Operationalising the African Medicines Agency (AMA)

FACTSHEET

Since 2009, the Africa Union Development Agency (AU-NEPAD), in collaboration with partners, has been leading the African Medicines Regulatory Harmonization Initiative (AMRH).

The AMRH aims to improve the fragmented regulatory system for medical product registration in Africa by changing from a country-focused approach to a collaborative regional one.

The vision is to gradually move from 55 countries acting independently to the five Regional Economic Communities (RECs) supporting AMA.

AMA is a specialized agency of the African Union (AU) established to enhance the capacity of State Parties and Regional Economic Communities (RECs), to regulate and improve access to quality, safe and efficacious medicines, medical products and technologies in Africa. Additionally, it will coordinate the ongoing regulatory initiatives and systems in the continent.

As of 24 November 2023, thirty-three (33) AU Member States have signed the AMA Treaty while twenty-six (26) have ratified and deposited the legal instrument of ratification at the AU Commission.

The Treaty for the establishment of the AMA—Assembly Decision Assembly/AU/Dec.735(XXXII)—was adopted by the 32nd Ordinary Session of the Assembly on 11 February 2019, in Addis Ababa, Ethiopia.

On 10 June 2023, the Republic of Rwanda signed the AMA Headquarters Host Country Agreement abiding to host the Agency at its capital, Kigali.

Access to safe, effective, quality and affordable medicines, medical products and technologies—core pillars of the AU Agenda 2063 and Universal Health Coverage (UHC)—are at the centre of Africa’s healthy and productive population.
AMA OBJECTIVES

1. **Provide a platform** for coordination and strengthening of ongoing regional and continental harmonization initiatives by pooling (and so optimizing) the use of limited resources such as technical expertise.

2. **Harmonize the regulatory landscape** and move Africa towards a single integrated block, especially when it comes to highly regulated medical products. Similarly, AMA will enhance standards, improve the ease of movement of medical products that meet accepted international standards, promote local production, encourage innovation, and ease introduction into the African market.

3. **Coordinate access to and network the services** available in quality control laboratory services within national and regional regulatory authorities.

4. **Promote and advocate** for the adoption of the AU Model Law on Medical Products Regulations in States Parties and RECs to facilitate regulatory and legal reforms at continental, regional and national levels.

All these efforts will ensure that products regulated within AU Member States and across the continent are of the highest quality and are safe and efficacious.

According to the World Health Organization (WHO), approximately 1 out of every 10 medical products circulating in low- and middle-income countries is substandard or falsified (SF). The COVID-19 pandemic has underscored the pressing need for both individual countries and the African continent to regulate medical products and establish local manufacturing capabilities to address demand and reduce the current 70% reliance on imports.

In many African Union (AU) Member States, limited capacities of the regulatory systems have also given rise to the circulation of SF medical products. This situation constitutes a major threat to public health.

SF medical products, which jeopardize patient safety, can lead to loss of life, economic repercussions, and diminished trust in healthcare service delivery. AMA will strengthen regulatory oversight to counteract the proliferation of SF medical products and enable competitiveness of locally produced medicines.

The AU Commission and AUDA-NEPAD are leading a strong call for more AU Member States to ratify the AMA Treaty, in order to boost robust local manufacturing capacity, enhance regulation and harmonization in Africa’s pharmaceutical sector and support health systems resilience on the continent.

LEARN MORE: www.nepad.org/microsite/african-medicines-agency-ama