



**MINISTRY OF
FOOD AND DRUG SAFETY**



Agenzia Italiana del Farmaco
AIFA

**Confidentiality Arrangement
Between
The Ministry of Food and Drug Safety of the Republic of Korea
and
The Italian Medicines Agency of the Republic of Italy**

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Italian Medicines Agency (AIFA) of the Republic of Italy (hereinafter referred to as the "Participants");

Being the respective authorities involved with and responsible for the regulation of therapeutic products in the two countries;

Desiring to enhance their relationship through increased cooperation in respect of the sharing of information;

Recognizing that each Participant has jurisdiction over specific products and defines those products differently;

Intending to cover all products regulated by, and common to the Participants and to encourage meaningful collaboration between the participants; and

Intending to include an expansion of scope by either Participant in the future;

Have reached the following arrangement:

Paragraph 1. Purpose

1. The purpose of this Arrangement is to facilitate increased access to safe, effective and high quality products in the two countries, and to share information related to these products. Consequently, the cooperation under this Arrangement is intended to provide improved regulatory performance and safety as a result of the involvement of the best regulatory expertise from the two Participants. This Arrangement is also intended to strengthen communication between the Participants and to enhance their ability to protect and promote the health and safety of the populations of their respective countries in carrying out their respective mandates.
2. This Arrangement is not intended to compromise the regulatory authority of either Participant to carry out its respective regulatory responsibilities and programs, nor is it intended to create any legally binding obligations on either Participant or to impose any obligation to share information with the other Participant.

Paragraph 2. Confidentiality

1. Each Participant understands that information exchanged between them may include confidential information that is not in the public domain in the country of the Participant providing the information. The Participants note that it is essential

that confidential information provided by one Participant will be treated as such by the other Participant. Each Participant will make every reasonable effort to prevent:

- (a) the public release of confidential information that has been shared for the purposes set out in this Arrangement; and
- (b) any other release of such information for the purposes not set out in this Arrangement.

2. Each Participant will advise the other Participant of the public or confidential status of the information at the time that the information is shared. When documents are shared, the Participants will mark each document clearly with its public or confidential status.
3. Confidential information may be shared with or used by the other Participant, or shared with other parties, as set out in subparagraph (4) below, without the prior written consent of the individual or entity to whom the information relates so long as it is only for the purposes contemplated in this Arrangement, and provided that such disclosure or use is in accordance with the national laws, regulations and policies of each Participant as well as its practices and procedures permitted by those laws and regulations.
4. Information provided by one Participant to the other Participant may be shared with the receiving Participant's employees, agents or contractors who require the information solely for work related to the delivering of the mandate of the Participant, who will only use that information for the purposes contemplated by this Arrangement, and who have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, a confidentiality contract or another document that permits those persons to use the information for the purposes of this Arrangement and requires them to protect the confidentiality of the information in accordance with the national laws, regulations and policies

of the Participant who receives or provides the information.

5. The Participants will consult with each other on each occasion where there is a request for public disclosure, or disclosure to parties other than those set out in subparagraph (4) above, of confidential information received from the other Participant.
6. Each Participant will make all reasonable efforts to inform the other Participant of any effort made by a judicial, legislative or other authority to obtain confidential information that has been provided by one Participant to the other Participant. If public disclosure is required by such authorities, the other Participant will consult with the Participant which provided the information before disclosing any information.
7. Each Participant will make all reasonable efforts to inform the other Participant of any changes to its national laws, regulations and policies of each Participant or its procedures that may affect its treatment of confidential information obtained from the other Participant.
8. The Participants consider it crucial to the sustainability of this Arrangement and future cooperation that confidential information shared between the Participants' respective agencies or branches will be protected from unauthorized use and disclosure in accordance with their national laws, regulations and policies of each Participant.

Paragraph 3. Liaison Officers

Requests for information will be made to designated officers responsible for the administration of this Arrangement within their own agency or branch. Unless otherwise notified in writing by one Participant to the other Participant, the contact points for matters relating to this Arrangement are as follows:

(a) for MFDS, the International Cooperation Office Director; and

(b) for AIFA, the International Relations Office Director.

Paragraph 4. Resolution of Differences

Any differences arising from the interpretation or implementation of this Arrangement will be resolved through consultations between the Participants.

Paragraph 5. Entry into Effect, Termination and Amendment

1. This Arrangement will come into effect on the date of its signature by the last Participant. This Arrangement will continue in effect unless it is terminated by either Participant by giving thirty (30) days' prior written notice to the other Participant.
2. Notwithstanding the termination of this Arrangement, the Participants will continue to treat confidential information that has been shared under this Arrangement as such and to protect it from unauthorized disclosure and use in accordance with the national laws, regulations and policies of each Participant as well as its practices and procedures permitted by those laws and regulations.
3. This Arrangement may be amended with the mutual written consent of the Participants.

Signed in duplicate in Beijing, on the 19th day of November, 2014 in the Korean, Italian and English language. 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

Kim Jinseok
MFDS Director General

김진석

For the Italian Medicines Agency
of the Republic of Italy

Luca Pani
AIFA Director General

Luca Pani