Zanzibar Food and Drug Agency
ZFDA
ISO CERTIFIED (9001:2015)

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-- Barua zote zielekezwe kwa Mkurugenzi Mtendaji --

B.107/108/02 **15/03/2024**

MKURUGENZI MKUU,
MAMLAKA YA DAWA NA VIFAA TIBA,
S.L.P 1253,
DODOMA,
TANZANIA.

YAH: MKATABA WA MASHIRIKIANO (MOU) KATI YA MAMLAKA YA DAWA NA VIFAA TIBA (TMDA) NA WAKALA WA CHAKULA NA DAWA ZANZIBAR (ZFDA)

Tafadhali rejea barua yako yenye Kumbukumbu Namba **BA. 204/224/01/10** ya tarehe **27 Febuari, 2024** yenye kichwa cha habari kilicho hapo juu.

ZFDA imepokea barua yako na nakala ya rasimu ya Hati ya Makubaliano uliyoituma, baada ya kuifanyia majadiliano ZFDA imekubaliana na yote yaliyomo katika rasimu hiyo.

Kwa barua hii, ZFDA inaiwasilisha kwako nyaraka hiyo kwa hatua za kuifanyia kazi ili kuweza kuleta udhibiti mzuri wa dawa, vifaa tiba na majaribio ya dawa kwa ajili ya kuimarisha upatikanaji wa dawa zenye ubora, salama na ufanisi kwa wananchi wa Tanzania.

Ahsante kwa mashirikiano yaliyopo.

ZANZIBAR FOOD AND DRUG AGENCY
TELEFAX:+255-24223
EXECUTIVE
DIRECTOR
DATE
MINISTRY OF HEALTH-ZANZIBAR

.....
DR. BURHANI OTHMAN SIMAI,
MKURUGENZI MTENDAJI.

MEMORANDUM OF UNDERSTANDING ON COOPERATION IN THE REGULATION OF MEDICAL PRODUCTS
BETWEEN
THE TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY AS REPRESENTED BY DIRECTOR GENERAL

AND
THE ZANZIBAR FOOD AND DRUGS AGENCY
AS REPRESENTED BY EXECUTIVE DIRECTOR

PREAMBLE

WHEREAS Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC). 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 Zanzibar Food and Drugs Agency as the statutory Regulatory Agency for food, drugs, cosmetics and medical devices (referred to as the "ZFDA") established under the Zanzibar Food, Drugs and Cosmetics Act, No. 2 of 2006 an its amendment Act No.3 of 2017; and

WHEREAS TMDA and ZFDA 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 ZFDA desire to operate within the framework of this Memorandum of understanding (hereinafter referred to as the "MoU") and

WHEREAS TMDA and ZFDA have noted the importance of cooperation in issuance of permits stipulated under the mentioned Acts.

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

Article 1: Objective

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

1.1.1 Evaluation and Registration of medicines and medical devices;

i. Each Party will recognize and use as technical input the data that will be submitted by the other party before registration of products;
ii. The registration of a product by either Party will be evidenced by a certificate of registration and/or registration mark issued by the Party;
iii. Both Parties commit to suspend the manufacture, importation and exportation, sale, distribution and storage of any product that does not comply with quality, safety and efficacy requirements to be traded in markets of either Party.

1.1.2 Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) Inspection and Quality Audit;

i. Each Party will share the Good Manufacturing Practices (GMP) inspection reports for medicines manufacturing facilities before deciding on the outcome of an inspection; and
ii. The GMP inspection conducted will be evidenced by a certificate issued by the other Party.
iii. Each party will share data on Quality Audits conducted at medical devices and diagnostics manufacturing facilities to verify conformity to ISO requirements.
iv. The quality audit reports will be evidenced by a certificate issued by the other party.

1.1.3 Post Marketing Surveillance;

i. Each Party will share information on post marketing surveillance (PMS) results from either Party;
ii. Each Party will share information on product recalls after confirming their quality defects to include batch numbers, quantities labels and address of manufacturers and any other details that may permit identification of products in each Party's market; and
iii. Each Party may seize and confiscate condemned products after thorough investigation depending on each jurisdictional legislative framework.

1.1.4 Quality Control Laboratory testing;

i. Each Party agree to establish quality control laboratories that will ensure compliance to standards;
ii. Each Part will share laboratory test results once requested to allow for regulatory decision making; and
iii. Each Party may conduct further testing of products for self-assurance in case of disputed results.

1.1.5 Training

i. Each Party may organize trainings on regulatory matters which may take place at any of the Party's territory or conducted using online Platforms;
ii. Both Parties may share or exchange their experts for mentorship, coaching and capacity building of either parties' staff.

1.1.6 Information sharing; and

i. Both Parties agree to share the information being accurate or suspicious concerning the quality, safety and efficacy of regulated products under the mandate of either Party through an established platform;
ii. Parties agree to follow up and analyse the information concerning quality, safety and efficacy shared including the outcome of the analysis; and
iii. Both Parties agree to exchange relevant information and documents subject to such restrictions and arrangements as may be considered necessary by either Party to preserve the confidential nature of certain information and documents.
iv. Both Parties agree to share information on new regulatory requirements includings laws, regulations and guidelines to facilitate compliance and protection of public health .

1.1.7 Other regulatory functions as may be deemed necessary by either Party

1.2 The collaboration will encompasses 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 United Republic of Tanzania to quality assured medicines and medical devices.

1.3 The Parties agree to work together in good faith, through joint and concerted co-operation in accordance with provisions of this MoU, in order to implement the objectives set forth above.

Article 2: Scope of the Memorandum

2.1 This MoU covers all products regulated by both Parties including human and veterinary medicines, herbal medicines, medical devices, diagnostics, biological products including vaccines.

2.2 The MoU defines the areas, institutional arrangements and general conditions that will govern the cooperation of the Parties.

2.3 The MoU constitutes the entire understanding of the Parties with respect to its subject matter and supersedes all oral communications and prior written documents; and

2.4 The Parties agree that this MoU does not confer any exclusivity regarding activities covered by this MoU and that they rectify may collaborate on similar activities with other partners.

Article 3: Areas of cooperation

Subject to the programme of work of the Parties and the provisions of this MoU, the Parties agree to carry out common initiatives in the areas of cooperation of mutual interest identified in Article 1 to this MoU, which may be modified from time to time by written agreement of the Parties.

Article 4: Focal points

For the purpose of facilitating the day-to-day implementation of this MoU, TMDA and ZFDA will nominate a focal point or a person(s) who will be responsible for coordinating all communication and the implementation of this MoU.

Article 5: Regulatory services fees and Charges

Regulatory service fees and charges on regulatory functions such as registration, import and export control, clinical trial authorization and others will continue to be paid in accordance with existing national legislative requirements.

Article 6: 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.

Article 7: Public Announcements

Either Party may issue press release or make public announcements relating to the areas of its competence to this MoU; however, a Party to this memorandum intending to issue a press release, may provide a draft of such press release for review by the other party before being issued.

Article 8: General conditions

8.1 **Financial contribution:** The implementation of activities envisaged in this MoU will be included in each party's annual budget in order to ease the availability of the necessary financial resource in accordance with the regulations, rules, instructions, directives and procedures in force.

8.2 **Liability and status:** Nothing in or relating to this MoU will be constructed as establishing a legal partnership (such as, by way of clarification, partnership Liability), joint venture, agency, exclusive arrangement, or other similar relationship between TMDA and ZFDA. Neither TMDA nor ZFDA or anyone to whom the Parties may employ will be considered as an agent of official of TMDA or ZFDA and, except as otherwise provided, will not be entitled to any privileges, immunities, compensation or reimbursement, nor will be authorized to commit TMDA or ZFDA to any expenditure or other obligations.

8.3 **Status of TMDA and ZFDA:** TMDA and ZFDA as both are government institutions under the ministries responsible for Health will respect each other. Nothing in or relating to this memorandum will be deemed as a waiver, express or implied, of any of the privileges and immunities of either party.

8.4 **Conformity with laws:** TMDA and ZFDA will respect the enacted laws within which the two Parties operate. Neither TMDA nor ZFDA will permit any official to receive a direct or indirect profit from this MoU or from any subsequent agreement(s) between the Parties.

8.5 **Assignment:** The Parties will not assign, transfer, pledge or make other disposition of the present MoU or any party thereof or of any of their rights, claims or obligations under the present MoU except with the prior written approval of other Party. Any of the aforementioned actions taken without such written approval will not be valid.

8.6 **Non-waiver:** Any waiver by a Party of a breach of a provision of this MoU will not operate or be construed to be waiver of any other breach of that provision or of any breach of any other provision of this MoU. A failure by a Party to insist upon strict adherence to any term of this MoU on one or more occasion will not be considered a waiver or deprive that Party of the right thereafter to insist upon strict adherence to that term or any other term of this MoU. Any waiver must be in writing and signed by the Parties against whom enforcement is sought.

8.7 **Indemnification:** Parties will hold harmless, defend and indemnify each other against all lawsuits, claims, costs and liabilities resulting from any intellectual property disputes or other disputes occurring under the present MoU and which arise out of acts or omissions of TMDA, ZFDA their agents or employees.

8.8 **Evaluation:** Subject to the provisions of any agreement concluded pursuant to the provisions of these Articles the results of each activity will be jointly evaluated by the Parties.

Article 9: Governing law and settlement of Disputes

9.1 The present MoU will be construed in accordance with general principles of Contract laws of Tanzania Mainland and Zanzibar to the exclusion of any single national system of law.

9.2 In the event of dispute, controversy or claim arising out of or relating to this MoU or to any agreement(s) concluded pursuant to this MoU, the Parties will use their best efforts to promptly settle such disputes through direct negotiation.

9.3 Any dispute that is not settled within sixty (60) days from the date a Part has notified the other of the nature of the dispute and of the measures that should be taken to rectify it will be resolved through consultation between the executive heads of Parties or their duly authorized representatives. If the dispute cannot be settled amicably through consultation, it will be settled by arbitration. The arbitration will be conducted in accordance with the modalities to be agreed upon by the Parties, or in the absence of agreement, with the rules defined by the Arbitration Act, Cap 30 and Arbitration Decree, Cap 25 of the Laws of Zanzibar.

9.4 The language of the arbitration will be English or Swahili and the place of arbitration will be within URT or as agreed by both Parties. The arbitral tribunal will not have the power to impose general, incidental, indirect, special, punitive or consequential damages, including, without limitation, for lost profits. The Parties will accept the arbitral ward as final.

9.5 If any term of this MoU is found to be invalid, illegal or unenforceable, it is the intention of the Parties that the remainder of this Memorandum will not be affected thereby: provide, however, that no Party's rights under this MoU have been materially adversely affected.

Article 10: Notification

The addresses for service of notices under the present MoU shall be: TMDA: Tanzania Medicines and Medical devices Authority, TMDA/ Mandela Road, Mabibo External, P.O. Box 77150, Dar es Salaam, E-mail info@tmda.go.tz and ZFDA: Zanzibar Food and Drugs Agency, Mombasa Area, along Changu Road, P.O. Box 3595, Zanzibar, E-mail info@zfda.go.tz

Article 11: Final Provision

11.1 This MoU will take effect upon its signature by the authorized representatives of the Parties;

11.2 This MoU is concluded for an initial period of 5 years as of the date of signature by the Parties, and it may be renewed, following mutual consultation, by exchange of letters for 5 years period or such other period as the Parties decide;

11.3 This MoU may only be changed, modified, amended or supplemented by written agreement of the Parties; and

11.4 The Parties may terminate this MoU by written agreement. Each party will have the right to terminate this MoU, for any reason and at any time, by giving sixty (60) days written notice to the other Party. 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.

IN WITNESS WHEREOF the undersigned, duly appointed representatives of TMDA And ZFDA respectively, have signed the present MoU, in English and in two originals, on the date(s) and at the place(s) set forth below:

For TMDA:

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Adam M. Fimbo
DIRECTOR GENERAL

Date 27/2/2024

For ZFDA

ZANZIBAR FOOD AND DRUG AGENCY
EXECUTIVE DIRECTOR

.....

Dr. Burhani Othman Simai
EXECUTIVE DIRECTOR

Date 12/03/2024.

Dodoma, Tanzania