Memorandum of Understanding
between
the Ministry of Food and Drug Safety of
the Republic of Korea
and
the National Directorate of Sanitary Surveillance of
the Republic of Paraguay on
Pharmaceuticals and Medical Devices Cooperation

The Ministry of Food and Drug Safety of the Republic of Korea (hereinafter referred to as the "MFDS") and the National Directorate of Sanitary Surveillance of the Republic of Paraguay (hereinafter referred to as the "DINAVISA") (hereinafter collectively referred to as "both Participants" or the "two Participants").

Desiring to strengthen a firm arrangement and cooperation in the field of pharmaceuticals and medical devices,

Have reached the following understanding:

Paragraph 1 Objective

The objective of this Memorandum of Understanding (hereinafter referred to as the "MoU") is to establish and solidify a cooperative system between both Participants according to the relevant legislations of both countries based upon the principles of equality and reciprocity and to enhance cooperation and exchange between both Participants in the field of pharmaceuticals and medical devices.

Paragraph 2 Areas of Cooperation

This MoU states what is mutually decided between the two Participants and in which both Participants mainly decide to cooperate. The areas of cooperation between two Participants will include, but not be limited to, the followings.

1) MFDS may provide training and consultancy to government officials of DINAVISA in the areas jointly decided by the two Participants (e.g. good manufacturing practice (GMP) according to international standards);
2) DINAVISA will make efforts to include the Republic of Korea in the list of countries with high sanitary surveillance stipulated in the Paraguayan healthcare law and to simplify the approval and registration process for Korean pharmaceuticals; and
3) DINAVISA will work on a resolution of Paraguay to include the Republic of Korea in the list of countries with high sanitary surveillance in order to simplify the registration process of medical devices.

Paragraph 3 Activities

Under this MoU, both Participants may arrange meetings between high-level officials, exchange of visits of director-level and working-level officials, staff training, information sharing and other activities.

Paragraph 4 Financing

Each Participants will bear its own costs necessary to implement the activities under this MoU, unless otherwise determined by both Participants.

Paragraph 5 Confidentiality

Either Participant will not disclose any information that has been provided by the other Participant in accordance with the applicable domestic laws and regulations of the two Participants. If either Participant is requested to share the information under its domestic laws, that Participant will notify it to the other Participant and take all reasonable measures to protect the information from the disclosure.

Paragraph 6 Agency Contact

For the purpose of effective implementation of this MoU, the two Participants will designate liaison officers responsible for the administration as follows for continuous communication between the two Participants:

- For the MFDS: International Cooperation Officer
- For the DINAVISA: Director of International and Inter-institutional Relations

Paragraph 7 Resolution of Differences

Any differences arising from the interpretation, application or implementation of this MoU will be resolved amicably through mutual consultations by the Participants.

Paragraph 8 Status of the MoU

1. This MoU will neither impede the regulatory power of each authority to implement its responsibilities, nor create any legally binding rights or

obligations between the two Participants under domestic or international law. Both Participants are subject to their respective domestic laws, policies and procedures.

2. This MoU will be implemented subject to the availability of the appropriated funds and personnel of the two Participants.
3. This MoU does not modify or terminate any other cooperative arrangements in effect at the time of signing this MoU nor it does preclude the conclusion of any special arrangement separate from this MoU in order to deal with specific activities more efficiently.

Paragraph 9 Entry into Effect, Amendment and Termination

1. This MoU will come into effect on the date of its signing by both Participants
2. This MoU will be effective for five (5) years and will be automatically renewed for successive five-year periods, unless either Participant notifies the other Participant at any time in writing of its intention to terminate this MoU six (6) months in advance of such termination. This MoU may be also terminated at any time upon mutual consent of the Participants.
3. This MoU may be amended at any time by mutual consent in writing between the Participants.
4. The termination of this MoU will not affect any ongoing arrangements or activities under this MoU, unless otherwise jointly decided by the both Participants.

Signed in two copies in the Korean, Spanish and English language on August 28, 2023 at Osong, the Republic of Korea and Asunción, the Republic of Paraguay and all texts being equally valid. In case of any discrepancy between interpretations, the English text shall always prevail.

For the Ministry of Food and Drug Safety of the Republic of Korea	**For the National Directorate of Sanitary Surveillance of the Republic of Paraguay**
오 유 경	
Minister	**National Director**
Yu-Kyoung Oh	Jorge Iliou Silvero