Memorandum of Understanding
between
the Brazilian Health Regulatory Agency of the Federative Republic of Brazil
and
the Ministry of Food and Drug Safety of the Republic of Korea
on Regulatory Cooperation in the Field of Health-Related Products

The Brazilian Health Regulatory Agency (hereinafter referred to as the "ANVISA") and the Ministry of Food and Drug Safety of the Republic of Korea (hereinafter referred to as the "MFDS"), (hereinafter jointly referred to as the "Participants");

Considering the important role of international cooperation in the work of regulatory authorities for health-related products (including food, pharmaceutical ingredients, drugs, biological products, medical devices, and cosmetics);

Intending to establish a framework for the exchange of information in the field of health-related products;

Desiring to strengthen their communication to facilitate and promote access to safe, effective and quality health-related products within their countries; and

Recognizing the mutual commitment of the Participants to promote global health and foster radical innovation in healthcare as a fundamental pillar for addressing contemporary health challenges, with a view to developing solutions for currently incurable diseases, mitigating the side effects of existing treatments, and substantially improving patients' quality of life;

Have reached the following understanding:

PARAGRAPH 1
Areas of Cooperation

1. This Memorandum of Understanding (hereinafter referred to as the "MoU") is intended to facilitate the exchange of information and cooperation regarding the regulation of health-related products. The areas of cooperation under this MoU may include:

a) exchange of information on relevant policies, guidelines and standards, laboratory testing, pre-market assessment, market authorization, post-market vigilance, enforcement, good manufacturing practices, and assessment of clinical trials;
b) mutual cooperation to facilitate the reliance pathways of the Participants, in accordance with their respective legal and regulatory frameworks;

c) mutual cooperation to promote technical exchange and regulatory harmonization for the introduction of cosmetics regulatory systems (including those for e-labeling and functional cosmetics); and
d) any other forms of cooperation that may be jointly decided upon by the Participants.

2 The Participants will cooperate in exchanging experiences on regulatory initiatives aimed at supporting innovation and the development of new products in their respective jurisdictions that address unmet medical needs and significantly improve people's health and quality of life.

PARAGRAPH 2
Information Exchange

The Participants will exchange the relevant information and documents necessary for the implementation of this MoU, without prejudice to their own laws, regulations, and procedures, and any restrictions or provisions that either Participant may require to ensure the confidentiality of information and documents, in compliancy with personal data protection regulations. The Participants will commit to handling the information with due protection of confidentiality, refraining from disclosing or making unauthorized or improper use of such information, in accordance with the applicable legal provisions, laws, regulations, and procedures, unless otherwise jointly decided in writing by the Participants.

PARAGRAPH 3
Confidentiality

1. Each Participant will treat documents, information, and any other data exchanged, received, or supplied for the implementation of this MoU as confidential, unless otherwise jointly decided in writing by the Participants.

2. The receiving Participant of confidential information will not transfer such confidential information to any third party without the prior written consent of the disclosing Participant.

3. Each Participant will inform the other Participant of any legislative or judicial decision that may give third parties access to confidential information exchanged between the Participants. Should any such legislative or judicial decision require the disclosure of confidential information provided by the disclosing Participant, the receiving Participant will, so far as it is lawful and practical to do so, prior to disclosure, promptly notify the disclosing Participant of such requirement with a view to providing the opportunity for the disclosing Participant to contest the disclosure or to otherwise consent to the timing and content thereof.

4. The Participants will inform each other, without delay, of any changes in their respective national laws, regulations, policies or procedures which may affect their capacity to implement the provisions of this MoU.

5. The Participants understand that, in the case of the expiration or termination of this MoU, confidential information already shared under this MoU will continue to be protected from unauthorized disclosure and will only be used in accordance with the provisions of this MoU.

PARAGRAPH 4
Contact Points

For the effective implementation of the cooperative activities under this MoU, the Participants will designate the following contact points to facilitate communication between the Participants:

a) For the ANVISA: the Head of the International Affairs Office (rel@anvisa.gov.br);
b) For the MFDS: the Director of the International Cooperation Office (intmfds@korea.kr).

PARAGRAPH 5
Financing

Each Participant will be solely responsible for the administration and expenditure of its own resources associated with the activities conducted under this MoU.

PARAGRAPH 6
Cooperative Initiatives

Any cooperative initiatives arising from the signing of this MoU will be jointly decided upon in advance by the Participants and formalized through a specific work plan, jointly developed by the Participants. The implementation of such initiatives will be subject to mutual interest, as well as the availability of human, material, and financial resources of the Participants.

PARAGRAPH 7
Resolution of Differences

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

PARAGRAPH 8
General Provisions

1. This MoU is not intended to create any legally binding rights or obligations under international laws.

2. This MoU 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 human resources of the Participants.

PARAGRAPH 9

Entry into Effect, Duration, Amendment and Termination

1. This MoU will become effective on the date of signature by the Participants.

2. This MoU will remain in effect for five (5) years after signature and will be automatically renewed for successive periods of five (5) years, unless either Participant formally notifies the other Participant, in writing, of its intention not to renew this MoU, provided that such notice is communicated at least three (3) months in advance.

3. Any amendment to this MoU will be made with the mutual written consent of the Participants.

4. Either Participant may also terminate this MoU at any time, upon (3) months' written notification to the other Participant.

5. Upon the entry into effect of this MoU, the Memorandum of Understanding between the Brazilian Health Surveillance Agency of the Federative Republic of Brazil and the Ministry of Food and Drug Safety of the Republic of Korea on Cooperation in the Field of Food, Medical Devices and Drugs, signed on the 18th day of November, 2014, will be terminated and replaced by this MoU.

Signed in duplicate at Seoul, on the 23rd day of February, 2026, in the Portuguese, Korean, and English languages, all texts being equally valid. In case of any divergence of interpretation, the English text will prevail.

For the Health Regulatory Agency of the Federative Republic of Brazil	For the Ministry of Food and Drug Safety of the Republic of Korea
Leandro Pinheiro Safatle	Yu-Kyoung OH
Director-President	Minister