

## Call to Heads of State of the African Union to Ratify the African Medicines Agency Treaty

Patients, Civil Society and Youth Organisations, Products Development Partnerships, Health and Pharmaceutical Industries, and all stakeholders who are striving to improve global public health - welcome the African Medicines Agency (AMA) Treaty made at the 32nd ordinary session of the Assembly of the African Union (AU) in 2019. We now call for all AU Member States to ratify the Treaty, which has already been signed by 19 countries and ratified by 8 countries. This is a strong commitment from AU Member States and we therefore urge all countries of the AU to ratify the Treaty as a matter of priority.

We believe it is critical to establish a continental regulatory body to reduce the complexity of regulatory frameworks and hence to enable all patients in Africa to have timely access to quality medicines that are safe and effective. This new agency is an integral part of the WHO Global Patient Safety Plan 2020-2030. We support the WHO African Region commitment towards the African Medicines Agency delivered by the Kenyan government at the WHO Executive Board in January 2021.

The COVID-19 pandemic has highlighted the importance of regulatory harmonisation in the context of public health emergencies and the need for a competent continent-wide regulatory authority to approve and monitor vaccines, repurposed medicines, innovative medicines and health technologies, in a timely manner.

Furthermore, a strong unified regulatory system would greatly contribute to combating falsified and substandard medicinal products on the African continent. Coordinated market surveillance, centralised information collection and sharing of data between countries is expected to complement and strengthen national efforts to reduce the circulation of falsified products and increase access to safe and innovative products.

The establishment of the African Medicines Agency will open-up more opportunities to boost local manufacturing capacities, country participation in clinical research and other scientific development activities.

## Considering this, we call for:

- 1. AU Member States to ratify the AMA Treaty and enable the operational implementation of the continental regulatory system that will benefit patients, regulators, and healthcare systems in Africa.
- 2. The African Medicines Agency Governing Board to draw upon all available expertise from academia, research bodies, private sector and community and patient groups to provide technical guidance on specific areas of regulatory expertise.
- 3. The African Medicines Agency Governing Board to recognise patients as key partners in the management structures and development of the future Agency.

The following organizations support this call:



































International Federation of Pharmaceutical Manufacturers & Associations























































