

**MEMORANDUM OF COOPERATION
BETWEEN
THE MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN
AND
THE FOOD AND DRUG ADMINISTRATION
OF MINISTRY OF PUBLIC HEALTH
OF THE KINGDOM OF THAILAND
ON MEDICAL PRODUCTS REGULATION DIALOGUE AND
COOPERATION FRAMEWORK**

The Ministry of Health, Labour and Welfare of Japan (MHLW) and the Food and Drug Administration (Thai FDA) of Ministry of Public Health of the Kingdom of Thailand, (hereinafter referred to collectively as the “Participants” and individually as “Participant”),

INTENDING to establish a Regulatory Dialogue and Cooperation Framework in regard to medical products such as pharmaceuticals, medical devices, and cosmetic products in accordance with the applicable laws and regulations of the Participants (hereinafter referred to as the “Framework”); and

DESIRING to 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,

Have reached the following recognition:

1. Purpose

1. The purpose of this Memorandum of Cooperation (hereinafter referred to as the “MOC”) is to facilitate a constructive regulatory dialogue on the laws and regulations in the areas of medical products, as well as other relevant matters. The Participants, furthermore, will contribute to strengthening the relationship and promoting the cooperation between them in the areas of medical products in line with their international responsibilities.
2. This MOC is not intended to create any legally binding obligations between the

Participants under national or international law.

2. Means of Cooperation

1. The Participants will hold an annual meeting, in principle, to discuss major topics related to the laws and regulations pertinent to medical products in Japan and the Kingdom of Thailand, and to consider possible cooperation aimed at sharing the best practices and regulatory updates on medical products of the Participants with a view to harmonize regulations in the area of common interest to the extent feasible.
2. The annual meetings will be held in the Kingdom of Thailand, unless otherwise jointly decided by the Participants.
3. English will be used as a common language for the annual meetings.

3. Working Group

A working group (hereinafter referred to as the “WG”) may be established at the annual meeting based on the Participants’ mutual interests. The WG will be committed to developing and implementing activities based on its to-be-developed and decided work plan. 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. 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.

4. Contact Points

The Participants hereby designate the following contact points in order to communicate with each other and exchange information on the Framework:

- a. For the Japanese side:

The Office of International Regulatory Affairs, General Affairs Division, Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labour and Welfare of Japan;

b. For the Thailand side:

The Office of International Affairs, Technical and Planning Division, Food and Drug Administration of the Ministry of Public Health of the Kingdom of Thailand.

5. Minutes

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

6. Financial Matters

Each Participant will bear its own costs in relation to the implementation of the cooperative activities under this MOC.

7. Resolution of Differences

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

8. Commencement, Modification and Termination

1. This MOC will commence on the date of its signature and will continue for a period of five (5) years. It will be automatically renewed for successive periods of five (5) years, unless 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 termination.

2. This MOC may be modified with the mutual written consent of the Participants.

Signed in duplicate as a non-legal binding document in Tokyo, Japan, on April 9th, 2018, in Japanese, Thai and English, all text having equal value. In case of any divergence of interpretation, the English text will prevail.

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

For and on behalf of The Food and
Drug Administration of the Ministry of
Public Health of the Kingdom of
Thailand

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

Wanchai Sattayawuthipong
Secretary-General
Food and Drug Administration,
Ministry of Public Health