

**MEMORANDUM OF UNDERSTANDING
IN THE FIELD OF PHARMACEUTICALS, COSMETICS AND
MEDICAL DEVICES
BETWEEN
THE MINISTRY OF FOOD AND DRUG SAFETY OF THE
REPUBLIC OF KOREA
AND
THE MINISTRY OF HEALTH OF THE UNITED MEXICAN
STATES THROUGH THE FEDERAL COMMISSION FOR THE
PROTECTION AGAINST SANITARY RISKS**

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Ministry of Health of the United Mexican States through the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), (hereinafter referred to as the "Sides");

Desiring to strengthen cooperation between the Sides in the field of pharmaceuticals, cosmetics and medical devices;,

Have reached the following understanding:

Paragraph 1 Objective

The Sides, in accordance with their respective national laws, regulations and any other provisions applicable of each country, will facilitate cooperation in the field of pharmaceuticals, cosmetics and medical devices, based on the principles of reciprocity and mutual benefit, in order to look to improve the efficiency of the applicable regulatory processes and Good Manufacturing Practices (hereinafter referred to as "GMP") inspections in the field of pharmaceuticals and medical devices.

Paragraph 2 Areas of Cooperation

The Sides will promote mutual cooperation in the following areas of common interest:

1. pharmaceuticals (including biological medicines and drug substances), including:
 - a) pharmaceutical safety management policy and research,
 - b) administrative procedures for obtaining commercial approval for pharmaceuticals,
 - c) GMP, post-marketing vigilance and inspection (pharmacovigilance), and
 - d) quality evaluation and test method development research, as well as research in the area of regulatory science.
2. cosmetics, including:

- a) cosmetic product safety management policy and research,
 - b) post-marketing vigilance system, and
 - c) GMP inspection and management of cosmetics.
3. medical devices, including:
- a) medical device regulations and research,
 - b) administrative procedures for obtaining commercial approval of medical devices,
 - c) post-marketing vigilance system (techno-vigilance), and
 - d) Quality Management System inspections of medical device manufacturers, and
4. any other areas of cooperation that may be jointly decided upon by the Sides

Paragraph 3 Forms of Cooperation

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

- 1. exchange of information;
- 2. exchange of personnel with high levels of expertise in areas of common interest;
- 3. participation in meetings and other events;
- 4. cooperation in joint symposia, workshops, conferences, and joint training programs in the field of pharmaceuticals, cosmetic products and medical devices;

5. look to improve the efficiency of the applicable regulatory processes and GMP inspections in the field of pharmaceuticals and medical devices.
6. any other forms of cooperation that may be jointly decided upon by the Sides.

Paragraph 4 Implementation

This Memorandum of Understanding will be carried out within the framework of the respective laws, regulations, institutional guidelines and any other applicable legal provisions of the two countries, and subject to the competencies of the two Sides.

Paragraph 5 Financing

1. The financing of the cooperative activities under this Memorandum of Understanding will be subject to the available budget of the Sides, as well as their administrative, scientific and personnel capacity.
2. Each Side will be responsible for the administration and expenditure of its own resources associated with its activities under this Memorandum of Understanding, including transportation, living, accommodation, medical, personal injury and life insurance expenses when appropriate.

3. The costs of any assistance provided by one Side to the other Side at the request of that other Side will be borne by the requesting Side, unless otherwise jointly decided by the Sides.

Paragraph 6 Intellectual Property

If, as a result of the cooperative activities performed under this Memorandum of Understanding, products of commercial value and/or intellectual property rights arise, they will be governed by the applicable national laws and regulations of the Sides and the relevant international conventions to which the two countries are party.

Paragraph 7 Confidentiality

1. Neither Side may disclose information received or generated under this Memorandum of Understanding to any third party or to the public, without the prior written consent of the other Side.
2. Any information the Sides received under this Memorandum of Understanding will be protected from disclosure according to the applicable national laws and regulations of each Side.

Paragraph 8 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 Director of the International Cooperation Office of the Ministry of Food and Drug Safety of the Republic of Korea; and

b) for the "COFEPRIS",:

The Executive Director of International Affairs of the Federal Commission for the Protection Against Sanitary Risks of the United Mexican States.

Paragraph 9 Working Relations

The personnel assigned by each Side to carry out cooperative activities under this Memorandum of Understanding will continue under the direction and benefits of the institution to which they belong. No employment relations will be created with the other Side, which will not be considered a substitute or co-employer.

Paragraph 10 Entry and Departure of Personnel

The Sides will work through their respective authorities to facilitate the entry into, stay in and departure from its country of the personnel of the other Side who are officially involved in cooperative activities under this Memorandum of Understanding. Such personnel will be subject to the immigration, tax, customs, sanitary and national security laws and

regulations of the host country and will not engage in any activity outside of their assigned duties, without the prior written consent of the competent authorities of the host country. The personnel will leave the host country, in accordance with the laws and regulations of that country.

Paragraph 11 Insurance

The Sides will ensure that their respective personnel involved in cooperative activities under this Memorandum of Understanding have medical, personal injury and life insurance provided by such personnel's respective institution, in order that, in case of an accident resulting from the development of such cooperative activities, any repair or compensation in relation to such accident is covered by the corresponding insurance company.

Paragraph 12 Unforeseen Circumstances

The Sides shall have no liability for any damages or losses that may arise as a consequence of an unforeseen circumstances or force majeure, that may prevent the execution of all or part of their commitments under this Memorandum of Understanding.

Once these events have passed, activities will resume in the form and terms set forth by the Sides.

Paragraph 13 Legal Obligations

1. This Memorandum of Understanding is not intended to create any legally binding obligations between the Sides under national or international laws.
2. The provisions of the Memorandum of Understanding will not to be interpreted to create any right or obligation for the two countries.
3. Nothing in this Memorandum of Understanding will impose an obligation on one Side to release information, either public or non-public, to the other Side.

Paragraph 14 Operation of Working-level Consultation

1. The Sides may establish a working-level group (hereinafter referred to as the "WG") to discuss priority cooperation areas and manage the cooperative activities and projects under this Memorandum of Understanding.
2. Meetings of the WG may be held whenever necessary, as jointly decided in advance by the Sides, and may be carried out in the Republic of Korea, the United Mexican States, or by telecommunication media.
3. The Sides may jointly decide to invite representatives from the relevant associations and industries to meetings of the WG with the request and written consent of the Sides.

Paragraph 15 Dispute Resolution

Any disputes arising from the interpretation, application and/or implementation of this Memorandum of Understanding will be resolved amicably through consultations between the Sides, and such resolution will be set out in writing.

Paragraph 16 Final Provisions

1. This Memorandum of Understanding will come into effect on the date of its signature. This Memorandum of Understanding will remain effective for a period of five (5) years and may be automatically renewed for successive periods of five (5) years, unless written notice is given by one Side to the other Side of its intention to terminate the Memorandum of Understanding, one hundred and eighty (180) days before the current expiration date.
2. This Memorandum of Understanding may be amended with mutual written consent of the Sides. Any such amendment will take effect on the date of signature of the corresponding amendment instrument.

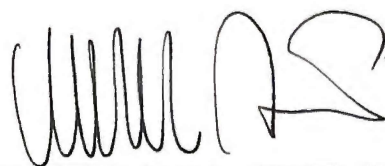
SIGNED in duplicate at Osong, Korea on the 27th day of May, 2014, in the Korean, Spanish and English languages, all texts being equally valid. In case of any divergence of interpretation, the English text will prevail.

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



Chung Seung
Minister of Food and Drug
Safety

For the Ministry of Health of the
United Mexican States through
the Federal Commission for the
Protection Against Sanitary Risks.



Mikel Andoni Arriola Peñalosa
Federal Commissioner for the
Protection Against Sanitary Risks