الوكالة الوطنية للمواد الصيدلانية
Agence Nationale des Produits Pharmaceutiques

TMDA
Tanzania Medicines & Medical Devices Authority

MEMORANDUM OF UNDERSTANDING

BETWEEN

THE NATIONAL AGENCY FOR PHARMACEUTICAL PRODUCTS (ANPP) OF THE PEOPLE'S DEMOCRATIC REPUBLIC OF ALGERIA

AND

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

ON

COOPERATION IN THE REGULATION OF MEDICAL PRODUCTS

PREAMBLE

WHEREAS Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health, TMDA which was formerly known as Tanzania Food and Drugs Authority (TMDA) was established in 2003 after enactment by the Parliament of the Tanzania Food, Drugs and Cosmetics Act, Cap 219. This Act was later amended in 2019 to Tanzania Medicines and Medical Devices Act, Cap 219 after the shift of responsibilities of regulating food and cosmetics to Tanzania Bureau of Standards (TBS). The change in legislative framework which was done through the Finance Act, No. 8 of 2019 also resulted into the change of name to TMDA; and

WHEREAS The National Agency for Pharmaceutical Products (ANPP), created in Algeria on July 2, 2018, is a financially autonomous public institution responsible for registering and approving pharmaceutical products and medical devices, conducting quality control and expertise, and ensuring the compliance of pharmaceutical product advertising. Under the supervision of the Ministry of the Pharmaceutical Industry, its core mission is to regulate the

market, foster local production, and act as a regional hub by approving and controlling pharmaceutical products and medical devices for human use.

WHEREAS TMDA and ANPP recognize the significant contribution that can be made by both Parties to their strategic objectives and therefore actively promote cooperation arrangements when enhancing the availability of safe, quality and effective medicines and medical devices; and

WHEREAS in order to achieve such cooperation when carrying out duties and promoting good reputation and understanding roles of the two Parties against consumers, TMDA and ANPP desire to operate within the framework of this Memorandum of Understanding (hereinafter referred to as the "MoU") and

NOW THEREFORE, TMDA and ANPP (hereinafter referred to as collectively as the Parties) wish to record in writing this Memorandum of Understanding in respective of the above and matters ancillary thereto

ARTICLE 1

PURPOSE OF THE MOU

The purpose of this MoU is to establish the cooperation on regulatory requirements between TMDA and ANPP hereafter referred to as "Parties" in the areas of collaboration should include but not limited to the following areas: -

The objective of this Memorandum (hereinafter referred to as MoU) is to promote cooperation between the Parties by facilitating the exchange of information, documentation and experiences in the pharmaceutical industry, through the encouragement of the development of bilateral cooperative activities in accordance with the laws and regulations

in force in each country. This Memorandum represents the agreement reached by the "Parties", considering, in particular, the following:

a) Each "Party" will aim to encourage meaningful collaboration between them;

b) Each "Party" will limit the information that may be made public, including whether publication would be detrimental to the commercial interests of any third party, violate confidentiality or privacy, reveal a trade secret, be contrary to the public interest or the interests of participants, or violate or contravene any legal obligations or conditions or other requirements imposed by the respective laws of each "Party".

ARTICLE 2 - AREAS OF COOPERATION

Establish a broad cooperative relationship through the exchange of information, joint work and the development of specific cooperation projects in the areas of:

a) Exchanges on regulatory provisions governing medicines and medical devices;

b) Exchange of information on pharmaceutical products and manufacturers;

c) Exchange of information on medical device approvals and classifications;

d) Exchange of information between regulatory authorities; guidelines, legislation, non-public information in all aspects of quality, safety and efficacy of the regulated products.

e) Exchange of knowledge in scientific fields,

f) Exchanges of information/report that may be made public in the fields of auditing and inspection related to Quality Audit and Good Manufacturing Practice (GMP).

g) Facilitation of registration products should base on recipients' contexts and also from Good Manufacturing Products or quality audit compliance.

h) Foster recognition and reliance between the Parties.

i) Other regulatory functions as may be deemed necessary and agreed by each Party.

ARTICLE 3 – TRAINING

The Parties agree to develop training and staff development activities for the Parties in the areas identified in Article 2, including:

1. The reception of trainees at the TMDA and the ANPP, within the relevant structures, to the extent of their reception capacities, where appropriate;
2. Expert appraisals conducted by ANPP and TMDA experts.

ARTICLE 4 – FINANCING

Each party to the MOU shall be responsible for any cost involved in the execution of this MOU on matters direct to their request. All cooperation activities outlined in Article 2 of this Memorandum of Understanding will be carried out within the limits of budgetary resources in accordance with the laws and regulations in force in each country. The cost shall be limited to air fares and subsistence allowances for the travelling officer(s) unless there are other special arrangements agreed upon by both parties.

ARTICLE 5 - MONITORING AND EVALUATION

The "Parties" ensure the monitoring and evaluation of cooperation activities, by sending progress reports pertaining to the implementation of this MOU as per Action Plan developed by these two institutions.

The following Focal Points designated by the Parties are responsible for the management, supervision and follow-up of this Memorandum:

a) By ANPP: Cooperation officer: bureau_cooperation@anpp.dz
b) By TMDA: Legal Service Unit: info@tmda.go.tz

ARTICLE 6 - THE COMPETENT AUTHORITIES

The management, supervision and monitoring of this Memorandum of Understanding is ensured by:

a) The National Agency for Pharmaceutical Products of the People's Democratic Republic of Algeria (ANPP);
b) Tanzania Medicines and Medical Devices Authority of the United Republic of Tanzania (TMDA).

ARTICLE 7 - CONFIDENTIALITY

Each Party will keep confidential all information received from the other Party (directly or indirectly) in relation to that Party, any aspect of its business, provided that Confidential Information will not include information which:

a) is or becomes available to the general public through no act of the receiving Party in breach of this Article,
b) is received by the receiving Party from a third Party in circumstances where the receiving Party is not aware that such third Party is breaching a duty of confidentiality,
c) was independently developed by the receiving Party without reference to or use of the Confidential Information received from the other Party, or
d) is required to be disclosed by the receiving Party pursuant to the operation of applicable laws, order of a court or other judicial or arbitral body or the direction or request of any governmental authority or body or as may be required to comply with audit requirements (but only to the extent of such disclosure).

ARTICLE 8 - INTELLECTUAL PROPERTY

Under this Memorandum of Understanding, each Party shall retain all intellectual property rights previously acquired or resulting from independent research. Each project implemented pursuant to this Memorandum of Understanding shall define the terms and conditions for the distribution of ownership of any results obtained in the context of joint research projects. In accordance with the laws and regulations in force in each country and with their international commitments.

ARTICLE 9 - WORKING RELATIONSHIP

The staff designated by each of the "Parties" to carry out cooperation activities shall continue their duties under the direction and authority of the institution to which they report, so that there will be no labor relations with the other Party which will not be considered as a substitute or joint employer.

ARTICLE 10 - SETTLEMENT OF DISAGREEMENT

Any disagreement arising from the application or interpretation of the provisions of this Memorandum of Understanding will be resolved amicably through diplomatic negotiations.

ARTICLE 11 - ENTRY INTO FORCE AND DURATION

This Memorandum of Understanding will take effect from the date of its signature; it will remain valid for three (3) years. Parties shall discuss and agree on whether to proceed with the MoU or terminate after the end of three years.

ARTICLE 12 – AMENDMENT

This Memorandum of Understanding may be amended in writing by mutual agreement between the Parties through diplomatic channels. The amendments shall enter into force in accordance with the same procedures for its entry into force.

ARTICLE 13 - GENERAL PROVISIONS

Each Party may notify the other Party, in writing and through diplomatic channels, of its intention to terminate this Memorandum of Understanding at least six (06) months before it takes effect.

Termination of this Memorandum of Understanding shall not affect the execution of any ongoing program, activity or project initiated under this Memorandum of Understanding unless the Parties otherwise agree.

Each Party may suspend, in whole or in part, the application of this Memorandum of Understanding for reasons of national security, public health or public policy. The introduction or revocation of such measures shall be notified to the other Party in writing. Such suspension will take effect from the date of notification to the other Party in writing through diplomatic channels.

This Memorandum of Understanding does not oblige either Party to exclusivity. Each Party retains the freedom to deal with other partners.

signed at Algiers, on November 28th 2025, in two (2) original versions, in Arabic and English, all texts being equally authentic.

For the National Agency for Pharmaceutical Products (ANPP) of the people's democratic republic of Algeria

Dr. Delih Cherif
Director General

For the Tanzania Medicines and Medical Devices Authority (TMDA) of the United Republic of Tanzania

Dr. Adam Fimbo
Director General