

MEMORANDUM OF UNDERSTANDING (MoU)

Between



BUSINESS REGISTRATIONS AND LICENSING AGENCY (BRELA)

AND



**TANZANIA MEDICINES AND MEDICAL DEVICES
AUTHORITY (TMDA)**

1. PREAMBLE

- a. **WHEREAS** the Business Registrations and Licensing Agency (hereinafter referred to as BRELA) is a Government Executive Agency established under the Executive Agencies Act No. 30 of 1997 through Government Notice No. 294A published on the 8th October, 1999 and it was officially inaugurated on the 3rd December, 1999.
- b. **AND WHEREAS** Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health (MOH). TMDA which was formerly known as Tanzania Food and Drugs Authority (TFDA) was established in 2003 after enactment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 by the Parliament. 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.
- c. **AND WHEREAS** in recognizing the formal, informal contacts and synergies that exist between them, the Parties wish to execute MoU in terms of which they will collaborate in the field of Intellectual Property.
- d. **AND WHEREAS** BRELA and TMDA are desirous to strengthen and further develop relations in sharing and exchange of information relating to Intellectual Property Rights (IPR) specifically in the area of Trade Marks;

NOW THEREFORE, the parties agree as follows;

2. INTERPRETATION

- 2.1 In this MoU unless clearly inconsistent with or otherwise indicated by the context:
 - 2.1.1 **"Agreement"** means this MoU and any annexure, schedules and addenda hereto;

2.1.2 **"Collaboration"** in this context refers to joint obligation of the Collaborating parties in execution of the objectives stipulated hereinafter;

2.1.3 **"Day"** means a day other than a Saturday, Sunday or a public holiday;

2.1.4 **"Effective Date"** means the date of signing of this MoU by the Parties.

2.1.5 **"Marks"** means Trade and Service Marks registered under the Trade and Service Marks Act Cap 326;

2.2 In this MoU unless the context indicates contrary intention an expression which denotes:

2.2.1 any gender includes female and male;

2.2.2 a natural person, includes a juristic person and vice versa;

2.2.3 the singular includes the plural and vice versa;

2.2.4 words and expressions defined in any clause shall, for the purpose of that clause bear the meaning assigned to such words and expressions in such clause;

2.3 This MoU shall be governed, construed and interpreted in accordance with the laws of the United Republic of Tanzania.

3. **PURPOSE OF THIS MoU**

3.1 The purpose of this MoU is to establish a broad working relationship between the Parties to set out a framework and the mechanisms for the implementation and monitoring of the aforesaid relationship.

3.2 Notwithstanding its general nature, the Parties enter into it with full confidence and loyalty in and towards each other and agree to treat it with

utmost seriousness and generally to direct their energies and resources to achieve its objectives.

4. DURATION

This MoU shall come into operation on the Effective Date and shall remain in full force and effect for a period of Five (5) years unless terminated earlier in accordance with the provisions of this MoU.

5. AREAS OF CO-OPERATION

5.1 The Parties agree to collaborate with each other regarding the following:

- 5.1.1 Sharing of information and data in respect of submitted applications of Medical devices and medicines to TMDA and registered marks to BRELA;
- 5.1.2 Conducting regular capacity building trainings and seminars to staff/technical from both parties in the area of Intellectual Property Rights and Medical devices, Medicines and the related matters;
- 5.1.3 Conducting a joint audit to ascertain Marks which are not registered by BRELA but having registration certificates of medicines/medical devices from TMDA for purposes of facilitating Products owners/dealers to register Marks of their products (where necessary) with BRELA;
- 5.1.4 Conducting joint stakeholders training, conferences, technology infrastructure, personnel and skills for awareness creation on issues of Intellectual Property, Medicines and Medical devices , promotion and dissemination of Intellectual Property Rights and Business Registrations and Licensing related knowledge;

- 5.1.5 Jointly offering short term staff placement avenues to both institutions in order to harness diverse practical skills, experience and knowledge on areas of common interests.
- 5.1.6 Exchanging or sharing of research and educational materials, publications and other information relating to Intellectual Property, business registrations, licensing, Medicines and Medical devices, and related issues.
- 5.1.7 Jointly organizing and participating in seminars, symposia, workshops, public exhibitions, outreach and community engagement tours, meetings in response to Government and public needs related to Intellectual Property, business registrations, licensing, Medicines and Medical devices, and related issues.
- 5.1.8 Jointly facilitating academic and non-academic innovations to staff and public in general;
- 5.1.9 Jointly cooperating in designing and conducting short courses to members of the public that are tailored with the functions of the parties generally;
- 5.1.10 Undertaking joint efforts in formulation of policies, conducting and or responding to various needy research calls or projects which are in line with the mandate and functions entrusted to the parties.
- 5.1.11 Facilitating promotion, protection, management practices and carrying relevant activities in Intellectual Property Management and commercialization of innovations;
- 5.1.12 Formulating technical teams to evaluate the Patent applications as per different fields of invention/innovations.

5.1.13 Collaborating in any other area of cooperation which will be of mutual benefit to the Parties and the country at large as may be determined by parties from time to time.

6. DEFINITIVE AGREEMENTS

- 6.1 The Parties agree that implementation of this MoU may require specific Definitive Agreements.
- 6.2 The aforementioned agreements may be contained in one composite contract or in a number of separate contracts as the Parties may determine.

7. IMPLEMENTATION AND MONITORING

- 7.1 Each Party shall designate a person responsible for coordinating the cooperation under this MoU as a Liaison person. The Liaison persons shall exchange and/or meet as may be necessary to ensure that cooperation under this MoU is efficient and effective.
- 7.2 In addition, each Party shall designate a coordinator for coordinating the execution of specific programme envisaged in clause 5 above.
- 7.3 For the purpose of this MoU the following departments will be designated for coordinating the relationship:

For BRELA

Directorate of Industrial Property/Designated Officer from the Patents Section/Trade and Service Marks Section.

For TMDA

Directorate of Medical Devices and Diagnostics Control and Directorate of Human and Veterinary Medicines.

8. CONFIDENTIALITY

- 8.1 Each Party shall keep confidential and shall not disclose to any other person, nor use for any purpose except for the purposes of this Agreement, any information obtained from the other Parties as a result of negotiating, entering into or implementing the activities contemplated by this MoU other than information which:
- 8.1.1 is required to be disclosed by operation of law any Rule or Regulation, with or without the force of law, or any binding judgment or order, or any requirement of a competent authority;
 - 8.1.2 is reasonably required to be disclosed in confidence to a Party's professional advisers for use in connection with the transactions contemplated herein and/or the matters contemplated herein; or
 - 8.1.3 is or becomes part of the public domain, otherwise than through the default of the recipient Party.
- 8.2 No public announcement or press release in connection with the subject matter of this MoU shall be made or issued by or on behalf of any Party without the prior approval of the other Party, except where required by law.

9. LIABILITY

- 9.1 Each Party agrees that it will be responsible for its own acts and the results thereof and shall not be responsible for the acts of the other Party and the results thereof, and will assume all risk and liability to itself, its employees, for any injury to persons or property resulting in any manner from the conduct of its own operations, and the operations of its employees under this MoU and for any loss, cost, damage or expense resulting at any time from any and all causes due to any act or acts of negligence or failure to exercise proper

precautions, of or by itself or its own employees under and pursuant to this Agreement.

- 9.2 This MoU does not constitute and shall not be interpreted as a partnership between the Parties nor does it constitute nor shall it be interpreted as an MoU of agency between the Parties.

10. FINANCIAL OBLIGATION

- 10.1 The financial arrangements to cover expenses for the cooperative activities carried out within the framework of this MoU should be mutually agreed upon by parties on a case-by-case basis and subject to the availability of funds and resources and in accordance with applicable regulations of each institution.

- 10.2 Except otherwise agreed, each Party shall bear its own expenses related to the activities conducted under this MoU.

11. SETTLEMENT OF DISPUTES

- 11.1 In the event of any dispute and or difference of opinion arise between the Parties regarding the interpretation of any or all the provisions of this MoU during the term of or termination thereof, the Parties undertake to negotiate in good faith to resolve such dispute and or difference of opinion amicably and in the best interests of pursuing this Agreement.

- 11.2 In the event that the dispute and/or disagreement cannot be amicably resolved as contemplated in clause 10.1 above, then either Party may give the other Party fourteen (14) days written notice requesting that the dispute and/or disagreement be resolved by the most senior officials of the Parties.

- 11.3 Should the disputes and/or difference of opinion not be resolved by the most senior official of the Parties, then either Party may refer the matter to Arbitration.

12. TERMINATION OF THE AGREEMENT

12.1 This MoU may be terminated in any of the following ways: -

12.1.1 By mutual agreement between the Parties;

12.1.2 By either Party, for whatever reason and without incurring any liability for such termination, upon that Party providing the other Party with two (2) calendar months written notice of such termination.

12.1.3 Provided, however, that in the event of any disagreement the Parties undertake to negotiate in good faith to resolve such disagreements amicably and in the best interests of pursuing this MoU.

13 GENERAL

13.1 No addition to or variation, consensual cancellation or notation of this MoU and no waiver of any right arising from this MoU or its breach or termination shall be of any force or effect unless reduced to writing and signed by all the Parties or their duly authorized representatives.

13.2 This MoU supersedes all prior representations, arrangements, understandings and agreements between the Parties, whether written or oral, relating to the proposed transactions and sets out the entire, complete and exclusive understanding between the Parties as has been contemplated and agreed in principle between the Parties.

- 13.3 This MoU may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same MoU as at the date of signature of the Party last signing one of the counterparts.

14 NOTICES

14.1 Notices in terms of this MoU must be in writing and delivered to the chosen *domicilium citandi et executandi* of the Parties by registered mail, electronic mail communication or by hand against written confirmation of receipt, or by facsimile

14.2 For the purposes of this MoU the Parties choose their *domicilium citandi et executandi* as follows:

BUSINESS REGISTRATIONS AND LICENSING AGENCY,

Chief Executive Officer

BRELA House, House No. 11

Plot No. 20, Block 23

Shaban Robert Street/Sokoine Drive

P. o. Box 9393,

Dar es Salaam.

TANZANIA MEDICINES & MEDICAL DEVICES AUTHORITY,

Director General

P.O Box 1253,

Dodoma.

14.1 Either Party may change the above *domicilium* to another address by giving written notice to the other Party.

SIGNED for and on behalf of:

BRELA

Mr. Godfrey S. Nyaisa
CHIEF EXECUTIVE OFFICER

Date: 12/08/2025

TMDA

Dr. Adam M. Fimbo
DIRECTOR GENERAL

Date: 12/8/2025

IN WITNESS OF

Signature: G. Umoti

Name: GRACE GOODLOVE UMOTI

Designation: SLGD

Date: 12/08/2025

Signature Nesta Kwarame

Name Nesta Kwarame

Designation Regul officer

Date 12/8/2025