Memorandum of Understanding between the Ministry of Food and Drug Safety of the Republic of Korea and the Health Sciences Authority of the Republic of Singapore on Good Manufacturing Practice for Pharmaceutical Products

The Ministry of Food and Drug Safety ("MFDS") of the Republic of Korea and the Health Science Authority ("HSA") of the Republic of Singapore (hereinafter collectively referred to as the "Sides" and individually referred to as the "Side"),

Considering the Memorandum of Understanding of 5 June 2010 between the Korea Food and Drug Administration of the Republic of Korea and the Health Sciences Authority of the Republic of Singapore regarding the Safety of Pharmaceutical Products, Cosmetics and Medical Devices;

Recognizing the importance of ensuring the quality and safety of pharmaceuticals, including investigational medicinal products, drug substances, biopharmaceuticals and herbal medicinal products which are used for the human body (hereinafter collectively referred to as "pharmaceuticals"), in order to protect and promote the health of their respective peoples;

Desiring to set up a framework for long-term cooperation to work toward a mutual recognition agreement (MRA) between the two countries on Good Manufacturing Practice (GMP) inspections of pharmaceutical products under the framework of the Korea-Singapore Free Trade Agreement, and to facilitate the exchange of information, experiences and visits in the field of pharmaceutical GMP inspections, on the basis of the principles of equality, reciprocity and mutual benefit;

Have reached the following understanding:

1. Objective

The Sides hereby confirm their intention to promote cooperation in the area of pharmaceutical GMP in accordance with this Memorandum of Understanding (hereinafter referred to as "MoU").

2. Scope of Cooperation

The Sides will promote mutual cooperation in the following areas:

(a) exchanging information on the relevant laws, regulations, standards, and administrative procedures regarding pharmaceutical GMP;

(b) sharing knowledge and experiences of pharmaceutical GMP in order to further explore the possibility of an MRA on GMP inspections for pharmaceutical products under the framework of the Korea-Singapore Free Trade Agreement;

(c) holding joint symposiums, workshops and conferences;

(d) exchanging information on pharmaceutical GMP manufacturing sites and pharmaceutical GMP inspection plans; and

(e) providing information on defects or recalls of pharmaceuticals which have been manufactured or distributed in the territory of one Side, at the request of the other Side and to the extent possible;

3. Confidentiality

Neither Side may disclose or distribute any confidential information received or generated under this MoU to any third party or to the public without prior written consent of the other Side.

4. Financial Arrangements

1) Each Side is responsible for the administration and expenditure of its own resources associated with the activities under this MoU.

2) The costs of any assistance provided by either Side at the request of the other Side will be borne by the requesting Side, unless otherwise jointly decided by the Sides.

5. Working Level Consultations

The Sides will establish a working-level consultation committee to discuss priority areas of interest and the cooperative activities under this MoU.

6. Contact Points

1) The Sides hereby designate the following contact points for ongoing communication to efficiently implement this MoU:
   (a) for the MFDS: Director of the Pharmaceutical Quality Division; and
   (b) for the HSA: Division Director of the Audit and Licensing Division.
2) Each Side will inform the other Side in advance in the case of any change in its designated contact point.

7. Implementation

1) This MoU will be carried out within the framework of the respective laws, regulations, institutional guidelines and any other applicable legal provisions of each Side.
2) This MoU is not intended to create any legally binding obligations for the Sides under national or international laws.

8. Resolution of Differences

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

9. Entry into Effect, Termination and Amendment

1) This MoU will come into effect on the date of its signature by the Sides. It will

remain effective for a period of five (5) years and may be automatically renewed for successive periods of five (5) years.

2) Either Side may notify the other Side in writing of its intention to terminate this MoU at least six (6) months in advance of the date of termination.
3) The termination of this MoU will not affect the duration or validity of any cooperative activities under this MoU which are in progress at the time of the notification of the termination of this MoU.
4) This MoU may be amended by mutual written consent of the Sides.

Signed in duplicate at Seoul, Republic of Korea, on 23rd November 2019 in the Korean and English languages, each text being equally valid. In case of any divergence of interpretation, the English text will prevail.

For the Ministry of Food and Drug Safety of the Republic of Korea	**For the Health Sciences Authority of the Republic of Singapore**
Dr. Lee, Eui Kyung	**Dr. Choong May Ling, Mimi**
Minister	**Chief Executive Officer**