TMDA
Tanzania Medicines & Medical Devices Authority

MEMORANDUM OF UNDERSTANDING

BETWEEN

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY (TMDA)

AND

PRIVATE HEALTH LABORATORIES BOARD (PHLB)

18/9/2025

06/10/2025

This Memorandum of Understanding (MoU) on cooperation is made on the.....day of 2025

Between

Tanzania Medicines and Medical Devices Authority, Plot No.56/1, Block E, Kisasa B Centre, Hombolo Road, P.O. Box 1253, Dodoma (Hereinafter referred to as TMDA) on the one hand,

And

Private Health Laboratories Board, Government City, Afya Street-Mtumba, P.O. Box 743, Dodoma (Hereinafter referred to as PHLB) on the other hand.

WHEREAS, TMDA is an Executive Agency under the Ministry of Health (MoH), which is responsible for regulating the safety, quality and effectiveness of medicines, medical devices and diagnostics;

WHEREAS, the functions of TMDA involves registration of premises for selling and manufacturing of medical devices and diagnostics, importation/exportation and registration of medicines, medical devices and diagnostics;

WHEREAS, TMDA main responsibility and its mandate is stipulated in the Tanzania Medicines and Medical Devices Act, Cap. 219. The Act provides for the efficient and comprehensive regulation and control of quality, safety and effectiveness of medicines, medical devices and diagnostics in Tanzania mainland;

WHEREAS, TMDA implements quality management system (ISO: 9001) through which the Authority is committed to provide quality services in response to customer needs and expectations without compromising public health;

WHEREAS, PHLB is the Government institution under the Ministry of Health (MoH) which is responsible for regulating the registration and management of Private Health Laboratories in Tanzania Mainland;

WHEREAS, the mandate of PHLB is stipulated in The Private Health Laboratories Regulation Act, Cap.136 for regulation of registration and management of private health laboratories managed by approved persons and in respect of private health laboratory services to be rendered by private health laboratories and for related matters;

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WHEREAS, the function of PHLB involves registration, inspection and monitoring of quality assurance of private health laboratories;

WHEREAS, PHLB oversees the implementation of ISO 15189 which requires the medical laboratory to ensure that externally provided products and services that affect laboratory activities are suitable when such products are used to support the operation of the laboratory;

WHEREAS, the functions of TMDA involve registration of premises for selling and manufacturing of medical devices and diagnostics; and those of PHLB involve registration and management of private health laboratories where such products are used;

WHEREAS, in fulfilling their legal mandates, TMDA is required to carry out inspections of medical devices, and diagnostics in the premises for sale, supply and use; while PHLB is required to carry out inspections of Private Health Laboratories. This often results into duplication of activities and unnecessary interruptions to the customers;

WHEREAS, TMDA and PHLB recognize the significant contribution that can be made by implementing these legal mandates by operating in coordinated manner and in cooperation within the framework of their strategic objectives for the Tanzanian public and economic development, quality health services as well as promoting and protecting public health; and

WHEREAS, in order to achieve such cooperation and resolve overlaps and duplication of functions when carrying out duties, promoting good reputation and understanding of the roles of the two parties, TMDA and PHLB desire to operate within the framework of this MoU.

NOW THEREFORE, TMDA and the PHLB (hereinafter collectively referred to as "the Parties") hereby declare as follows:

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Article 1: Purpose

The purpose of this MoU is to identify and establish areas of cooperation in inspection of medical devices and diagnostics in private health laboratories in order to bring about efficiency between the two parties when carrying out their duties.

In this context functions of the two parties are interrelated by law as follows:

1. The functions and duties of both parties are cross-cutting with mutual interest of improving diagnostic services in the country that is inspection of medical devices and diagnostics by TMDA and inspection of private health laboratories by PHLB.
2. The products registered and regulated by TMDA (medical devices and diagnostics) are stored and used in private health laboratory premises that are registered and regulated by PHLB.
3. Inspections and supervision carried out by both parties for different purposes involve the same private health laboratory premises, infrastructure and interaction with the same laboratory personnel.

Therefore, if these two Parties continue to work independently there is a possibility of duplication of resources, time and inconveniences to customers. This justifies the choice for the common area of interest and collaboration as well as the modalities of cooperation proposed in the articles of this MoU.

Article 2. Responsibilities of the parties

Subject to respective law, rules, regulations, practices, procedures and availability of resources;

2.1 TMDA will;

a. recognize and cooperate with inspectors from PHLB who can perform the duties as inspectors of TMDA as may be directed by the PHLB Registrar;
b. provide and share necessary information as regards to private health laboratories that is needed to attain the common goal under this MoU;
c. provide technical assistance related to implementation of this MoU;
d. provide necessary resources for implementation of this MoU;
e. appoint a coordinator for the collaboration and follow up of agreed activities.

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f. recognize reports for medical devices and diagnostics defects reported by PHLB inspectors;

g. do such other act, which is necessary for the furtherance of the objectives of this MoU.

2.2 PHLB will;

a. recognize and cooperate with inspectors from TMDA who can perform the duties as inspectors of PHLB as may be directed by the Director General;

b. provide and share necessary information related to the quality, safety, performance and any other information of medical devices and diagnostics from private health laboratory;

c. provide and facilitate communication and cooperation between PHLB and TMDA;

d. provide technical assistance related to implementation of this MoU;

e. provide necessary resources for implementation of this MoU;

f. appoint a coordinator for the collaboration and follow up of agreed activities;

g. do such other act, which is necessary for the furtherance of the objectives of this MoU.

2.3 Both TMDA and PHLB will;

a. conduct joint routine inspection in the private health laboratories as may be determined by the two parties.

b. collaborate in the design, planning and implementation of operation/special inspections and training of inspectors

c. provide necessary and appropriate resources needed for the agreed activities.

d. disseminate information emanating from joint activities to stakeholders

e. adhere to the Action Plan which is attached as part of this MoU. **(See Annex 1: Implementation Plan for the Memorandum of Understanding (MoU) between Tanzania Medicines and Medical Devices Authority (TMDA) and Private Health Laboratories Board (PHLB) from 2025 to 2028)**

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Article 3: MoU implementation Task force

TMDA and PHLB will form a task force to oversee the implementation of this MoU which will be composed of six (6) members in equal numbers from each party. The chairperson will be elected from among the members. The task force will meet at least twice a year or as the chairperson of the parties may deem it appropriate.

TMDA and PHLB will form a secretariat, consisting of at least two (2) representatives; one from each party, which will be responsible for planning and implementation of specific activities.

Article 4: Communication and decision making

The relationship between TMDA and PHLB will be mutually respectful with clearly established channels of communication and involvement in decision making. The process of communication and decision making will be as follows:

a. Requests for official support from both parties will be directed to the Director General or the Registrar as the case may be from the responsible persons for TMDA or PHLB respectively.

b. The Director General or the Registrar will communicate in writing on activities to be collaborated between TMDA and PHLB.

c. Decisions in relation to the planned activities will be made jointly by the Director General and the Registrar.

Article 5: Entry into force, Duration and Termination

This MoU shall come into effect upon the last signature of the parties and will remain valid for a period of three (3) years unless terminated earlier by giving 30 days prior written notice to the other party. The MoU may be extended with the consent of both parties in writing for a further agreed period and terms to be agreed upon during the time of renewal.

In the event of termination, steps will be taken to ensure that the termination does not affect any prior obligation or activity already in progress.

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Article 6: Implementation Cost.

Both Parties will be responsible for operating expenses required during implementation of this MoU.

Article 7: Confidentiality

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.

Article 8: Amendment Modification of MoU

This MoU may be amended in writing by mutual consent of the parties.

Article 9: Resolution of Disputes.

The Parties will use their best efforts to settle amicably any dispute or controversy arising out of or relating to this MoU.

Article 10: Governing Law

This MoU will be construed in accordance with laws of Tanzania.

Article 11: Relationship between the Parties

Nothing contained herein will be construed as establishing a relation of master and servant or of agent and principal as between the parties.

Article 12: Notification

Any notice or request required or permitted to be given or made under this MoU will be given or made in writing at the address specified hereunder;

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For TMDA:

Director General,

Tanzania Medicines and Medical Devices Authority,

Plot No.56/1, Block E,

Kisasa B Centre, Hombolo Road,

P.O. Box 1253,

DODOMA.

For PHLB:

Registrar,

Private Health Laboratories Board,

Government City, Afya Street- Mtumba,

P.O. Box 743,

DODOMA.

In **WITNESS WHEREOF,** the duly authorized representatives of the Parties have signed this Memorandum of Understanding in two (2) originals as indicated hereunder.

For TMDA:

Name: DR. ADAM M. FIMBO

Signature: .....

Date: 18/9/2025

Director General

In presence of;

Name: Martha S. Malle

Signature: .....

Title: Acting Manager Legal Services

Date: 18/9/2025

For PHLB:

Name: DOMINIC J. FWILUPGAFU

Signature: .....

Date: 06/10/2025

Registrar

In presence of;

Name: DICKSON R. KANANDA

Signature: .....

Title: LEGAL OFFICER

Date: 06TH October, 2025