Memorandum of Understanding between the Ministry of Food and Drug Safety of the Republic of Korea and the National Medical Products Administration of the People's Republic of China on Regulatory Cooperation of Medicines, Medical Devices and Cosmetics

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the National Medical Products Administration (NMPA) of the People's Republic of China (hereinafter referred to as "the Parties"), desiring to further enhance the close exchanges and cooperation in the field of regulation on medicines, medical devices and cosmetics, through amicable negotiation, have set out the following understandings which they have jointly agreed:

Article Ⅰ Purpose

The purpose of this MOU is to establish a mechanism of cooperation under which the Parties, in accordance with their respective laws and regulations and on the basis of equality and reciprocity, facilitate the exchange and cooperation in the field of regulation on medicines, medical devices and cosmetics between the two nations.

Article Ⅱ Areas of Cooperation

This MOU represents the understandings reached by the Parties. The main areas which the Parties have agreed to co-operate on are set out below. These areas are not exhaustive and are not intended to exclude other areas from cooperation.

i. Exchange of information on laws and regulations regarding medicines, medical devices and cosmetics.

ii. To promote an understanding between the Parties of each other's regulatory framework, requirements and processes; and to facilitate future regulatory cooperation for both Parties.

iii. Exchange of safety information, including pharmacovigilance and adverse events where there is a particular safety concern related to the other Party. This includes safety concerns relating to medicines, medical devices and cosmetics.

iv. Exchange of information on the review and approval of medicines, medical devices and cosmetics.

v. Collaboration on detection of and enforcement of counterfeit, falsified and substandard medicines, medical devices and cosmetics.

vi. Collaboration on training in the field of regulation on medicines, medical devices and cosmetics.

vii. Other areas agreed by the Parties.

Article Ⅲ Activities

Under the framework of this MOU, the Parties may arrange senior official meetings, exchange of visits at DG level and working level, training of staffs, information sharing, joint working groups and other specific activities.

Article Ⅳ Expenditure

The Parties will bear their own costs for activities under this MOU. The costs of any assistance provided by one Party at the request of the other Party will be borne by the requesting Party, unless otherwise jointly decided by the Parties.

Article Ⅴ Confidentiality

Any proprietary information shared by the Parties, under this MOU shall, in so far as it is possible in accordance with their respective national laws, be treated as confidential. Where information is required to be shared under national legislation, the Party concerned will give

notice to the other Party and take all reasonable measures possible to it to protect the information from disclosure.

Article Ⅵ Contact Points

The Parties hereby designate the following contact points for the ongoing communication between the Parties to efficiently implement this MOU:

- for MFDS: Director of International Cooperation
- for NMPA: Division Director of bilateral cooperation

Article Ⅶ Amendments

Any change to this MOU shall be made by mutual written consent of the Parties.

Article Ⅷ Disputes

Any dispute between the Parties concerning the implementation and interpretation of this MOU shall be settled amicably through bilateral consultations and negotiations.

Article IX Status

This MOU is not a legally binding obligation.

This MOU is not considered as an international treaty and does not establish any right or obligation regulated by international law.

Article Ⅹ Supplementary Provisions

This MOU will come into effect on the date of its signature and will remain in force for a period of five years unless terminated earlier by either Party with six months prior notice to

the other Party. The termination of the 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.

SIGNED in Beijing, on the 26th of February 2019, with two original copies in the Korean, Chinese and English languages, each text being equally authentic. In case of a dispute, the English version will prevail.

For Ministry of Food and Drug Safety of the Republic of Korea	For National Medical Products Administration of the People's Republic of China
Minister RYU Youngjin	Commissioner JIAO Hong