

**MEMORANDUM OF UNDERSTANDING ON COOPERATION BETWEEN THE MINISTRY OF FOOD
AND DRUG SAFETY OF THE REPUBLIC OF KOREA AND THE MINISTRY OF HEALTH OF THE
REPUBLIC OF PERU**

The Ministry of Food and Drug Safety of the Republic of Korea (MFDS) and the Ministry of Health of The Republic of Peru (MINSA), hereinafter collectively referred to as "the Parties" and individually referred to as "the Party";

Being both Parties the regulatory authorities of their respective countries responsible for the marketing authorization and other regulatory mechanisms regarding pharmaceuticals (including biological products), medical devices and cosmetics, intended for administration to or use by human beings which are marketed, distributed, manufactured or assembled in the Republic of Korea and in the Republic of Peru,

Being both Parties responsible for issuing the sanitary authorization of operation of pharmaceutical establishment and for making the control and sanitary surveillance of manufacturing, commercialization, import, export, warehouse, distribution, and other activities related;

Desiring to strengthen cooperation between the Parties in the areas of pharmaceuticals, medical devices and cosmetics for protecting and promoting health of their respective population, the Parties have reached the following understanding:

Article 1

Objective

The Parties, in accordance with their respective laws, regulations and any other provisions applicable, will further cooperate and facilitate information exchange in the field of pharmaceuticals, medical devices, and cosmetics based on the principles of reciprocity and mutual benefit, in order to ensure quality and safety of pharmaceuticals, medical devices, and cosmetics.

Article 2

Scope of Cooperation

The Parties will promote mutual cooperation in the following areas of interests:



R. VILLARÁN C.



R.C. CASILDO C.



V. FLORES V.



C. RICSE



1. Exchange of information on the relevant laws, regulations, standards and administrative procedures regarding pharmaceuticals, medical devices, and cosmetics, especially for their safety management, commercial approval and post-marketing vigilance and inspection;
2. Exchange of personnel with high levels of expertise in areas of common interest;
3. Joint symposia, workshops, conferences, and joint training programs in the field of pharmaceuticals, medical devices, and cosmetics;
4. Technical assistance related to the regulatory process and Good Manufacturing Practices - GMP inspection in the field of pharmaceuticals, medical devices, and cosmetics; and
5. Any other areas of cooperation that may be jointly decided upon by the Parties.

Article 3 Confidentiality

1. Neither Party may disclose or distribute any 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 Party.
2. Any information the Parties received under this Memorandum of Understanding will be protected from disclosure according to the applicable national laws and regulations of each Party.


R. VILLARÁN C.

Article 4 Expenses

1. Each Party will cover its own expenses and costs arising from the cooperation activities under this Memorandum of Understanding.
2. The cost of any assistance provided by either Party at the request of the other Party will be borne by the requesting Party, unless otherwise jointly arranged by the Parties.


R.C. CASILDO C.



Article 5 Contact Points

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

- a) For the MFDS: The Director for International Cooperation
- b) For the MINSA: Director of the General Direction of Medicines, Supplies and Drugs - DIGEMID


V. FLORES V.


C. RICSE

Handwritten signature and initials

Article 6
Dispute Resolution

Any disputes arising from the interpretation and/or Implementation of this Memorandum of Understanding will be resolved amicably through consultations between the Parties.

Article 7
Implementation

1. 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 each Party.
2. This Memorandum of Understanding is not intended to create any legally binding obligations between the Parties under national or international laws.

Article 8
Entry into Effect, Duration, Termination and Amendment

1. This Memorandum of Understanding will come into effect on the date of its signature. It will remain in effective for three (3) years and will be automatically renewed for a successive three-year period, unless either Party notifies the other in writing of its intention to terminate this Memorandum of Understanding at least six (6) months before the expiration date.
2. This Memorandum of Understanding may be modified by the Parties through the signing of the respective Addenda.

Signed on _____, 2016 in two original copies in English, two in Spanish and two in Korean, being all of them equally valid. In case of any divergence of interpretation, the English version will prevail.



Sohn Mungi
Minister of Food and Drug Safety
Republic of Korea



Patricia J. Garcia Funegra
Minister of Health
Republic of Peru



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