MEMORANDUM OF COOPERATION

between

the Ministry of Food and Drug Safety of the Republic of Korea

and

the Ministry of Health, Labour and Welfare of Japan

on

Medical Products Regulatory Dialogue and Cooperation Framework

The Ministry of Food and Drug Safety of the Republic of Korea (MFDS) and the Ministry of Health, Labour and Welfare of Japan (MHLW) (hereinafter referred to collectively as the " Sides" and individually as "Side"),

INTENDING to establish the Regulatory Dialogue and Cooperation Framework in regards to medical products, including pharmaceuticals, raw materials for pharmaceutical use, biological products, regenerative medicine products, medical devices, quasi-drugs and cosmetic products (hereinafter referred to as the "Framework"); and

DESIRING to promote the exchange of information and cooperation in areas pertinent to medical products and the relevant administrative and regulatory matters within the jurisdiction of the Sides:

Have reached the following recognition:

Paragraph 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 pertinent to medical products, as well as other relevant matters. The Sides, furthermore, will contribute to strengthening the relationship between the Republic of Korea and Japan in the areas of medical products in line with their international responsibilities.

2. This MOC is not intended to create any legally binding obligations under national or international law.

Paragraph 2 - Means of Cooperation

1. The Sides will hold an annual meeting, to discuss major topics related to the laws and regulations pertinent to medical products in the Republic of Korea and Japan, and to consider possible cooperation aimed at the harmonization of regulations in areas of common interest.

2. The annual meetings will be held alternately in the Republic of Korea and Japan, unless otherwise jointly decided by the Sides.

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

Paragraph 3 - Working Group

A working group (hereinafter referred to as the "WG") may be established at the annual meeting based on the Sides' mutual interests. The WG will be committed to developing and implementing activities based on its work plan. The WG may consider the holding of related meetings, symposia and training workshops in association with the annual meeting. The Sides 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.

Paragraph 4 - Contact Points

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

a. For the Korean Side:

the International Cooperation Office of the Ministry of Food and Drug Safety of the Republic of Korea.

b. For the Japanese Side:

the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare of Japan;

Paragraph 5 - Minutes

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

Paragraph 6 - Financial Arrangements

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

Paragraph 7 - Resolution of Differences

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

Paragraph 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 Side to the other Side of its intention to terminate this MOC ninety (90) days before the current expiration date.

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

Signed in duplicate in Osong, Republic of Korea, on August 17, 2015, in Korean, Japanese and English, each text being equally valid. In case of any divergence of interpretation, the English text will prevail.

For and on behalf of the Ministry of Food and Drug Safety of the Republic of Korea	For and on behalf of the Ministry of Health, Labour and Welfare of Japan
K. S. Kim.	神田裕二
Director General Pharmaceutical Safety Bureau Ministry of Food and Drug Safety	Director General Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare