MEMORANDUM OF COOPERATION
BETWEEN
THE DEPARTMENT OF HEALTH AND THE FOOD AND DRUG ADMINISTRATION
OF THE REPUBLIC OF THE PHILIPPINES
AND
THE MINISTRY OF HEALTH, LABOUR AND WELFARE AND THE PHARMACEUTICALS AND MEDICAL DEVICES AGENCY
OF JAPAN
ON
MEDICAL PRODUCTS REGULATION DIALOGUE AND COOPERATION FRAMEWORK

The Food and Drug Administration (FDA) under the Department of Health (DOH) of the Republic of the Philippines and the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, hereinafter referred to collectively as "Participants" and individually as "Participant",

INTENDING to promote mutually 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 within the jurisdiction of each Participant:
   a. Pharmaceutical products;
   b. Biological products; and
   c. Medical devices.

3. The Participants will also encourage 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 regular meetings to discuss major topics related to the areas of cooperation.

2. The meetings will be held in the Philippines or in Japan in-person, or other mechanisms, including virtual means, as mutually decided upon by the Participants.

3. English will be used as a common language for the meetings.

4. Working Group

1. A Working Group (hereinafter referred to as "the WG") will be established in the meetings 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 other related meetings, symposia and training workshops in association with the meetings, 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 meeting.

5. Minutes

Minutes of the meetings will be prepared in English and approved 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 FDA: Director-General, FDA
B. For MHLW and PMDA: Office Director, Office of International Regulatory Affairs, General Affairs Division, Pharmaceutical Safety Bureau, MHLW and Office Director, Office of Asia Training Center and International Cooperation, PMDA

7. Financial Arrangements

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 secure funds from third parties to support the activities under this MOC.

8. Resolution of Differences

1. Any differences arising from the interpretation and/or implementation of this MOC will be resolved amicably by consultations between the Participants.

2. Should both Participants be unable to settle an issue, such inability may be considered as a ground for the discontinuation of this MOC by either of the Participants.

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 other Participant.

This Paragraph will remain in operation, notwithstanding the discontinuation of this MOC.

10. Commencement, Modification and Discontinuation

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 discontinue this MOC to the other Participant at least ninety (90) days before the intended date of discontinuation.
3. This MOC may be modified with the mutual written consent of the Participants. Such modification will commence in line with 10(1) and will be an integral part of this MOC
4. The discontinuation of this MOC will not affect the implementation of on-going cooperation, project or other activities which have been confirmed upon before the date of the discontinuation of this MOC, unless the Participants decide otherwise.

SIGNED in duplicate in Tokyo on 24 April 2025 in English and Japanese languages, all texts having equal value. In case of any divergence of interpretation of the texts, the English text will prevail.

For FDA,

SAMUEL A. ZACATE, MD

Director General
Food and Drug Administration

For MHLW and PMDA,

JO KATSUFUMI

Director General
Pharmaceutical Safety Bureau
Ministry of Health, Labour and Welfare

FUJIWARA YASUHIRO, MD, PhD

Chief Executive
Pharmaceuticals and Medical Devices Agency