

**Memorandum of Understanding between
the Ministry of Food and Drug Safety of the Republic of Korea
and**

**the Brazilian Health Surveillance Agency of the Federative Republic of Brazil
on Cooperation in the Field of Food, Medical Devices and Drugs**

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Brazilian Health Surveillance Agency (ANVISA) of the Federative Republic of Brazil (hereinafter referred to as the "Participants")

Desiring to encourage bilateral cooperation and facilitate the mutual exchange of information and expertise on matters pertaining to food, medical devices and drugs;

Intending to encourage exchanges and cooperation on the basis of the principles of equality, mutual benefit and reciprocity;

Have reached the following understanding:

Paragraph 1 – Forms of Cooperation

Cooperation between the Participants in the fields of food, medical devices and drugs may take the following forms:

- (a) exchange of information, including information on best practices;
- (b) exchange of visits of staff and experts from both Participants; and
- (c) any other forms of cooperation in the fields of food, medical devices and drugs that may be jointly decided upon by the Participants.

Paragraph 2 - Sharing of Information

The Participants consider that from time to time circumstances will arise where the sharing of information held by one Participant will assist the other Participant in carrying out its regulatory functions in relation to food or medical devices, or to ensure the safety, quality and efficacy of drugs for human use.

Information that may be shared between the Participants includes, but is not limited to:

- (a) post-authorization vigilance data held by one Participant which raises safety concerns about a product manufactured or distributed in the territory of the other Participant;
- (b) inspection reports done by one Participant which are of significant public health interest to the other Participant;
- (c) information on quality defects identified or product recalls made by one Participant in relation to drugs and medical devices which are distributed or have been manufactured in the territory of the other Participant; and
- (d) information contained in marketing authorization applications and applications to vary a marketing authorization received by one Participant which are of significant public health interest to the other Participant.

Paragraph 3- Confidentiality

The Participants acknowledge that the information exchanged under this Memorandum of Understanding (MOU) may be confidential and not in the public domain in the territory of the Participant that originated the information. At the moment of exchanging the information, the originating Participant will inform the receiving Participant of the confidentiality of such information. In this case each Participant understands that confidential information will be shared on a secure basis and in accordance with the applicable laws, policies and procedures of each country. Each Participant will make its best efforts to avoid:

- (a) public disclosure of confidential information that has been exchanged under MOU; and

(b) any other disclosure of information for purposes that are not established by this MOU.

Paragraph 4 - Implementation

1. Each Participant will bear its own costs arising from activities under this MOU.
2. Cooperative activities under this MOU are to be coordinated between the Participants on a regular basis, after mutual consultations and in accordance with the needs of each Participant.
3. Cooperative activities under this MOU will be subject to the availability of appropriated funds and other resources of the Participants, as well as to the applicable laws and regulations of each country.

Paragraph 5 - Single Point of Contact

Each Participant will designate a single point of contact (SPOC). The SPOC will serve as the principal coordinator for the sharing of information and cooperative activities between the Participants.

Paragraph 6 - Dispute Resolution

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

Paragraph 7 - Entry into Effect, Termination and Amendment

1. This MOU will come into effect upon its signature by both Participants, and will remain in effect until further notice. This MOU may be terminated, with six months' written notice, by either Participant.
 2. This MOU may be amended at any time by mutual written consent of the Participant.
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