

**MEMORANDUM OF UNDERSTANDING
BETWEEN
THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF
KOREA
AND
THE MINISTRY OF PUBLIC HEALTH OF THE REPUBLIC OF ECUADOR
IN THE FIELD OF SURVEILLANCE AND CONTROL OF DRUGS, MEDICAL
DEVICES, COSMETIC PRODUCTS, PROCESSED FOOD**

THE SIDES

Desiring to conclude the present instrument by one side, the Ministry of Public Health of the Republic of Ecuador, represented by the Magister Carina Vance Mafla in her faculty as Minister, in accordance to the Executive Order No. 1272, of 22 August 2012, published in the Official Register No. 788 of 13 September 2012, designation ratified by Executive Order No. 2 published in the Official Register No. 5 of 31 May 2013, hereinafter referred to as **"MINISTRY OF PUBLIC HEALTH OF THE REPUBLIC OF ECUADOR"**; and by the other side the Ministry of Food and Drug Safety of the Republic of Korea, represented by Jang Byungwon, in his faculty as Viceminister, hereinafter referred to as **"MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA"**.

The Ministry of Public Health of the Republic of Ecuador and the Ministry of Food and Drug Safety of the Republic of Korea, referred to collectively as the "Sides", and each individually as the "Side", in their free and voluntary faculty and being able to contract and bind, have reached the following understanding:

**Paragraph I
OBJECT**

The Sides subscribe this Memorandum of Understanding with the objective of promoting and developing cooperation actions and programs for advising, training and exchange of experiences in the field of health surveillance and sanitary control based on principles of reciprocity and mutual benefit and according to the legislation and regulation of each country.

Paragraph II
AREAS OF COOPERATION

The Sides will promote mutual cooperation for advising, training and exchange of experiences in the following areas of common interest; systems of health surveillance and sanitary control for: drugs, medical devices, cosmetic products, and processed food.

1. About advising, training and exchange of experiences in drugs, the Sides commit to cover the following subjects:

1. Policy making in health surveillance and sanitary control of drugs.
2. Process for approval and regulation of drugs (including herbal medicine) and biologics.
3. Control of post-registration and post-marketing of drugs in general, homeopathic, natural and biologics.
4. Evaluation of clinical research protocols, as well as inspection and audits to facilities where clinical trials are conducted.
5. Studies of bioequivalence and bioavailability of drugs.
6. Comparability studies of biosimilar drugs and immunogenicity studies.
7. Dossier evaluation for biosimilars (authorization).
8. Risk assessment of drugs for postmarketing surveillance.
9. Pharmacovigilance.
10. Good manufacturing practices, as control process in the pharmaceutical industry.
11. Drug stability studies.
12. Strategies and initiatives in the fight against counterfeit and fraudulent drugs.

2. About advising, training and exchange of experiences in medical devices, the Sides commit to cover the following subjects:

1. Policy making in health surveillance and sanitary control of medical devices.
2. Criteria of homologation of sanitary registers for medical devices and medical devices for in vitro diagnostic.
3. Classification by risk level of medical devices (rules and application; international harmonization).

4. Systems of health surveillance and sanitary control in medical devices through the application of post-marketing surveillance.
5. Audits of quality systems for regulatory aspects.
6. GMP for medical devices, medical devices for in vitro diagnostic and biomedical equipment.
7. Control processes of medical devices, medical devices for in vitro diagnostic through technovigilance.
8. Training in ISO Standards 13485 and 14791.

3. About advising, training and exchange of experiences in cosmetic products, the Sides commit to cover the following subjects:

1. Public Policy making in the field of health surveillance of cosmetic products.
2. Regulation for the post-register control and sanitary control of cosmetic products.
3. Inspection, surveillance and sanitary control of cosmetic products.
4. Good manufacturing practices, as control processes in the cosmetic industry.
5. Exchange of experiences in the application of the regulations related with the health surveillance and sanitary control of cosmetic products.
6. Implementation of cosmetovigilance systems.

4. About advising, training and exchange of experiences in processed food, the Sides commit to cover the following subjects:

1. Policy making in food safety.
2. Regulation for the health surveillance and sanitary control of processed food.
3. Sanitary authorization processes for the commercialization of processed food.
4. Verification processes (inspections) of the compliance of the health regulations in the food industry.
5. Control processes for verification of the quality and safety of processed food.
6. Control processes in the food industry about the following:
 - Good Manufacturing Practices – GMP.
 - Hazard analysis and critical control points – HACCP.

7. Verification processes (inspections) of the compliance of the health regulations in collective feeding facilities.
8. Control processes and traceability of GMO foods.
9. Stability studies in processed food.

Cooperation between the Ministry of Public Health of Ecuador (the National Agency of Regulation, Control and Health Surveillance ARCSA) and the Ministry of Food and Drug Safety of the Republic of Korea, established in this Memorandum of Understanding, can be provided in the following modalities:

- a. Exchange of information.
- b. Exchange of experts and delegations between the Sides in order to transmit experiences in priority subjects for both countries.
- c. Participation in conferences and other events.
- d. Develop joint projects and training for the technician personnel in the field of proposed subjects.
- e. Develop projects for the development and execution of a computer system for drugs control, medical devices, cosmetic products and processed food.
- f. Any other way of cooperation in the field of health surveillance and sanitary control that may be decided between the Sides.

The Sides will exchange, under request of either Side, information about their legislation and regulatory activities in the field of health surveillance and sanitary control.

The Sides will promote direct cooperation in areas of common interest and they commit to act in good faith and be in contact with the purpose of accomplishing the mutual interest in relation to the acquired commitments in this legal instrument.

This Memorandum of Understanding is not intended to create any legal obligations under national or international law.

Paragraph III

EXPENSES

1. The expenses related to personnel exchange, including transportation, maintenance, and accommodation will be paid in the way that the Sides mutually agree.
2. The expenses of the other cooperation activities established in this Memorandum of Understanding will be assumed according to the mutual decision of both Sides, stipulated in the specific instruments that will be signed in accordance with current regulation and legislation.

Paragraph IV

EXECUTION UNITS

The Sides hereby designated the following focal points to assure the efficient implementation of this Memorandum of Understanding:

- a) For the Ecuadorian side, the National Division of Health Surveillance and Sanitary Control, the National Agency of Regulation, Control and Health Surveillance ARCSA, and the Division of International Cooperation and International Relations.
- b) For the Korean side, the International Cooperation Office of the Ministry of Food and Drug Safety of the Republic of Korea.

The mentioned Institutions are responsible for the coordination, supervision, and evaluation of the commitments acquired by The Sides in the framework of this Memorandum of Understanding.

Paragraph V

TERM

This Memorandum of Understanding will come into effect for a period of five (5) years from the date of its subscription and will be renewed automatically by the same period, unless either of the Sides expresses its intention to terminate this legal instrument by giving the other Part a written notice no later than two (2) months before the expiry of the current period.

Paragraph VI

TERMINATION

This Memorandum of Understanding will be ended by the following causes:

For contractual compliance;

For unilateral termination by either of The Sides, when either of one Side does not comply with one or several commitments established in this Memorandum of Understanding,

For mutual arrangement of The Sides; and,

For causes of force majeure or fortuitous event in accordance with those suggested by the Ecuadorian Civil Code that preclude the contractual execution.

It will be considered a breach by the Sides when the object and assumed commitments are not carried out in accordance with the provisions stipulated in this Memorandum of Understanding. If one of the Sides wishes to end this commitment before time, it should communicate to the other Side with a written notice no later than thirty (30) days in advance, informing the reasons of termination.

The Memorandum of Understanding will end by the consent of the Sides when it is not possible or convenient for institutional interests to totally or partially execute the Memorandum of Understanding, due to unexpected technical or economical circumstances or causes of force majeure or fortuitous event. The Sides can approve the extinction of all or some commitments by mutual consent

It will not be considered a breach the produced caused by fortuitous event or force majeure.

Paragraph VII

CONTROVERSIES

In case of any dispute or controversy relating to the compliance of approved commitments, the Sides will endeavor to amicably resolve it direct and in common arrangement.

Since this legal instrument is signed in Korean, Spanish and English, in case of disputes arise as to the interpretation thereof, the English language shall prevail.

Paragraph VIII**ADDRESS, JURIDICION AND NOTICES**

For all purposes of this Memorandum of Understanding and for communications and notices the Sides set their address as follows:

MINISTRY OF PUBLIC HEALTH OF ECUADOR: Av. República del Salvador
No. 950 between Suecia y Naciones Unidas.

MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA:
Osong Health Technology Administration Complex, 187, Osongsaengmyeong
2-ro, Osong-eup, Cheongwon-gun, Chungcheongbuk-do, 363-700, Korea

Paragraph IX**ACCEPTANCE**

In accordance with all the established paragraph, the Sides subscribed this Memorandum of Understanding in six copies of equal content and legal effect in Korean, Spanish and English, in Quito on the 11th day of March 2014. In case of any other divergence in interpretation, the English will prevail.

For the **MINISTRY OF FOOD AND
DRUG SAFETY OF THE
REPUBLIC OF KOREA:**

For the **MINISTRY OF PUBLIC
HEALTH OF THE REPUBLIC OF
ECUADOR:**

장영진



[Signature]