The Time is Now: AMATA Calls for the rapid operationalisation of the African Medicines Agency and for regulatory system strengthening to be recognized as a key element of preparedness for future pandemics and post-pandemic recovery

December 15, 2022, **Kigali, Rwanda** – The founding members of the African Medicines Agency Treaty Alliance (AMATA), an alliance representing African patients, academia, civil society, and industry, call for the rapid operationalisation of the African Medicines Agency to seize this historic opportunity to improve access to quality, safe and efficacious medicinal products on the Continent and therefore be better prepared to face future pandemics. This was announced at an official side event taking place at the 2nd Conference on Public Health in Africa, which is organized by the African Union and the Africa CDC.

Invested by the power of civil society, community actors and the private sector, we now call upon the African Union and its Member States to ensure that:

The African Medicines Agency (AMA) headquarters is operational, and a Director-General is appointed without undue delay

A road map is implemented to set up a solid governing structure and methods of work are agreed upon that rely on multistakeholder collaboration.

The Agency is equipped with sustainable funding and adequate human resource capacity to fulfil its mandate.

The AMA builds and reinforces the African regulatory ecosystem that exists at national and regional levels. Specifically enhancing National Regulatory Authorities (NRAs) and AU recognized Regional Economic Communities (RECs) to work in collaboration and reinforce each other's capacities.

The pharmaceutical regulatory processes, procedures, and expectations of manufacturing, market authorization is streamlined to prevent duplication of efforts and delays in access to life-saving medicines and vaccines to all patients.

AMA as a modern regulatory agency adopts digital solutions and reliance-based procedures to accelerate access to health products and vaccines, especially the most innovative and complex treatments that are available globally. And by doing so to foster a conducive environment for innovation and local production to flourish.

AMA to adopt a strategy to propel the African pharmaceutical industry towards the global arena. To have a role in the African Union Science, Innovation and Technology Strategy of Africa (STISA) through collaboration with the AU institutes of Pan African University (PAU); and to provide a framework for the African industrial chamber of pharmaceuticals, cosmetics and medical appliances.

A framework for engagement with patients and non-state actors is set up early on to leverage all available resources and expertise

AMA to set a medical devices regulatory framework, including safety requirements for medical devices under registration or re-registration.

AMA provides the underpinning structure to support the emergence of centers of excellence for research, as well as the strengthening and security of supply chains to prevent falsified and substandard medicines reaching patients.

In addition, AMA to set and to develop norms and standards for traditional and complementary medicines in collaboration with the World Health Organization.

The AMA Treaty is unanimously ratified by all 54 AU Member States to confer the legitimacy that it deserves in order for policies provide the unified Continental regulatory oversight in Africa.

We stand ready to engage and collaborate for the African Medicines Agency to deliver on its promise for a better future for patients in Africa and the world.