



식품의약품안전처
Ministry of Food and Drug Safety



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Memorandum of Confidentiality on Information Exchange
between
the Ministry of Food and Drug Safety
of the Republic of Korea
and
the Danish Medicines Agency of
the Kingdom of Denmark

The Ministry of Food and Drug Safety (hereinafter referred as to the “MFDS”) of the Republic of Korea and the Danish Medicines Agency (hereinafter referred as to the “DKMA”) of the Kingdom of Denmark (hereinafter jointly referred to as the “Sides”),

CONSIDERING the necessity of strengthening their cooperation on the exchange of information and expertise 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 biological products, raw materials for pharmaceutical use and medical devices, 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 medicinal 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 and, where practical for undertaking collaborative activities, personnel exchange to the extent jointly decided 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. 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 disclosing Side, whether that information is confidential or not.
5. If necessary, other forms of cooperation in the field of medicine may be discussed and jointly decided upon by the Sides.

Paragraph 2: Information exchange

1. When information is exchanged under this Memorandum, it is understood that the Sides, as well as their respective staffs, 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. The Sides may carry out cooperative activities under this Memorandum on a regular basis, after mutual consultations and in accordance with the requirements of the Sides.
5. The information to be shared upon request from either Side may include the following. These areas are examples, not exhaustive and are not intended to exclude other areas from information sharing:
 - a) the information on laws and regulations regarding medicines and medical devices;
 - b) the information on safety, including pharmacovigilance and adverse events regarding medicines and medical devices;
 - c) the information on review and approval of medicines and medical devices;
 - d) the information on regulations of clinical trials;
 - e) the information on inspections of manufacturers of medicines and medical devices;
 - f) the information on quality test, including specification and test methods, test result of medicines and medical devices; and
 - g) any other information that may be jointly decided upon by the Sides.

Paragraph 3: Definition of confidential information

For the purpose of this Memorandum, the term “confidential information” means information submitted and listed as confidential by the disclosing Side, information relating to medical files and, in general, information protected by Korean or Danish laws and regulations.

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 disclosing 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 an authority, judicial, legal or other entity, 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 the receiving Side, the receiving Side may decide whether such information will be disclosed or not through consultation with the disclosing 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 staffs 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 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 disclosure of confidential information.
3. Any other use of confidential information is not allowed.

Paragraph 6: Respect for information confidentiality by the Sides

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 information confidentiality by experts, external organizations

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 staffs 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 disclosing Side that:

- a) the information was legally in its possession and was already known (without any confidentiality commitment) prior to the disclosure by the disclosing Side (as verified by written reports or other acceptable evidence);
- b) the information was already in the public domain or publicly known at the time of the disclosure by the disclosing Side;
- c) the information came into the public domain or was brought to public attention in the absence of any fault of the receiving Side;
- 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 disclosing 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: Points of contact

The Sides appoint the following point of contact for information enquiries and exchange under this Memorandum.

- a) For the MFDS: intmfds@korea.kr
- b) For the DKMA: ls@dkma.dk

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: Funding

Each Side will bear its own costs arising from the activities under this Memorandum, unless otherwise jointly decided in advance by the Sides.

Paragraph 14: Amendment

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

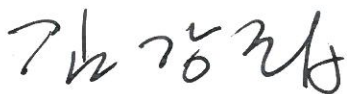
Paragraph 15: Entry into effect and termination

1. This Memorandum will become effective on the date of the signature by both Sides and will remain in effect until terminated.
2. This Memorandum may be terminated at any time, by either Side, upon six (6) months' notice by recorded delivery with acknowledgment of receipt.

3. In the event of new laws and regulations affecting the implementation of this Memorandum or making it incompatible with the status of the respective Sides, the other Side will be given a notice of termination by recorded delivery three (3) months prior to termination.

SIGNED in duplicate at Seoul on 13 November, 2020 in the English language.

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



Kim Ganglip
Minister

**For the Danish Medicines Agency of
the Kingdom of Denmark**



Thomas Senderovitz
Director General