



Office of Global Policy and Strategy

OGPS STATEMENT

June 17, 2026

FDA and African Medicines Agency Sign Historic Statement of Cooperation

Dear International Colleague,

The U.S. Food and Drug Administration (FDA) and the [African Medicines Agency \(AMA\)](#) have signed a [Statement of Cooperation \(SOC\)](#), establishing a formal framework for regulatory cooperation between the FDA and the African Union's continental medicines regulatory agency.

The signing represents a historic milestone in regulatory cooperation between the two agencies, advancing regulatory convergence, harmonization, and information exchange and reflecting a shared interest in promoting science-based regulatory approaches for medical products.

The SOC provides a mechanism for continued engagement as AMA develops into a regulatory agency that serves more than 1.4 billion people across Africa. Areas of cooperation include reliance-based regulatory pathways, clinical trial oversight for innovative medical products, emergency regulatory response, quality management systems, digital transformation, and efforts to combat substandard and falsified medical products.

The cooperation framework recognizes the essential role of reliance, which enables regulatory authorities to leverage scientific assessments, inspections, and decisions conducted by trusted authorities while maintaining sovereignty and independent decision-making. As AMA develops continental regulatory frameworks, its engagement with the FDA will provide opportunities for reliance on FDA regulatory decisions. One of the world's leading regulatory authorities, the FDA has long served as a trusted reference authority whose decisions can help promote efficient, science-based regulatory pathways and reduce duplication of regulatory effort.

In anticipation of this work, the FDA established the FDA African Medicines Agency Liaison Office (AMALO) at the U.S. Embassy in Kigali, Rwanda, in September 2025. AMALO serves as the FDA's permanent presence supporting engagement with AMA and African regulatory authorities.

Africa's pharmaceutical market is projected to exceed \$50 billion by 2030, increasing the importance of effective and mature regulatory systems that protect public health while facilitating access to quality-assured medical products. More efficient, transparent, and harmonized regulatory pathways can reduce barriers to market entry, support U.S. competitiveness, facilitate the introduction of innovative American medical products, and expand opportunities for U.S. companies operating across the continent.