Union Development Agency (AUDA-NEPAD). “The current pandemic has reinforced the need for the continent to have very strong continental health institutions and the AMA working in tandem with the African CDC will be the key to collectively address the continental health challenges,” she added. She encouraged Tanzania to move to the next step of ratifying the Treaty for the establishment of AMA.

H.E. Liberata Mulamula, stated that the establishment of the AMA Agency is very timely particularly during the ongoing COVID-19 pandemic. “The United Republic of Tanzania was determined to sign the Treaty establishing AMA in order to mitigate the challenge of combating falsified medical products at regional level,” H.E Mulamula further encouraged the other Member States that have not signed the Treaty to do so at the earliest.

The United Republic of Tanzania has demonstrated her commitment to guarantee quality-assured, safe and efficacious medical products that are fundamental to the health and safety of her people and Africa as a whole.

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. The African Medicines Agency aspires 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 recognized Regional Economic Communities (RECs) and Regional Health Organizations (RHOs), to facilitate harmonization of regulatory requirements and practice among the national medicines authorities (NMRAs) of the AU Member States.

AMA will be the second specialized health agency of the African Union after the [Africa Centres for Disease Control and Prevention \(Africa CDC\)](#). The agency will among other functions 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 the State Parties. AMA will also promote cooperation, partnership and recognition of regulatory decisions, in support of regional structures

and National medicines regulatory authorities (NMRAs), that takes into account mobilization of financial and technical resources to ensure sustainability of the AMA.

The Agency will further convene, in collaboration with the WHO, the African Medicines Regulators Conference (AMRC) and other bodies, meetings related to medical products regulation in Africa. In addition, AMA will 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 investigations and clinical trials.

Fifteen (15) member states have ratified the AMA Treaty. The AMA Treaty will enter into Force 30 days upon the deposit of the 15th instrument of ratification at the Commission. The African Union Commission encourages all its Member States to sign and ratify the Treaty for the establishment of AMA in the interest of public health, safety and security. The Treaty is available for signature at the Headquarters of the Commission in Addis Ababa, Ethiopia.

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