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MEMORANDUM OF UNDERSTANDING ON COOPERATION



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THE TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY WHOSE HEADQUARTERS ARE LOCATED AT PLOT NO. 56/1, BLOCK E, KISASA B CENTRE, SWASWA ROAD, DODOMA AS REPRESENTED BY DIRECTOR GENERAL, MR. ADAM M. FIMBO

AND

THE VETERINARY COUNCIL OF TANZANIA, WHOSE HEADQUARTERS ARE LOCATED AT NBC HOUSE ALONG NYERERE ROAD, DODOMA AS REPRESENTED BY THE REGISTRAR DR. BEDAN MASURULI

WHEREAS TMDA as a Statutory Regulatory Agency for Medicines and Medical Devices (hereinafter referred to as the "TMDA") is responsible for promoting and protecting public health by ensuring the safety, quality and effectiveness of Medicines and Medical Devices stipulated under the Tanzania Medicines and Medical Devices Act, Cap 219; and

<u>WHEREAS</u> Veterinary Council of Tanzania, as Professional statutory body corporate under the Ministry of Livestock and Fisheries, established under the Veterinary Act, Cap 319 (hereinafter referred to as the "VCT") is responsible for the registration, enrolment or enlistment of paraprofessional and paraprofessional assistants also as overseer to determine the minimum standards and for veterinary practice facilities including conduct and scope of practice activities for veterinary professionals; and

<u>WHEREAS</u> TMDA and VCT 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 and quality veterinary medicinal products for the Tanzanian public and economic development as well as promoting and protecting public health; and

<u>WHEREAS</u> 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, VCT and TMDA desire to operate within the framework of this Memorandum of Understanding (hereinafter referred to as the "MoU");

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

Article 1: Objective

The objectives of this MoU is to identify areas of cooperation in order to resolve overlaps and duplication of functions between the two parties when carrying out

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their duties and promote good reputation and understanding of the roles of the two parties against consumers in Tanzania mainland.

- 1.1 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 approve this MoU between the parties;
 - b. To recognize the registration of veterinary practice facility permits issued by VCT
 - c. To recognize the registration of wholesale permits issued by TMDA
 - d. To register and license premises for veterinary medicines as provided for in the existing laws.
 - e. To conduct joint inspection operations in veterinary facilities and premises;
 - 1.2 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

- 2.1 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;
- 2.2 The MoU constitutes the entire understanding of the Parties with respect to its subject matter and supersedes all oral communications and prior written documents; and
- 2.3 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.

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Article 4: Recognition of permits

- 4.1 Parties do hereby agree to recognize the veterinary practice facilities registered by VCT so that no subsequent permits shall be issued by TMDA in premises where any valid permit for veterinary practice facilities has been issued by VCT;
- 4.2 The veterinary practice facilities referred to in sub article 4.1 herein provided in the Veterinary Act, Cap 319 shall include veterinary hospitals, veterinary clinics, veterinary centres, quarantine facilities, ambulatory services, veterinary diagnostic laboratories, veterinary consulting firms and artificial insemination centres; and
- 4.3 TMDA shall issue permits for wholesale of veterinary pharmaceuticals and that case no subsequent permits shall be issued by VCT where any valid permit for a wholesale veterinary premises has been issued by TMDA.
- 4.4 In the event of any unforeseeable violation to this MoU, it shall be presumed that both parties had good faith to ensure that only one permit should be issued to be considered valid for both TMDA and VCT purposes in that any subsequent permits issued to a premises with a valid permit from either of the Party shall be void

Article 5: Inspection of veterinary pharmaceutical premises

- 5.1 TMDA and VCT will conduct joint inspections in the entire veterinary medicines supply chain at least twice a year or as may be determined by the two Parties:
- 5.2. 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 TMDA and VCT 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 from TMDA and or VCT, and will incorporate the General Conditions contained in Article 8 below;
- 5.3 The Parties shall form a Joint Committee to be known as the "Committee" to oversee the implementation of this MoU;
- 5.4. The chairperson of the Committee shall be selected from among the members of the Committee. The Committee shall be composed of not less than six members appointed in equal number from each Party;
- 5.5. The Committee shall meet at least twice a year or as the Chief Executive of the Parties may deem it appropriate; and

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5.6. The Parties may form working groups, consisting of representatives from each Party, which will be responsible for planning and implementation of specific activities.

Article 6:

Exchange of Information and Documents

The 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 depending upon request from any of the parties in writing or any mode of communication acceptable to the parties.

Article 7:

Focal Points

- 7.1 For the purpose of facilitating the day-to-day implementation of this MoU, direct contacts will be made between representatives of the Parties; and
- 7.2 TMDA and VCT will nominate focal points or persons who will be responsible for coordinating all communication and the implementation of this MoU.

Article 8:

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, will first save a copy of the draft of such press release for review and comments by the other Party before being issued.

Article 9:

General Conditions

- 9.1 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 TMDA and VCT;
- 9.2 <u>Liability and Status</u>: 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 TMDA and VCT. Neither VCT nor TMDA or anyone to whom the Parties may employ will be considered as an agent or official of TMDA or VCT and, except as otherwise provided, will not be entitled to any privileges, immunities, compensation or reimbursements, nor will be authorized to commit TMDA or VCT to any expenditure or other obligations;
- 9.3. Status of TMDA and VCT: VCT and TMDA as both are government institutions under the Ministry responsible for Livestock and Fisheries 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 party;

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- 9.4. Conformity with Laws: VCT and TMDA will respect the enacted laws within which the two Parties operate. Neither TMDA nor VCT will permit any official to receive a direct or indirect profit from this MoU or from any subsequent agreement(s) between the Parties;
- 9.5. <u>Assignment</u>: 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;
- 9.6. 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;
- 9.7. 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, VCT, their agents or employees;
- <u>9.8.</u> <u>Evaluation:</u> Subject to the provisions of any agreement concluded pursuant to the provisions of Article 3, the results of each activity will be jointly evaluated by the Parties

Article 10:

Governing Law and Settlement of Disputes

- 10.1 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:
- 10.2 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;
- 10.3 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. 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;

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- The language of the arbitration will be English or Swahili and the place of arbitration will be Dar es Salaam or Dodoma, Tanzania. 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 award as final; and
- 10.5 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; provided, however, that no Party's rights under this MoU have been materially adversely affected.

Article 11:

Notification

The addresses for service of notices under the present MoU shall be: TMDA Plot No. 56/1, Block E, Kisasa B Centre, Swaswa Road,, P.O. Box 1253 Dodoma and VCT: NBC House, Nyerere Road, Box 2870, Dodoma

Article 12:

Final Provisions

- 12.1. This MoU will take effect upon its signature by the authorized representatives of the Parties.
- 12.2. 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 a 5 year period or such other period as the Parties may decide.
 - 12.3. This MoU may only be changed, modified, amended or supplemented by written agreement of the Parties
 - 12.4. 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 TMDA and VCT respectively, have signed the present Memorandum of Understanding, in English and in two originals, on the date(s) and at the place(s) set forth below:

For TMDA:

Adam M. Fimbo Director General

Dodoma Date:

For VCT:

Dr. Bedan Masuruli

Registrar

Dodoma Date: