

**Memorandum on Confidentiality of Information Exchange  
Between  
The Ministry of Food and Drug Safety of the Republic of Korea  
And  
The National Agency of Medicines and Health Products Safety  
of the French Republic**

The Ministry of Food and Drug Safety of the Republic of Korea and the National Agency of Medicines and Health Products Safety of the French Republic (hereinafter jointly referred to as the “Sides”),

CONSIDERING the necessity of strengthening their cooperation on information exchange to successfully achieve their respective missions;

INTENDING to establish a framework for the exchange of information between the Sides in the field of medicine, including raw materials for pharmaceutical use, biological products, medical devices and cosmetic products, in order to promote such exchanges;

DESIRING to strengthen communication between the Sides in order to protect and enhance public health and the safety of the people in their respective countries by advancing their respective expertise; and

DESIRING to facilitate and increase access to safe, effective and high quality medicine products, and to contribute to improving quality and safety in terms of control, with the help of leading experts from both countries in that field;

Have reached the following understanding:

**Paragraph 1: General principle**

1. This Memorandum of Confidentiality (“hereinafter referred to as the “Memorandum”) applies to information exchange to the extent jointly determined by the Sides. Within the framework of this Memorandum, the collaboration covers all products regulated by the Sides and their relevant activities. The Sides acknowledge that each Side has jurisdiction over specific products, for which they may have different definitions

2. This Memorandum is not intended to create any legally binding obligations to share confidential information between the Sides. This Memorandum does not restrict the Sides' powers granted by the laws and regulations in their respective countries to fulfill their respective responsibilities.
3. This Memorandum will be carried out in accordance with the respective laws and regulations of the two countries and subject to the availability of appropriated funds and personnel of the Sides.
4. Nothing in this Memorandum will be interpreted as conferring upon the receiving Side any rights to the information transmitted by the providing Side, whether that information is confidential or not.

#### **Paragraph 2: Information exchange**

1. When information is exchanged under this Memorandum, it is understood that the Sides, as well as their respective staff, advisory committee members and, when appropriate, external experts or organizations appointed by them, may have access to information that may be considered confidential.
2. The commitment to protect the confidentiality of information exchanged under this Memorandum will not prevent the Sides from using that information to carry out the tasks entrusted to them provided that such confidentiality is protected.
3. The Sides may use information exchanged under this Memorandum to ground their health policy decisions.
4. Working-level consultation meetings may be held when necessary, to discuss specific details of information exchanged through mutual consent of the Sides, except in a case that the Sides decide differently through mutual consent. It could be face to face meetings during international conference or held by video or tele-conference.

#### **Paragraph 3: Definition of confidential information**

1. For the purpose of this Memorandum, the term "confidential information" means:
  - a) information submitted and identified as confidential by the providing Side; or

- b) trade secret information; or
  - c) commercial and financial information; or
  - d) information protected by Korean or French laws and regulations in general.
2. Information relating to personal privacy of an individual or the secrecy of personal files such as medical files is strictly confidential and is excluded from any exchange between the Sides.

#### **Paragraph 4: Respect for information confidentiality**

1. The Sides understand that the information exchanged under this Memorandum may include information that is non-public in the country of the providing Side. The Sides will inform each other of the confidential nature of information when such information is exchanged. Within the framework of this Memorandum, each Side commits to protect the confidentiality of all confidential information received from the other Side and not to disclose that information to any third party.
2. The Sides confirm that they have the authority to protect the confidential information received during the implementation of this Memorandum.
3. Each Side will take all necessary measures to inform the other of any effort made by a governmental authority, judicial, legal or other authority, to obtain confidential information provided by one Side to the other.
4. If public disclosure of confidential information is required under the laws and regulations of its country, the receiving Side may decide whether or not such information will be disclosed through consultation with the providing Side. If such information is disclosed, the receiving Side will take all appropriate legal measures to ensure that the information is disclosed in a manner that protects the information from subsequent unauthorized disclosure.
5. The Sides will take all necessary measures to inform each other of any changes to the laws, policies or procedures in their respective countries that would affect the processing of confidential information received from the other Side.

#### **Paragraph 5: Persons or institutions to which confidential information may be transmitted**

1. Provided that the provisions of Paragraphs 6 and 7 of this Memorandum are complied with, information provided by one Side to the other may be transmitted to the staff and the advisory committee members of the receiving Side, or to experts or external institutions appointed by the receiving Side.
2. Disclosure of confidential information will be strictly limited to the persons or institutions mentioned in subparagraph 1 who need to be aware of the confidential information directly for work purposes, to issue advice, to strengthen their expertise or to work on the issue that prompted the request for the disclosure of confidential information.
3. Any other use of confidential information is not permitted.

**Paragraph 6: Respect for information confidentiality by the Sides and their employees**

1. The Sides will ensure that confidential information exchanged under this Memorandum will not be disclosed, circulated or commented upon in any way by their employees.
2. The Sides will ensure that their employees exercise professional discretion and observe their duty of confidentiality.

**Paragraph 7: Respect for confidentiality by experts, external organizations and their staff**

The Sides will take all necessary measures to prevent the disclosure or use of confidential information by advisory committee members, experts or external organizations and their staff who have been appointed by the receiving Side for the purpose of achieving its mission and who have had access to confidential information transmitted within the framework of this Memorandum.

**Paragraph 8: Limits on confidentiality and restricted use**

The principles of confidentiality and restricted use mentioned above do not apply to information for which the receiving Side can clearly indicate and provide concrete evidence to the providing Side that:

- a) the information was legally in its possession and was already known (without any confidentiality commitment) prior to the disclosure by the providing Side (as verified by written reports or other acceptable evidence); or
- b) the information was already in the public domain or publicly known at the time of the disclosure by the providing Side; or
- c) the information came into the public domain or was brought to public attention in the absence of any fault of the receiving Side; or
- d) the information was made available to the receiving Side by a third party without breach of any legal confidentiality commitment; or
- e) the information is the result of activities carried out independently by or on behalf of the receiving Side without having access to the information of the providing Side.

**Paragraph 9: Duration of confidentiality commitment**

1. The confidentiality commitment in relation to confidential information transmitted within the framework of this Memorandum is not limited in time.
2. Notwithstanding the termination of this Memorandum, the Sides will continue to protect confidential information against unauthorized disclosure or unauthorized use.

**Paragraph 10: Discretion on non-confidential information**

The Sides will protect all information received within the framework of this Memorandum, which is not considered confidential information but is not in the public domain, from any unauthorized public disclosure. Such information will not be published in any form, including on the internet.

**Paragraph 11: Information enquiries**

The Sides will send their information enquiries to the following representatives:

- a) For the Korean Side, Director of International Cooperation Office
- b) For the French Side, the designated person in charge of the relationship with the Korean counterpart

**Paragraph 12: Resolution of differences**

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

**Paragraph 13: Amendment**

Any amendment to this Memorandum will be made by mutual written consent of the Sides.

**Paragraph 14: Entry into effect**

This Memorandum will become effective on the date of the signature by both Sides.

**Paragraph 15: Termination**

1. This Memorandum may be terminated at any time, by either Side, upon two (2) months' notice by recorded delivery with acknowledgment of receipt.
2. This Memorandum will terminate automatically and immediately in the event of new laws and regulations affecting its implementation or making it incompatible with the status of the respective Sides. Any such termination will be immediately notified to the other Side.

Signed in duplicate at Paris on 20 December 2019, in the Korean, French and English languages, all texts being equally valid. In case of any divergence of interpretation, the English text will prevail.

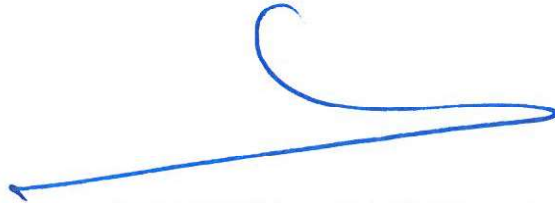
FOR THE MINISTRY OF FOOD  
AND DRUG SAFETY OF THE  
REPUBLIC OF KOREA



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Lee, Eui Kyung  
Minister

FOR THE NATIONAL AGENCY OF  
MEDICINES AND HEALTH  
PRODUCTS SAFETY OF THE  
FRENCH REPUBLIC



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Dominique Martin  
Director General