



AMATA Statement at WHO Regional Committee for Africa

Agenda item 11: Regional strategy on regulation of medical products in the African Region, 2026–2035.

The members of the African Medicines Agency Treaty Alliance (AMATA) welcome and strongly support the Regional Strategy on Regulation of Medical Products in the African Region, 2026–2035.

Access to safe, effective, quality-assured medical products depends on a strong regulatory system. However, a truly harmonized and effective regulatory system cannot be achieved without continental coordination and leadership.

We therefore call strongly for all 55 AU Member States to ratify the Treaty for the establishment of the African Medicines Agency, and to support the Agency's full operationalization.

Universal ratification of the African Medicines Agency (AMA) Treaty would:

- strengthen **regulatory coherence across the continent**, helping to harmonize standards and reduce duplication in medicines regulation.
- facilitate **faster and more equitable access to safe, effective and quality-assured medicines**, while strengthening national and regional capacity to detect and respond to substandard or falsified products.
- reinforce **Africa's regulatory sovereignty**, enabling African institutions and Member States to collectively shape regulatory priorities in line with the continent's health needs.
- support a more coordinated and resilient continental response to **public-health emergencies**, including the rapid assessment, authorization and deployment of essential medicines, vaccines and other medical products.

We call on African Union Member States to renew their political commitment and translate it into predictable domestic financing that ensures AMA's functionality, independence and sustainability.

Ratifying the AMA Treaty and financing its operationalisation is not merely a bureaucratic exercise. It is an investment in saving lives, protecting patients from substandard and falsified products, and expanding equitable access to safe, effective and quality-assured medicines, vaccines and health technologies.