STATEMENT OF COOPERATION
BETWEEN
THE AFRICAN MEDICINES AGENCY
AND
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
REGARDING
COOPERATION TO ENHANCE ACTIVITIES OF MUTUAL INTEREST

The African Medicines Agency ("AMA") and the United States Food and Drug Administration ("FDA") (collectively "the Participants") recognize the importance of timely and effective communication and collaboration in the promotion and protection of public health. The Participants share a mutual high regard for the critical role of their respective regulatory systems in the medical products each regulates.

As a Specialized Agency of the African Union ("AU"), AMA's primary objective is to enhance the capacity of Regional Economic Communities and AU State Parties to regulate medical products in order to improve access to quality, safe and efficacious medical products across the continent. The AMA works to achieve its mission by building a continental regulatory system anchored in strong national authorities and regional collaboration.

I. PURPOSE

This Statement of Cooperation ("SOC") is intended to strengthen existing structures and develop new opportunities for cooperative engagement in regulatory and scientific matters and public health protection that are related to the medical products the Participants regulate.

II. SCOPE

This SOC covers medical products regulated by, and efforts and activities within the mandate of, both Participants. The Participants intend to develop a plan to exchange information and strengthen regulatory cooperation and explore a mechanism for regular meetings and other types of engagement.

The Participants, in accordance with their respective laws and regulations, expect to work together as appropriate to implement the intent of this SOC. This work is intended to develop a mutually developed work-plan with activities that:

- Facilitate effective exchange of information;
- Develop new or strengthen existing cooperative efforts and initiatives, including in relevant international initiatives for medical product regulation; and
- Coordinate, when appropriate, with stakeholder groups relevant to medical product regulation in line with their respective mandates.

III. CONFIDENTIALITY

The Participants expect that most of the information exchanged under this SOC may be provided in a form appropriate for public dissemination under the laws governing the transmitting Participant. Any non-public information exempt from public disclosure should only be shared as permitted by the laws and regulations governing each Participant respectively and their relevant disclosure procedures and policies.

IV. SOURCE OF FUNDING

Each Participant recognizes the other's responsibility to fund and implement its respective activities subject to, and to the extent made possible by, the availability of appropriated funds, personnel, and other resources. Special arrangements for funding of selected activities may be made by appropriate mutual decision.

V. NON-BINDING INTENT

This SOC is not an international agreement and is not intended to, nor does it, create binding obligations under international or domestic law. Nothing in this SOC is intended to limit or restrict the Participant's responsibility or ability to carry out its regulatory activities and programs in accordance with its respective laws and regulations.

No provision of this SOC restricts either Participant from conducting its own regulatory activities within the jurisdictional boundaries of the territory represented by the other Participant when necessary to meet the needs of its own regulatory programs and/or individual missions.

VI. DURATION AND PROCESS

This SOC commences upon the Participants' last signature and is intended to remain operative for a period of five (5) years. Thereafter, the Participants may extend this SOC for successive five-year periods. This SOC may be modified by mutual written decision of the Participants and may be discontinued by either Participant. A Participant should give sixty (60) calendar days' written notice to the other Participant of its intent to discontinue implementation of this SOC.

SIGNED, in duplicate, in the English language.

FOR THE AFRICAN MEDICINES AGENCY:

-/s/-
Dr. Delese Afia Amoakoa Darko
Director General
African Medicines Agency

Date: _____6/08/2026_____

City: _____Kigali, Rwanda_____

The African Medicines Agency
KN 3 Ave
Kigali, Rwanda

FOR THE UNITED STATES FOOD AND DRUG ADMINISTRATION:

-/s/-
Mark Abdoo
Associate Commissioner
Office of Global Policy and Strategy

Date: _____6/15/2026_____

City: ____Philadelphia, Pennsylvania___

The United States Food and Drug Administration
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