

**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE MINISTRY OF FOOD AND DRUG SAFETY
OF THE REPUBLIC OF KOREA
AND
THE MINISTRY OF HEALTH
OF THE SOCIALIST REPUBLIC OF VIET NAM
FOR COOPERATION ON THE SAFETY OF FOOD,
PHARMACEUTICALS, COSMETICS AND MEDICAL DEVICES**

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Ministry of Health (MOH) of the Socialist Republic of Viet Nam (hereinafter referred to individually as a “Side” and collectively as the “Sides”),

In accordance with the functions, duties and competences of the Sides, applicable laws and regulations of their respective countries and the treaties to which each country is a member,

Desiring to cooperate in the regulatory affairs, approval, standards, specifications, import and export, and safety of food, pharmaceuticals, cosmetics and medical devices (including artificial intelligence (AI)-based or digital medical devices) (hereinafter referred to as “subject of cooperation”),

Based on the principles of equality, reciprocity and mutual benefit,

Have reached the following understanding:

Paragraph 1: Basic Principles

The Sides hereby confirm their intention to promote cooperation in accordance with this Memorandum of Understanding (hereinafter referred to as this “Memorandum of Understanding”) and the relevant laws and regulations of each country.

Paragraph 2: Scope of Cooperation

This Memorandum of Understanding will apply to the following areas controlled by the Sides, including:

- (a) Food, including:
 - (i) information exchange of laws, regulations and standards regarding food safety and quality standards, food control system and imported food inspection system;
 - (ii) safety requirements and technical regulations of processed food under the control of the Sides;
 - (iii) safety standards and specifications of supplemented food, health supplements, medical food and food for special dietary uses, food additives and processing aids, food utensils, containers, packages and food contact material;
 - (iv) food safety management, including inspection, post-marketing surveillance and laboratory testing;
 - (v) food safety communication; and
 - (vi) active provision of information of the other Side's relevant systems such as recognized inspection agencies and registration procedures for imported and exported food (including types of Certificates of Health, Certificates of Free Sale and Certificates of Analysis);

- (b) Pharmaceuticals, including:
 - (i) pharmaceuticals registration regulations;
 - (ii) pharmaceuticals quality management (including GMP, quality testing, pre- and post-review, BA/BE, counterfeit/substandard products, drug recall, etc.);
 - (iii) pharmaceuticals safety management policy; and
 - (iv) regulatory experience in the field of pharmaceutical and bio-pharmaceuticals;

- (c) Cosmetics, including:
 - (i) cosmetics management policy and regulations;
 - (ii) cosmetics safety surveillance; and
 - (iii) cosmetics quality management (including GMP, post-marketing surveillance, counterfeit cosmetic combat, etc.);

- (d) Medical devices, including:
 - (i) medical devices safety management policy and research;
 - (ii) administrative procedures for obtaining commercial approval of medical devices;
 - (iii) post-marketing vigilance; and
 - (iv) evaluation of medical device manufacturing and quality control;

- (e) Any other areas of cooperation that may be jointly decided upon by the Sides within the scope of their competence.

Paragraph 3: Forms of Cooperation

Cooperative activities accepted by the Sides under this Memorandum of Understanding, may include, but are not be limited to:

- (a) Establishing cooperative framework, including clinical trials, project development and expert exchange in new technology innovation areas such as AI, digital, and biohealth;
- (b) Mutual support, including information exchange to address medical product shortages and stabilize supply chains;
- (c) Facilitating regulatory harmonization, promoting bilateral dialogue on global issues;
- (d) Exchange of information in compliance with the applicable laws and regulations of the Republic of Korea and the Socialist Republic of Viet Nam, including:
 - (i) information on the relevant regime, laws, regulations and standards, regulatory approval, technology and other relevant policies of the subject of cooperation;
 - (ii) information on counterfeit or substandard pharmaceuticals, food products, medical devices and cosmetics; adverse reaction of pharmaceuticals, drug resistance situation and medical devices or products recall situation and deficits;
 - (iii) mutual cooperation and joint coordination, including information sharing, to enhance access to medical products and facilitate regulatory reliance pathways between the Sides;
 - (iv) prompt notification to the exporting Side of the safety problems detected in imported food products, investigation and corrective measures by the exporting Side upon the receipt of the notification, and notification to the importing Side on the results, including the name of the product, the risk detected, the name and address of the exporter, importer and manufacturer and relevant information;
 - (v) strengthening cooperation in information exchange and international harmonization activities of the subject of cooperation; and
 - (vi) formalizing the channel for the exchange of information between the Korean Pharmaceutical Regulatory Authority and the Drug Administration of Viet Nam regarding relevant findings and regulatory decisions relating to market surveillance and control activities conducted by both Sides
- (e) Active utilization of “Officially Authorized Inspection Agencies in Foreign Countries”, the “Prior Inspection Completion System” and “Pre-confirmation based Registration System” to secure safety of food imports and vitalize food trade by preemptively identifying any food safety hazards in producing facilities. Where either Side designates Officially Authorized Inspection Agencies in the other country, the designating Side will provide the other Side with a list of such agencies;
- (f) Cooperation to expedite onsite inspection of exporters' facilities on food;
- (g) Holding joint symposiums, workshops, conferences and/or offering joint training courses, subject to the availability of the resources and funds of each Side; and
- (h) Any other areas of cooperation that may be jointly decided upon by the Sides within the scope of their competence.

Paragraph 4: Operation of High-level Consultation

1. The Sides will establish the Consultation between High-level Officials (hereinafter referred to as the “High-level Consultation”) to promote and discuss cooperative activities under this Memorandum of Understanding.
2. The High-level Consultation will be headed by the Minister of Food and Drug Safety of the Republic of Korea and the Minister of Health of the Socialist Republic of Viet Nam, or the representatives designated respectively by the Ministers of the Sides.
3. The meeting of the High-level Consultation will be held in the Republic of Korea and the Socialist Republic of Viet Nam upon the mutual decision of the Sides.
4. The Working-level Consultation of each area as laid down in Paragraph 5 may be established to support the activities of the High-level Consultation and to achieve substantive cooperation in each area. The Working-level Consultation will be in operation in accordance with the High-level Consultation.
5. The composition and agenda for the meeting of the High-level Consultation will be decided upon by the Sides in advance.
6. The Sides will designate their respective contact points to ensure efficient operation of the High-level Consultation.

Paragraph 5: Operation of Working-level Consultation

1. Pursuant to Paragraph 4, the Working-level Consultation will be divided into specialized areas such as food safety, pharmaceuticals, medical devices and other relevant fields within the scope of their competence and will assist the High-level Consultation.
2. In principle, the Meetings of the Working-level Consultation will be held annually and alternately in the Republic of Korea and the Socialist Republic of Viet Nam, unless otherwise jointly decided upon by the Sides. The Working-level Consultation in the area of Food Safety will involve food standard experts from the MFDS and the Vietnam Food Administration (VFA) in order to include discussions related to food standards in the Working-level Consultation.
3. Heads of the Working-level Consultation will be respective officials at the Director-General level or the representatives designated respectively by the Directors-General of the Sides.
4. Where deemed necessary for its operation, the Working-level Consultation may involve private experts or stakeholders of the industry with the consent of the Sides.

5. The composition and agenda of meetings for each area of the Working-level Consultation will be decided upon by the Sides in advance.
6. The Sides will designate their respective contact points to ensure efficient operation of the Working-level Consultation.

Paragraph 6: Contact Points

The Sides hereby designate the following contact points in order to ensure the efficient implementation of this Memorandum of Understanding:

- (a) for the MFDS, the International Cooperation Office;
- (b) for the MOH, the International Cooperation Department.

Paragraph 7: Financial Arrangements

1. Each Side will bear its own costs in relation to cooperative activities under this Memorandum of Understanding.
2. Cost of any assistance provided by either Side at the request of the other Side will be borne by the requesting Side, unless otherwise decided by the Sides.

Paragraph 8: Confidentiality

1. The Sides will treat the documents, information and any other data exchanged, received or supplied for the implementation of this Memorandum of Understanding or any other arrangements or communications made under this Memorandum of Understanding as confidential, unless jointly decided otherwise in writing by the Sides.
2. Neither Side will transfer any of the confidential information exchanged pursuant to this Memorandum of Understanding to any third party without the written consent of the other Side.
3. The Sides will inform each other of any legislative or judicial decision that may give third parties access to confidential information exchanged between the Sides pursuant to this Memorandum of Understanding. The Side that is being required to give access to the confidential information will take all necessary measures to ensure that the confidential information is disclosed in a manner that prevents it from being made available to third parties or the public.

4. The Sides understand that, in the case of the termination of this Memorandum of Understanding, confidential information already shared under this Memorandum of Understanding will continue to be protected from unconsented disclosure and be used in accordance with the provisions of this Memorandum of Understanding.

Paragraph 9: Resolution of Differences

Any differences arising from the interpretation and/or implementation of this Memorandum of Understanding will be resolved amicably through consultations between the Sides.

Paragraph 10: Status of the Memorandum of Understanding

1. This Memorandum of Understanding is not intended to create and/or give rise to any legally binding obligations between the Sides under domestic or international law. This Memorandum of Understanding will not affect the rights and obligations of either Government/State arising from the treaties to which each country is a member.
2. This Memorandum of Understanding 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 Sides

Paragraph 11: Entry into Effect, Amendment and Termination

1. This Memorandum of Understanding will come into effect on the date of its signature and will remain effective for a period of five (5) years. It will be automatically renewed for successive periods of five (5) years, unless either Side notifies the other Side in writing of its intention not to renew this Memorandum of Understanding six months in advance.
2. Either Side may terminate this Memorandum of Understanding at any time by giving written notification to the other Side at least six months in advance.
3. This Memorandum of Understanding may be amended with the mutual written consent of the Sides.
4. The termination of this Memorandum of Understanding will not affect the duration or validity of any cooperative activities under this Memorandum of Understanding, which are in progress at the time of the notification of the termination of this Memorandum of Understanding.

5. Upon its entry into effect, this Memorandum of Understanding will terminate and replace the Memorandum of Understanding between the Ministry of Food and Drug Safety of the Republic of Korea and the Ministry of Health of the Socialist Republic of Viet Nam for Cooperation on the Safety of Food, Pharmaceuticals, Cosmetics and Medical Devices, that was signed at Ha Noi, Viet Nam, on the 16th day of May, 2018.

Signed at Ha Noi, Viet Nam, on the 22nd day of April, 2026, in two original copies in English, both texts being equally valid.

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



Yu-Kyoung OH
Minister

For the Ministry of Health
of the Socialist Republic of Viet Nam



Dao Hong Lan
Minister