MEMORANDUM OF UNDERSTANDING

BETWEEN

MUHIMBILI NATIONAL HOSPITAL (MNH)

AND

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

MEMORANDUM OF UNDERSTANDING ON COOPERATION

BETWEEN

THE MUHIMBILI NATIONAL HOSPITAL, WHOSE HEADQUARTERS ARE LOCATED AT WEST UPANGA, KALENGA STREET, P.O. BOX 65000, DAR ES SALAAM, AS REPRESENTED BY THE EXECUTIVE DIRECTOR, PROF. MOHAMED JANABI

AND

THE TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY, WHOSE HEADQUARTERS ARE LOCATED AT DODOMA, P.O BOX 1253, AS REPRESENTED BY THE DIRECTOR GENERAL, MR. ADAM MITANGU FIMBO

WHEREAS, Muhimbili National Hospital (MNH) is a National Referral Hospital and University Teaching Hospital with two (2) campuses at Upanga and Mloganzila. The Hospital is under the Ministry of Health (MoH) and established by the Muhimbili national Hospital Act, Cap 290 *(hereinafter referred to as the 'MNH')*. MNH is mandated to provide referral and specialized medical care, facilitate medical training and research, and participate in policy formulation. The Hospital has 2,108 bed facilities, attending to 2,500 outpatients daily and admitting 1,500 inpatients per day; and

WHEREAS, Tanzania Medicines, and Medical Devices Authority is a statutory executive agency for regulating the quality, safety, and effectiveness of medicines, medical devices, diagnostics, biocidals, and tobacco products. The Authority is under the MoH and it was established in 2003 after the enactment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 which was amended in 2019 *(hereinafter referred to as 'TMDA')*; and

WHEREAS, MNH and TMDA recognize the significant contribution that can be made by both parties to their strategic objectives and therefore actively promote cooperation arrangements to improve the health of mankind by enhancing the management of diseases, strengthening the surveillance systems, and ensure the availability of safe and quality medicines, medical devices and in-vitro diagnostics; and

Both are among the functional units of the MoH and therefore are responsible for the implementation of national planning frameworks that include National Development Vision, National Strategy for Growth and Reduction of Poverty, National Health Policy, and Health Sector Strategic Plan.

WHEREAS, in order to achieve such cooperation in the most effective way when carrying out duties and promoting a good reputation and understanding of the roles of the two parties against the public, MNH and TMDA desire to operate within the framework of this Memorandum of Understanding (hereinafter referred to as the 'MoU').

THEREFORE, MNH and TMDA (hereinafter referred to as collectively as 'the Parties') hereby declare as follows:

ARTICLE 1: PURPOSE

The purpose of this MOU is to establish the general working parameters under which MNH shall collaborate with TMDA on activities that are of common interest to both parties.

Background

MNH being the National Referral Hospital and TMDA as the Authority mandated to regulate the safety and quality of health commodities they complement each other in the provision of health care services and protection of public health. Since their establishment, MNH and TMDA had collaborated in many ways as government institutions and currently, MNH is the leading pharmacovigilance (PV) hub for TMDA. MNH alone is responsible for reporting Adverse Drugs Reactions (ADRs) at an average rate of 800 cases per month. At the same time, TMDA coordinated PV training for MNH pharmacy staff, purchased a computer and provided ADRs form to facilitate PV activities.

On the other hand, at MNH during the provision of clinical services and especially when resistant strains of microbial emerges. It is empirical to conduct a culture sensitivity test to identify the microorganism and subjects them to different antimicrobials to establish effective patterns of medicines. On various occasions, a sensitive microorganism during the test becomes unresponsive when subjected to the actual medicine given to the particular patient. These events bring uncertainty about whether the tests were not performed according to the standards or whether the disc or medicines are of questionable quality. Having TMDA on board will help to resolve these dilemmas since samples can be collected and submitted to TMDA for further analysis at the right time.

Pharmacovigilance and post marketing surveillances (PMS) are crosscutting with a mutual benefit for both parties as they aim to protect public health. Hence to sustain the gains of this collaboration is necessary for TMDA to facilitate MNH to institute a quality management system (QMS) for the start at the Pharmacy Department. This will help to streamline the processes between parties and will institute efficiency and accountability on designing and implementation of different activities.

Having realizing this, there is a need to establish common areas of interest and explore modalities of working together in a cost effective and under limited resources available.

Key Areas of Interest

The MNH and TMDA have identified three (3) key areas of collaboration that will complement each other and hence further strengthen the quality of healthcare services. Priority areas are:-

1. Strengthening Pharmacovigilance Surveillance at MNH;

2. Establishing a robust system for information sharing regarding Post Marketing Surveillance System (PMS); and

3. TMDA to facilitate MNH on the institutionalization of a Quality Management System (QMS) by starting with the Pharmacy Department.

ARTICLE 2: RESPONSIBILITIES OF THE PARTIES

Subject to their respective laws, rules, regulations, practices, procedures, and the availability of funds and other resources,

2.1 The MNH agrees to:

1. Provide office space for PV and PMS activities

2. Allocate sufficient staff which will coordinate PV and PMS activities

3. Collect and post ADRs cases in the vigiflow system

4. Immediately notify TMDA on serious cases of ADRs

5. Collect and submit to TMDA for further analysis of medicines and culture discs with questionable qualities.

6. Facilitate and dedicate a number of staff who will be trained on QMS and PMS

7. Provide a conducive environment and support for the implementation of QMS and PMS activities.

8. Provide technical and financial assistance to implement this MoU.

9. Facilitate communications and cooperation between MNH and TMDA.

10. Provide necessary, allowable, and allocable material, equipment, transport, and human resources support to implement the work plan to be agreed upon between the parties.

11. Appoint coordinator(s) for the collaboration and follow-up of agreed activities.

12. Ensure the availability of key staff and other personnel to provide guidance and facilitate the implementation of activities.

2.2 The TMDA agrees to:-

1. Build the capacity of MNH staff on PV and PMS.
2. Refurbish and equip the PV office with the necessary infrastructure such as computers, printers, office tables, stand-up banners and chairs.
3. Respond promptly to investigate serious cases of ADRs reported and collect samples for further analysis.
4. Analyses samples of medicines and culture discs received from MNH at the cost of the supplier/importer and share the report.
5. Build the capacity of MNH staff on QMS and systems.
6. Facilitate the institutionalization of QMS at the Pharmacy Department.
7. Assist to develop and implement the road map to accreditation with ISO standards.
8. Facilitate Pharmacy Department to meet ISO accreditation.
9. Provide and share the necessary information needed to attain the common goal under this MOU.
10. Facilitate communications and cooperation between TMDA and MNH.
11. Provide technical and financial assistance related to this MOU.
12. Provide necessary, allowable, and allocable material, equipment, transport, and human resource support to implement the work plan agreed upon by both parties.
13. Appoint a coordinator(s) for the collaboration and follow-up of agreed activities.
14. Ensure availability of key staff and other personnel to provide guidance and facilitate implementation of activities.

2.3 Both MNH and TMDA jointly agree to:

1. Collaborate in the design, planning, budgeting and implementation of agreed activities on PV, PMS, and QMS.
2. Jointly develop annual work plans of activities to be completed including training.
3. Oversee the implementation of agreed activities including supervision, monitoring, and evaluation.
4. Provide necessary and appropriate resources needed for the tracking of activity progress and performance reviews.

5. Report and discuss any challenges faced on the course of implementing this MoU.

ARTICLE 3: COMMUNICATIONS AND DECISION MAKING

The relationship between MNH and TMDA should be mutually respectful with clearly established channels of communication and involvement in decision-makin that affect the other party.

1. Requests for official support from both parties should be directed to the Executive Director and Director General respectively from the responsible persons for MNH and TMDA.

2. The Executive Director and Director General will communicate in writing on activities to collaborate between MNH and TMDA.

3. The responsible persons for MNH and TMDA shall jointly discuss activities proposed in the annual work plan. They shall work collaboratively to ensure mutual consent and agreement upon designated activities in the work plan and an overall estimated level of funding and resources needed.

ARTICLE 4: DURATION OF THE MOU

1. This Memorandum of Understanding will be valid for the period of three (3) years (from March, 2023 to March, 2026).

2. Should additional time be required to undertake the above-mentioned activities as outlined in this MOU, the responsible persons from MNH and TMDA shall modify the end date of this MOU through a letter of modification to the MOU that does not require a counter signature.

ARTICLE 5: COSTS

Any transfer of funds associated with this agreement will depend on activities agreed to in the jointly developed work plan. Both Parties shall be responsible for basic operating expenses incurred as a result of work performed under this MOU.

ARTICLE 6: CONFIDENTIALITY

1. In the process of collaborating with each other, each party may become privy to certain confidential information including that relating to the business practices of the other Party. Each Party agrees that it will clearly designate proprietary and confidential information where possible and not divulge or transmit such information to any other person or organizations without the expressed written permission of the owner of the information.

2. Each Party agrees that information need not be marked as confidential to be considered and treated as such under the terms of this clause.

3. All such confidential information shall be considered proprietary unless it is provided specifically for disclosure to the public or other entities.

4. All Parties agree to share information related to agreed activities and issues of relevance and within the limits of applicable laws and regulations to ensure the successful implementation of the agreed activities.

5. All Parties agree not to disclose proprietary information to any third party and not to use such information without express written approval from the other Party.

6. Each Party further agrees to honor any copyright, trademark rights, and other proprietary rights of information shared in the process of carrying out joint activities. Both Parties also agree not to quote any portion of reports or documentation out of context, misrepresent the findings of either Party or otherwise use the information inappropriately.

7. This confidentiality obligation survives the termination of this MOU.

ARTICLE 7: AMENDMENT AND TERMINATION

1. This MOU shall be amended in writing by mutual consent of each Party's duly authorized representative.

2. This MOU may be terminated for convenience by mutual agreement of the two parties.

3. In the event of a termination of this MOU, the parties shall complete the remaining obligations in effect at the time of termination subject to the availability of funds and other resources.

ARTICLE 8: RESOLUTION OF DISAGREEMENTS

1. The Parties agree to use their best efforts to settle amicably any disagreement or controversy that may arise out of or relating to this MOU.

2. Any disagreement or any such dispute, controversy or claim between the parties arising out of and not mutually resolved by the parties shall result in the termination of this memorandum without further notice.

3. The parties by signing this MOU understand that since there is a transfer of funds between the parties, there can be claims made on a party by the other party.

ARTICLE 9: ENTIRETY OF AGREEMENT

1. This MOU contains the entire agreement of the mutual collaboration and understanding between the parties.

2. All future projects will be accommodated in this MOU between the two parties.

In **WITNESS WHEREOF**, the duly authorized representatives of the parties sign this Memorandum of Understanding in two (2) originals in the places indicated below and for each Party to retain an original each for their files.

For MNH

Prof. Mohamed Yakub Janabi
EXECUTIVE DIRECTOR – MNH

16th.06.2023
DATE

EXECUTIVE DIRECTOR
MUHIMBILI NATIONAL HOSPITAL
P. O. Box 65000
DAR-ES-SALAAM

Witnessed by:

Name: VERONICA HELUAZ

Position: HEAD OF LEGAL UNIT

Signature: _____

For TMDA

Mr. Adam Mitangu Fimbo
DIRECTOR GENERAL – TMDA

16/6/2023
DATE

Witnessed by:

Name: Martha S. Malle

Position: Senior Legal Officer

Signature: _____