

MEMORANDUM OF UNDERSTANDING

BETWEEN

**THE NATIONAL MEDICINE REGULATORY AUTHORITY (ANARME, IP) OF
THE REPUBLIC OF MOZAMBIQUE**

AND

**THE TANZANIA MEDICINES AND MEDICAL DEVICES
AUTHORITY (TMDA) OF THE UNITED REPUBLIC OF TANZANIA**

ON

THE REGULATION OF MEDICINES AND BIOLOGICAL PRODUCTS

The **TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY**, with Headquarters at Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma – Tanzania, in this act represented by **Adam Mitangu Fimbo** grants in the capacity of Director General, with sufficient powers for the act, hereinafter referred to in abbreviated form as “**TMDA**” or “**Party**”

AND

The **NATIONAL MEDICINE REGULATORY AUTHORITY, PUBLIC INSTITUTE**, with headquarters at Av. Agostinho Neto / Salvador Allende in Maputo in this act represented by **Ricardo Ambrósio Sampaio Mtumbuida** who grants in the capacity of Mozambique High Commissioner to Tanzania, with sufficient powers for the act, hereinafter referred to in abbreviated form as “**ANARME, IP**” or “**Party**”.

PREAMBLE

ENCOURAGED by the desire to promote their cooperative links;

REAFFIRMING that international cooperation is one of the tools available to states to find solutions to problems they share with other nations;

Therefore, it is freely and within the scope of the principles of good faith that this Memorandum of Understanding of Cooperation is concluded under the terms and conditions contained in the following articles:

ARTICLE I PURPOSE

The purpose of this Memorandum of Understanding is to establish the framework under which the Parties will develop technical-scientific cooperation activities in matters of mutual interest, to enrich and optimize the regulatory capacity of each Party, in strict compliance with the provided for in the applicable national legislation and by their respective powers and attributions.

**ARTICLE II
COOPERATION MODALITIES**

1. The Parties agree that the cooperation matters referred to in this Memorandum of Understanding will be carried out through the following modalities:
 - a. exchange of information and experiences related to matters of common interest;
 - b. promoting the development of training activities between the Parties;
 - c. exchange of information, experiences and good practices on regulatory processes related, among others, to evaluation, quality control and surveillance and vigilance of medicines, vaccines and other health products;
 - d. Exchange of information aimed at creating and strengthening notification platforms and joint actions for the prevention and combat of crimes related to medicines and other health products;
 - e. promoting the strong capacity for sampling and testing of medicines and other health products;
 - f. promote the exchange of samples for the analytical testing of medicines, vaccines and other biological products;
 - g. Exchange of information related to Quality Management System; and
 - h. any other modality of cooperation that the Parties agree.
2. The Parties are not obliged to cooperate in those activities where there is an internal prohibition derived from law, regulations and institutional procedures.

**ARTICLE III
COMPETENCE**

The Parties undertake to carry out the cooperation activities within the scope of this Memorandum of Understanding, with absolute respect for their respective powers, institutional procedures and applicable national legislation.

**ARTICLE IV
OPERATIONALIZATION**

1. The operationalization of the objectives defined in this MoU in Article II will be based on contracts or other Specific Cooperation Agreements, in which the activities to be carried out are detailed, specifying, for each one, the following aspects: objectives and activities to be developed; schedule

- of work; financing; commitments of each of the Parties; allocation of human and material resources; monitoring, supervision and evaluation mechanism, and any other information deemed necessary;
2. The Specific Cooperation Agreements, once signed, will form an integral part of this Memorandum of Understanding.

ARTICLE V

PARTIES WARRANTIES AND GENERAL CONDITIONS

1. The Parties guarantee that they have all the legal powers and professional competencies necessary for the execution of this Memorandum of Understanding, and to carry out the subsequent actions and activities that may prove necessary.
2. The Parties also acknowledge that the person who will sign this Memorandum of Understanding on their behalf has the corresponding powers of representation and is hereby able to bind the respective entity with the terms agreed on it.

ARTICLE VI

FINANCING

1. The Parties undertake to finance the cooperation activities referred to in this Memorandum of Understanding, with the resources allocated in their respective budgets, in accordance with their availability, budget allocation and the provisions of their national legislation.
2. The Parties, if they deem it appropriate, and as permitted by applicable national law, may request financial support from external sources for the implementation of specific cooperation activities based on this Memorandum of Understanding.

**ARTICLE VII
CONTACT POINTS**

The Parties designate the following points of contact to communicate, exchange information, coordinate, monitor and report on cooperation activities carried out under this Memorandum of Understanding:

- **For ANARME, IP**
Legal and Cooperation Office (anarme.ip@anarme.gov.mz)

- **For TMDA-**
The Director General
Tanzania Medicines and Medical Devices Authority (TMDA)
TMDA Headquarters
Plot No.56/1. Block E, Kisasa B Centre
Dodoma
Email: info@tmda.go.tz

**ARTICLE VIII
PROTECTION OF INFORMATION, MATERIALS AND/OR EQUIPMENT**

If during the implementation of the cooperation activities established in this Memorandum of Understanding, information, materials and/or equipment that must be protected and classified are identified, the Parties shall inform the competent authorities and shall establish in writing the corresponding measures in accordance with the provisions of its legislation.

**ARTICLE IX
CONFIDENTIALITY**

1. The Parties agree that they may not disclose, in whole or in part, information classified as reserved or confidential, derived from cooperation activities under the terms of this Memorandum of Understanding, without the prior written consent of the other Party.
2. The obligation to protect confidential information, documentation and data obtained under this Memorandum of Understanding remains even if the Parties cease to be bound by this Memorandum of Understanding.

**ARTICLE X
ANTI-CORRUPTION**

The Parties undertake not to offer, directly or indirectly, advantages to third parties, nor solicit, promise or accept, for their benefit or that of third parties, offers with the purpose of obtaining a favourable judgment on the services to be provided, under the terms of the legislation applicable.

**ARTICLE XI
DISPUTE RESOLUTION**

Any divergence that may arise in the interpretation or application of this Memorandum of Understanding shall be resolved by the Parties by mutual agreement.

**ARTICLE XII
CHANGES**

This Memorandum of Understanding may be amended by mutual consent of the Parties, formalized through written communications specifying the date on which such amendments enter into force.

**ARTICLE XIII
LEGAL STATUS**

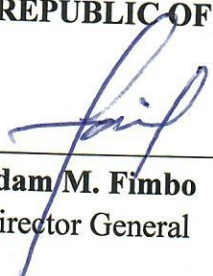
This MoU is not at any time intended to create binding relationship between Parties.

**ARTICLE XIV
FINAL DISPOSITIONS**

1. This Memorandum of Understanding enters into effect on the date of its signature. It remains in force for five (5) years, may be renewed upon written consent of the Parties, using a written notification addressed to the other Party, sixty (60) days in advance.
2. Termination of this Memorandum of Understanding does not affect the completion of cooperation activities that have been formalized during its term unless the Parties agree otherwise in writing.

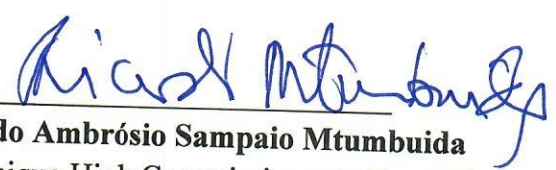
SIGNED in DAR ES SALAAM, on the 8TH day of MAY of the year 2025, in two original copies, in English and Portuguese, both being of equal content and legal value.

**FOR THE TANZANIA MEDICINES AND
MEDICAL DEVICES AUTHORITY OF
THE UNITED REPUBLIC OF TANZANIA**



Adam M. Fimbo
Director General

**FOR THE NATIONAL MEDICINE
REGULATORY AUTHORITY, IP, OF THE
REPUBLIC OF MOZAMBIQUE**



Ricardo Ambrósio Sampaio Mtumbuida
Mozambique High Commissioner to Tanzania