

**UNITED REPUBLIC OF TANZANIA**



**MEMORANDUM OF UNDERSTANDING ON COOPERATION**  
**BETWEEN**  
**THE TANZANIA FOOD AND DRUGS AUTHORITY**  
**AND**  
**THE TANZANIA BUREAU OF STANDARDS**  
**NOVEMBER, 2016**

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# **MEMORANDUM OF UNDERSTANDING ON COOPERATION**

**BETWEEN**

**THE TANZANIA FOOD AND DRUGS AUTHORITY, WHOSE  
HEADQUARTERS ARE LOCATED OFF MANDELA ROAD, MABIBO EXTERNAL,  
DAR ES SALAAM**

**AND**

**THE TANZANIA BUREAU OF STANDARDS, WHOSE HEADQUARTERS ARE  
LOCATED AT THE JUNCTION OF MOROGORO/SAM NUJOMA ROADS,  
UBUNGO, DAR ES SALAAM**

**WHEREAS** Tanzania Food and Drugs Authority as a Statutory Regulatory Authority for food, medicines, cosmetics and medical devices (hereinafter referred to as the "TFDA") is responsible for promoting and protecting public health by ensuring the safety, quality and effectiveness of food, medicines, cosmetics and medical devices as stipulated under the Tanzania Food, Drugs and Cosmetics Act, Cap 219; and

**WHEREAS** Tanzania Bureau of Standards as the Statutory body for National Standards under the Standards Act, Cap 130 (hereinafter referred to as the "TBS") as overseer of standardization and quality assurance by the industry and commerce sectors with a view to complement national efforts to offer products of better quality and higher competitive edge on both the internal and external markets, with the overall objective of promoting the availability of good and safe products for the Tanzanian public and enhancing economic development; and

**WHEREAS** TFDA and TBS recognize the significant contribution that can be made by both Parties to their legal mandates and strategic objectives and therefore actively promote cooperation arrangements when enhancing the availability of safe and quality products for the Tanzanian public and economic development 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 and promoting good reputation and understanding of the roles of the two Parties against consumers, TBS and TFDA desire to operate within the framework of this Memorandum of Understanding (hereinafter referred to as the "MoU").

**NOW THEREFORE**, TFDA and TBS (hereinafter referred to as collectively as "the Parties") hereby declare as follows:

## **Article 1: Objective**

The objective of the MoU is to identify and establish areas of cooperation in order to resolve overlaps and duplication of functions between the two Parties when carrying out their duties and promote good reputation and understanding of the roles of the two Parties against industries and consumers in Tanzania mainland.

1. The Parties mutually agree that they will cooperate closely and consult one another on matters of mutual interest in order to achieve their objectives, which include:
  - a. To establish this MoU between the Parties;
  - b. To advocate for development of the National Quality Policy and National Food Safety Policy;
  - c. To advocate for revision of the relevant sections in the establishing Laws of the Parties;
  - d. To create awareness to stakeholders;
  - e. To establish formal consultation mechanisms between the Parties;
  - f. To recognise the TFDA certificates and permits as a pre-requisite for issuance of Certificate of Conformity by TBS;
  - g. To establish a joint inspection operations at least twice a year;
  - h. To establish a joint mechanism to support the micro and small enterprises to comply with requirements for safety and conformity assessment; and
  - i. To conduct joint trainings on inspection and laboratory techniques.
2. The Parties agree to work together in good faith, through joint and concerted cooperation in accordance with the provisions of this MoU, in order to implement the objectives set forth above.

#### **Article 2: Scope of the Memorandum**

1. This MoU establishes a framework for cooperation between the Parties and determines the conditions and modalities within which the Parties will collaborate to achieve their objectives. The MoU defines the areas, institutional arrangements, and general conditions that will govern the cooperation of the Parties.
2. The MoU constitutes the entire understanding of the Parties with respect to its subject matter and supersedes all oral communications and prior written documents.
3. The Parties agree that this MoU does not confer any exclusivity regarding activities covered by this MoU and that they may collaborate on similar activities with other partners.

#### **Article 3: Areas of Cooperation**

Subject to the programme of work of the Parties and to 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: Joint Activities**

1. TFDA shall register micro and small scale food processing facilities without any payment of registration fees for respective food products registered while the TBS shall not charge any initial fees for certification of food products locally manufactured by micro and small scale Industries with a view to promote safety and quality of food as well as trade and growth of economy for micro and small scale Industries;
2. The Parties shall share and mutually recognize the use of any laboratory tests results for samples upon which a test has been conducted by laboratories of either of the Parties for purposes of any regulatory decision or

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conformity assessment need to be made instead of casting the burden to customers submitting samples to both Parties laboratories;

3. The Parties agree to explore possibilities for joint collaboration on activities in the areas of cooperation as opportunities arise. The Action Plan annexed to this MoU contains activities that have been identified by the Parties which shall be read as one and the same as this MoU stipulate;
4. The Parties will negotiate in good faith the terms of any subsequent agreement(s) that are required to implement their collaboration at the implementation level. Such agreement(s) will normally be concluded in the form of an exchange of letters setting out the deliverables and responsibilities of the Parties in respect of the activities, including the financial and other support the Parties will provide to implement. Such agreement(s) will be subject to the regulations, rules, instructions, directives and procedures in force in both Parties, and will incorporate the General Conditions contained in Article 8 below.
5. The Parties shall form a committee to be known as the "the joint committee" to oversee the implementation of the MoU.
6. The Chairperson and Secretary of the joint committee shall be selected from among the members of the committee on rotational basis between the Parties. The committee shall be composed of not less than six members appointed in equal number from each party.
7. The joint committee shall meet once a quarter or as the Chief Executives of the Parties may deem it appropriate.
8. All raw and packaging materials of whatever nature which are directly involved in domestic production of pharmaceuticals shall be exempted from preshipment verification of conformity to standards (PVoC) by TBS upon proof of TFDA approval.
9. Without prejudice to the generality of article 4 of this MoU, products manufactured by micro and small scale industries within the scope of the legal mandate of the Parties shall be treated in the same way as provided under sub-article 1.

#### **Article 5: Exchange of Information and Documents**


The Parties agree to undertake an exchange of 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.

#### **Article 6: Focal Points**

1. For the purpose of facilitating the day-to-day implementation of this MoU, direct contacts will be made between representatives of the Parties.  
The Parties will nominate a focal point or a person from among members of the joint committee who will be responsible for coordinating all communication and the implementation of this MoU.

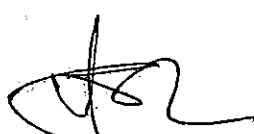
#### **Article 7: Public Announcements**

Either Party may issue press releases 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 or announcements of mutual interest with the MoU shall need to notify the other party before the same is issued.



## **Article 8: General Conditions**

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 resources in accordance with the regulations, rules, instructions, directives and procedures in force for TFDA and TBS.
2. **Liability and Status:** Nothing in or relating to this MoU will be construed as establishing a legal partnership (such as, by way of clarification, partnership liability), joint venture, agency, exclusive arrangement, or other similar relationship between TFDA and TBS. Neither TBS nor TFDA or anyone to whom the parties may employ will be considered as an agent or official of TFDA or TBS and, except as otherwise provided, will not be entitled to any privileges, immunities, compensation or reimbursements, nor will be authorized to commit TFDA or TBS to any expenditure or other obligations.
3. **Status of TFDA and TBS:** TBS and TFDA as both are government agencies under the Ministry responsible for Industry and Trade and the Ministry responsible for Health, respectively 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 TBS or TFDA.
4. **Conformity with Laws:** TBS and TFDA will respect the establishing laws within which the two parties operate. Neither TFDA nor TBS will permit any official to receive a direct or indirect profit from this MoU or from any subsequent agreement(s) between the Parties.
5. **Assignment:** The Parties will not assign, transfer, pledge or make other disposition of the present MoU or any part thereof or of any of their rights, claims or obligations under the present MoU except with the prior written approval of the other Party. Any of the aforementioned actions taken without such written approval will not be valid.
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 a 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.
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 TFDA, TBS, their agents or employees.



8. **Evaluation:** Subject to the provisions of any agreement concluded pursuant to the provisions of Article 4, the results of each activity will be jointly evaluated by the Parties.

**Article 9: Governing Law and Settlement of Disputes**

1. The present MoU will be construed in accordance with general principles of contract laws of Tanzania, to the exclusion of any single national system of law.
2. In the event of a 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 dispute through direct negotiation.
3. Any dispute that is not settled within sixty (60) days from the date a Party 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 the Parties or their duly authorized representatives.
4. 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; provided, 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: **TFDA:** located off Mandela Road, Mabibo external P.O. Box 77150, Dar es Salaam and **TBS:** Ubungo area, along Morogoro/Sam Nujoma Roads, P.O. Box 9524, Dar es Salaam.

**Article 11: Confidentiality**

1. For the purposes of this MoU confidential information shall include:
  - (a) information of whatever nature relating to the parties which is obtained by the parties, officers, employees, agents or advisers in written, pictorial or oral form from or pursuant to discussions with any of the officers, employees, agents or advisers of the parties;
  - (b) analysis, compilations, studies and other documents prepared by parties, officers, employees, agents or advisers which contain or otherwise reflect or are generated from the information specified in this MoU
  - (c) letters and the facts of the discussions or negotiations are taking, or have taken place between the parties or any of the terms, conditions or other facts with respect to the implementation of this MOU.
  - (d) unless otherwise provided the confidential information shall not be allowed to be disclosed to any third party who is not a party to this MOU without official approval by the parties.



## 2. Exclusions

It shall be understood that the following obligations shall not apply to Confidential Information or such of it which:

- (a) at the time of disclosure such information is within the public domain; or
- (b) after disclosure comes into the public domain, other than by reason of breach of any of the undertakings below; or
- (c) is already lawfully in your advisers' possession (as can be demonstrated by written records or other reasonable evidence) provided that the source of such information was not subject to any agreement or other duties relating to confidentiality under this MoU; or
- (d) becomes lawfully available to your advisers (as can be demonstrated by written records or other reasonable evidence), other than the parties' officers, employees, agents or advisers, provided that the source of such information is not then subject to any agreement or other duties relating to confidentiality under this MoU.

### **Article 12: Final Provisions**

- 1. This MoU will take effect upon its signature by the authorized representatives of the Parties.
- 2. This MoU is concluded for an initial period of 3 years as of the date of signature by the Parties, and it may be renewed, following mutual consultation, by exchange of letters for a 3 year period or such other period as the Parties may decide.
- 3. This MoU may only be changed, modified, amended or supplemented by written agreement of the Parties.
- 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 six months 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 TFDA and TBS respectively, have signed the present MoU of Understanding, in English and in two originals, on the date(s) and at the place(s) set forth below:

**For TFDA:**

  
**Mr. Hiiti B. Sillo**  
**Director General**

Dar es Salaam, Date: 2016-11-11

**For TBS:**

  
**Dr. Egid B. Mubofu**  
**Ag. Director General**

Dar es Salaam Date: 2016-11-11