

**MEMORANDUM OF COOPERATION  
BETWEEN  
THE MINISTRY OF HEALTH, LABOUR AND WELFARE  
OF JAPAN  
AND  
THE INDONESIAN FOOD AND DRUG AUTHORITY OF  
THE REPUBLIC OF INDONESIA  
ON  
MEDICAL PRODUCTS REGULATION DIALOGUE  
AND COOPERATION FRAMEWORK**

The Ministry of Health, Labour and Welfare of Japan (MHLW) and the Indonesian Food and Drug Authority of the Republic of Indonesia (Indonesian FDA), (hereinafter referred to collectively as “the Participants” and individually as a “Participant”),

INTENDING to promote mutual beneficial cooperation in the area of medical products in accordance with the applicable laws and regulations of the respective countries ,

HAVE REACHED the following recognition:

**1. Purpose**

1. The purpose of this Memorandum of Cooperation (hereinafter referred to as “this MOC”) is to establish and facilitate a constructive regulatory dialogue in the areas of medical products.
2. This MOC is not intended to create any legally binding obligations between the Participants under national or international law.

**2. Areas of Cooperation**

1. The Participants will promote the exchange of information and cooperation in the areas of medical products and the relevant administrative and regulatory matters within the jurisdiction of the Participants;

2. The Participants will encourage cooperation in the following areas:
  - a. Pharmaceutical products;
  - b. Biological products; and
  - c. Traditional medicines;
3. The Participants will also encourage to conduct cooperation in the fields of:
  - a. Scientific collaboration;
  - b. Personnel trainings; and
  - c. Cooperation in multilateral fora.
4. Any other areas of cooperation mutually decided upon subsequently by the Participants in writing.

### **3. Means of Cooperation**

1. The Participants will hold an annual meeting, in principle, to discuss major topics related to the areas of cooperation.
2. The annual meetings will be held in Japan or in the Republic of Indonesia in-person basis, or other mechanisms including virtual way as mutually decided upon by the Participants.
3. English will be used as a common language for the annual meetings.

### **4. Working Group**

1. A Working group (hereinafter referred to as “the WG”) will be established at the annual meeting based on the Participants’ mutual interests.
2. The WG will be committed to developing and implementing activities based on its to-be-developed and decided work plan.
3. The WG may consider the holding of related meetings, symposia and training workshops in association with the annual meeting, based on the Participants’ mutual decisions.
4. The Participants may jointly decide to invite representatives from the relevant industries and academia to participate in the WG, depending on the agenda of the annual meeting.

## **5. Minutes**

The minutes of the annual meetings will be drawn up in English by the Participants after each meeting.

## **6. Contact Points**

The Participants will designate the following respective contact points for the implementation of this MOC:

- a. For MHLW: Director, Office of International Regulatory Affairs
- b. For Indonesian FDA: Head, Bureau of Cooperation and Public Relations

## **7. Financial Matters**

1. Each Participant will bear its own costs in relation to the implementation of the cooperative activities under this MOC.
2. When deemed necessary and by mutual consent, the Participants may invite funds from any third party to support the activities under this MOC.

## **8. Resolution of Differences**

Any differences arising from the interpretation and/or implementation of this MOC will be resolved amicably through consultations between the Participants including through diplomatic channels.

## **9. Confidentiality of Information**

The Participants will use the information and documents exchanged between them only within the scope of the decided purposes; and each Participant will not disclose any exchanged information to a third party without the written consent of the Participant which is the source of it.

## 10. Commencement, Modification and Termination

1. The cooperation under this MOC will commence on the later date of its signature and will continue for a period of five (5) years.
2. This MOC will be automatically renewed for another successive period of five (5) years, unless a written notice is given by either Participant of its intention to terminate this MOC to the other Participant at least ninety (90) days before the intended date of termination.
3. This MOC may be modified with the mutual written consent of the Participants and will be an integral part of this MOC.
4. The termination of this MOC will not affect the validity or implementation of on-going cooperation, project or other activities which have been confirmed upon before the date of the termination of this MOC, unless the Participants decide otherwise.

SIGNED in duplicate in Tokyo and Jakarta on August 27, 2021, in Japanese, Indonesian, and English languages, all texts having equal value. In case of any divergence of interpretation of the texts, the English text will prevail.

For  
The Ministry of Health, Labour and  
Welfare of Japan,

For  
The Indonesian Food and Drug  
Authority of the Republic of Indonesia,

**KAMATA Mitsuaki**  
Director General  
Pharmaceutical Safety and  
Environmental Health Bureau  
Ministry of Health, Labour and Welfare

**Dr. Penny K. Lukito, MCP**  
Chairperson  
The Indonesian Food and Drug  
Authority