Memorandum of Confidentiality on Information Exchange Between the Ministry of Food and Drug Safety of the Republic of Korea and the Council of Europe, European Directorate for the Quality of Medicines and HealthCare

The Ministry of Food and Drug Safety (MFDS)[1] of the Republic of Korea and the Council of Europe, European Directorate for the Quality of Medicines and HealthCare (EDQM), hereinafter jointly referred to as "the Sides",

Sharing the common goal of protecting public health and safety by ensuring the quality and safety of substances for pharmaceutical use, i.e. active pharmaceutical ingredients (API) and excipients that are used in the production or preparation of medicinal products.

Desiring to co-operate to facilitate the sharing of information related to the quality and manufacture of substances for pharmaceutical use and, in particular, APIs of common interest, including non-public and proprietary information,

Have reached the following understanding:

1. The information to be shared by EDQM includes:

(a) information on actions taken regarding Certificates of suitability to the monographs of the European Pharmacopoeia (CEPs), or applications for CEPs in the context of the EDQM inspection programme;

(b) information on actions taken regarding CEPs, or applications for CEPs, as a consequence of a failure from the holder or intended holder to meet the requirements of the certification procedure;

(c) upon request from MFDS, information on inspections of manufacturers of pharmaceutical substances carried out by EDQM (typically inspections reports);

(d) upon request from MFDS, to help the assessment of licensing applications referring to a CEP, and subject to the prior agreement of the holder of the CEP, evaluation reports for CEP applications; and

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[1] It means 6 regional offices and National Institute of Food and Drug Safety Evaluation (NIFDSE) under MFDS.

(e) upon request from MFDS, information on technical guidance.

2. The information to be shared by MFDS includes:

(a) information on actions taken regarding Drug Master Files (DMFs), or applications for DMFs;

(b) upon request from EDQM, information on inspections of manufacturers of pharmaceutical substances carried out by MFDS in the Republic of Korea or elsewhere; typically information on the outcomes of inspections or inspection reports; and

(c) upon request from EDQM, information on technical guidance or changes in regulations.

3. Both Sides will consider collaboration for training or the exchange of staff between the two institutes related to the review of the quality of substances for pharmaceutical use.

4. Both Sides understand that some of the information they receive from each other may include non-public information exempt from public disclosure under the applicable laws and regulations, including each side's internal rules, such as confidential commercial information, trade secret information, private personal information, law enforcement information and/or information on their internal operations. Both Sides understand that this non-public information is shared in confidence, and that it is critical that the confidentiality of the information is maintained.

5. Both Sides will inform each other of the non-public status of information at the time the information is shared. They will ensure confidentiality in accordance with the applicable laws and regulations, including their own internal rules.

6. Both Sides understand that this Memorandum of Confidentiality (MOC):

(a) does not affect the authority of the Sides to carry out their regulatory responsibilities;

(b) does not create any obligation to share any private and/or secret personal data, including economic position of an individual, or any other information;

(c) does not require either Side to provide information to the other Party.

7. This MOC is not intended to give rise to any binding legal obligations under national or international law.

8. This MOC will be carried out in accordance with the respective laws and regulations by which the two Sides are bound and subject to the availability of appropriated funds and personnel of both Sides.

9. Any disputes or differences with respect to the interpretation or implementation of this MOC will be resolved amicably through good faith consultations between the Sides.

10. This MOC will come into effect on the date of its signature by both Sides. Either Side may terminate this MOC at any time by giving a three-month written notice to the other Side.

11. This MOC may be amended with the mutual written consent of the Sides.

Signed in duplicate at Strasbourg, France on Dec. 19, 2019, in the English language.

For the Ministry of Food and Drug Safety of the Republic of Korea	For the Council of Europe, European Directorate for the Quality of Medicines and HealthCare
Dr. Lee, Eui Kyung Minister	Dr. S. Keitel Director