MEMORANDUM OF UNDERSTANDING

BETWEEN

THE TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

AND

THE BOTSWANA MEDICINES REGULATORY AUTHORITY

(BoMRA)

FOR PROMOTION OF COLLABORATION AND EXCHANGE OF INFORMATION IN THE REGULATION, MONITORING AND CONTROL OF QUALITY, SAFETY AND EFFICACIOUS / PERFORMANCE OF MEDICINES AND MEDICAL DEVICES

This Memorandum of Understanding (MOU) sets out the terms and conditions between the Tanzania Medicines and Medical Devices Authority, hereinafter referred to as TMDA and the Botswana Medicines Regulatory Authority, hereinafter referred to as BoMRA.

1. Introduction

1.1 Tanzania Medicines and Medical Devices Authority (TMDA)

TMDA is the National Medicines Regulatory Authority under the Ministry Health responsible for protecting and promoting public health by ensuring quality, safety and effectiveness / performance of medicines, medical devices, in vitro diagnostics and other health related products for all in Tanzania.

1.2 Botswana Medicines Regulatory Authority (BoMRA)

BoMRA is the Medicines Regulatory Authority in Botswana. It is a statutory body established by an Act of Parliament, the Medicines and Related Substances Act of *2013* to regulate medicines, medical devices and cosmetics. BoMRA regulates the sale, distribution, importation, exportation, manufacture and dispensing of medicines and related substances as well as cosmetics.

1.3 Statement of Purpose

Now therefore, recognizing the available strengths and challenges within the two NMRAs, and successful engagements under their previous MOU and desirous of renewing and continuing this. This MOU sets the framework bilateral collaboration between TMDA and BoMRA in regulation, monitoring and control of medicines and medical devices with the general objective of protecting and promoting public health. The areas of collaboration shall include but not limited to the following: -

1.3.1 Evaluation and Registration of medicines and medical devices;
1.3.2 Market inspections, Good Manufacturing Practices (GMP) and Quality Audit;
1.3.3 Pharmaco-vigilance and Clinical Trials;
1.3.4 Laboratory testing of medicines and medical devices;
1.3.5 Quality and Risk Management System;
1.3.6 Management Information System;
1.3.7 Development and Strengthening of Post Marketing Surveillance systems and Structures;
1.3.8 Development or review of legislative frameworks that support the Authority's functions;
1.3.9 Capacity building of staff on regulatory functions; and

1.3.10 Monitoring and evaluation of regulated products.

The collaboration will encompass exchange of regulatory information, exchange of technical expertise, working together and work-sharing and hence foster mutual trust, confidence and cross-learning between the participating staff members from the two NMRAs. Ultimately, it will contribute to access of the people in the Republic of Botswana and the United Republic of Tanzania to quality assured medicines and medical devices.

2. Areas of Collaboration/Terms of the MoU

Specifically, the parties hereby agree to:

2.1 Exchange information upon request, and expertise in setting up good Quality Management Systems in areas such as the IEC ISO17020, ISO 9001:2015, ISO 17025, Evaluation and Registration of medicines and medical devices, Pharmacovigilance and Clinical trials, Inspection and Enforcement, Pharmaceuticals Good Manufacturing Practices (GMP), Quality Audit, WHO Prequalification, GPPQCL, ISO 13485 for medical devices, legislative frameworks among others.

2.2 Assist in building capacity in regulatory excellence and professional development for regulatory affairs professionals through system audits, training and capacitation.

3. Costs and Expenses

Each party to the MoU shall be responsible for any costs involved in the execution of this MoU on matters direct to their request. The costs 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.

4. Governance Structure

4.1 Each Party shall nominate its Liaison Officer who shall coordinate the implementation of the MoU.

4.2 The Liaison Officer of each Party shall commit the full support of his or her organization to this MoU by preparing action plans and providing quarterly implementation report to respective head of institution the heads.

4.3 The specific agreed areas of collaboration shall be spearheaded by the Heads of the Organizations, in the case of TMDA, the Director **General, Mr. Adam M. Fimbo** and in the case of BOMRA, the Acting **Chief Executive Officer, Dr Seima Dijeng.**

5. Publicity

5.1 Nothing in this MoU shall be construed as granting either Party permission to use the other Party's official names, logos, trademarks, copyright or protected insignia in any promotional, publicity, or advertising materials without the express written consent of the other Party.

6. Modification of the MoU

6.1 This MOU may be modified by mutual consent of authorized officials from TMDA and BOMRA.

6.2 This MOU shall become effective upon the date of the last signature and shall continue in effect for a period of three (3) years thereafter unless terminated as provided for herein. At the end of its effective period, this MoU may be renewed upon written consent of the Parties.

6.3 If a Party wishes to terminate this MoU it shall notify the other Party in writing, not less than two (2) months before the proposed termination date. By mutual consent, the Parties will determine the fate of any pending activities under this MoU.

7. General Provisions

7.1 Clause 2 sets out a statement of intent of the Parties and is not intended to create any legally binding rights or obligations between the Parties.

7.2 This MoU is not mutually exclusive, as such, the Parties will continue to operate their respective programs and duties in accordance with their established policies, rules and procedures.

8 Confidentiality

Each Party shall 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 shall not include information which (i) is or becomes available to the general public through no act of the receiving Party in breach of this Clause, (ii) 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, (iii) was independently developed by the receiving Party without reference to or use of the Confidential Information received from the other Party, or (iv) 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). For the avoidance of doubt, This Clause is legally binding on the Parties and is enforceable.

9 **SIGNATURES**

For: Tanzania Medicines and Medical Devices Authority (TMDA)
THE DIRECTOR-GENERAL, **MR. ADAM M. FIMBO**

Signature: _____ Date: 16/8/2023

For: The Botswana Medicines Regulatory Authority (BOMRA)
THE ACTING CHIEF EXECUTIVE OFFICER, **DR SEIMA DIJENG**

Signature: _____ Date: 05/09/2023