

**MEMORANDUM OF UNDERSTANDING (MoU)**

**BETWEEN**

**THE INDONESIAN FOOD AND DRUG  
AUTHORITY**

**THE REPUBLIC OF INDONESIA**

**AND**

**TANZANIA MEDICINES & MEDICAL DEVICES  
AUTHORITY (TMDA)**

**THE UNITED REPUBLIC OF TANZANIA**

**ON**

**COOPERATION IN THE FIELD OF  
PHARMACEUTICAL PRODUCTS AND  
REGULATORY FUNCTIONS**

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The Indonesian Food and Drug Authority (Indonesian FDA) and Tanzania Medicines and Medical devices authority (TMDA) (hereinafter jointly referred to as the "Parties" and individually referred to as the "Party");

**RECOGNISING** the existing friendly relations between their respective countries and desiring to strengthen and further develop regulatory cooperation between the two countries in the field of pharmaceutical products (including medicinal products, biological products and natural medicinal product);

**CONVINCED** of the necessity of a lasting and effective cooperation in the interest of both countries;

**RECOGNISING** that such cooperation would serve their common interest and contribute to the enhancement of the above-mentioned field and social development of both countries; and

**PURSUANT TO** the prevailing laws and regulations of their respective countries.

**HAVE REACHED** the following understanding:

## **Article I**

### **OBJECTIVE**

The objective of this Memorandum of Understanding (hereinafter referred to as "MoU") is to strengthen cooperation in the field of pharmaceutical products (including medicinal products, biological products, and natural medicinal product) on the basis of equality and mutual benefits between both parties.

## **Article II**

### **FORMS OF COOPERATION**

The parties will promote cooperation in the following areas:

1. Exchange and sharing information, best practices, knowledge and skills regarding standards and regulations;
2. Facilitate information sharing to support TMDA in the implementation of regulatory reliance on the Indonesian FDA, in accordance with the terms mutually agreed upon by the Parties;
3. Undertaking capacity building programs (technical assistance), including workshop and training;
4. Facilitate the procedures for access to pharmaceutical products from both countries, in accordance with laws and regulations of each Party;
5. Development of notification system in case of contaminated, substandard and falsified medical products, or other related situations in each Party's territory that could potentially effect the public health of both Parties;
6. Exchange of visits of high-level delegations and experts;
7. Participation in international events organized by either Party; and
8. Any other forms of cooperation mutually agreed upon by the Parties in writing.

### **Article III**

#### **IMPLEMENTATION**

1. The Parties agree to conclude an action plan for any activities to implement this MoU annually. Such action plan shall defined the specific items of cooperation.
2. The Parties agree to carry out monitoring and evaluation of the implementation of the action plan periodically every year.

### **Article IV**

#### **FINANCIAL ARRANGEMENTS**

1. Activities conducted under this MoU shall be subject to the availability of funds and resources of each Party.
2. Each Party will bear its own expenses related to the activities conducted under this MoU.

### **Article V**

#### **DISCLOSURE OF INFORMATION**

1. Neither Party may disclose nor distribute to any third Party any confidential information transmitted by the other Party (referred to as the Disclosing Party) except as and to the extent authorized in writing to do so by the Disclosing Party.
2. All information and documents to be exchanged pursuant to this MoU will be kept confidential by the Parties and will be used subject to such terms as each Party may specify. The parties will not use the information for the purposes other than that specified without the prior written consent of the other Party.
3. All confidential information will remain the exclusive property of the Disclosing Party even after the termination or after this MoU comes to an end. The Parties agree that this MoU and the disclosure of the confidential information do not grant or imply any licence, interest. or right to the recipient in respect of any intellectual property right of the other Party.

4. Unpublished information, whether oral, in writing or otherwise, discovered or conceived by the scientists or technicians and exchanged under the provisions of this MoU will not be transmitted to a third Party, unless otherwise agreed by the Parties.

## **Article VI**

### **CHANNELS OF COMMUNICATION**

Notices and any exchange of information under this MoU will be delivered by registered mails or electronically to the Parties at the following address:

- a) For the Indonesia Food and Drug Authority  
Bureau of Cooperation and Public Relations  
Address: Jl Percetakan Negara No. 23 Central Jakarta, 10560, Indonesia  
Phone: +62 21 428 75379  
Email: [kerjasamahumas@pom.go.id](mailto:kerjasamahumas@pom.go.id); [ksin.bilateral@gmail.com](mailto:ksin.bilateral@gmail.com)
- b) For The Tanzania Medicines and Medical Devices Authority  
Address: The Director General  
Tanzania Medicines and Medical Devices Authority (TMDA)  
TMDA Headquarters  
Plot No. 56/1. Block E, Kisasa B centre  
P.O. Box 1253  
DODOMA  
Phone: +255 22 262961989/262961990  
Email: [info@tmda.go.tz](mailto:info@tmda.go.tz)

## **Article VII**

### **PARTICIPATION OF THIRD PARTY**

Each Party may invite the participation of a third party in joint activities and/or programmes being carried out under this MoU upon the agreement of the other Party. In carrying out such joint activities and programmes, the Parties will ensure that the third party will comply with the provisions of this MoU.

## **Article VIII**

### **SUSPENSION**

Each Party reserves the right to suspend temporarily, either in whole or in part, the implementation of this MoU on the ground of national security, national interest, public order or public health. The suspension will take effect immediately after written notification has been given to the other Party through diplomatic channels.

## **Article IX**

### **REVISION, MODIFICATION AND AMENDMENT**

1. Either Party may request in writing to revise, modify or amend all or any part of this MoU.
2. Any revision, modification or amendment agreed to by the Parties will be in writing and will be an integral part of this MOU.
3. Such revision, modification or amendment will come into force on such date as may be determined by the Parties.
4. Any revision, modification or amendment will not prejudice the rights and obligations arising from or based in this MoU prior or up to the date of such.

## **Article X**

### **LEGAL STATUS**

This MoU does not create any right or obligations under international law.

## **Article XI**

### **SETTLEMENT OF DISPUTE**

Any difference or dispute between the Parties concerning the interpretation and/or implementation and/or application of any of the provisions of this MoU will be settled amicably through mutual consultations and/or negotiations between

the Parties through diplomatic channels, without any reference to any third party or international tribunal.

**Article XII**  
**PARTICIPATION IN SIMILAR ACTIVITIES**

This MoU does not restricts the parties from participating in similar activities with other public or private agencies.

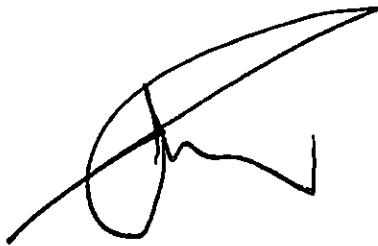
**Article XIII**  
**ENTRY INTO EFFECT, DURATION AND TERMINATION**

1. This MoU will enter into effect on the date of its signing by the Parties.
2. The MoU will remain in effect for a period of three (3) years, and may be renewed for another period of three (3) years by mutual consent through exchange of notes between the Parties through diplomatic channels.
3. The MoU may be terminated by either Party by giving a written notice of its intention to terminate this MoU three (3) months before the intended date of.
4. The termination of this MoU will not affect the implementation of any on-going activities and/or programmes which have been agreed upon before the termination of this MoU.

IN WITNESS WHEREOF, the undersigned have signed this MOU.

SIGNED in duplicate in Nusa Dua, Bali on 3 September 2024, in the English and Indonesian languages, all texts being equally authentic. In the event of divergence in the interpretation of any provisions under this MOU, the Parties will refer to Article XI of this MoU.

FOR THE INDONESIAN FOOD AND  
DRUG AUTHORITY OF THE  
REPUBLIC OF INDONESIA

A stylized handwritten signature in black ink, featuring a large loop and a long horizontal stroke extending to the right.

TARUNA IKRAR  
CHAIRPERSON

FOR TANZANIA MEDICINES AND  
MEDICAL DEVICES AUTHORITY,  
THE UNITED REPUBLIC OF  
TANZANIA

A handwritten signature in black ink, consisting of a series of loops and a long vertical stroke.

DR. ADAM M. FIMBO  
DIRECTOR GENERAL