MEMORANDUM OF UNDERSTANDING ON INTERINSTITUTIONAL COOPERATION BETWEEN THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA AND THE NATIONAL ADMINISTRATION OF DRUGS, FOODS AND MEDICAL DEVICES OF THE ARGENTINE REPUBLIC

The Ministry of Food and Drug Safety of the Republic of Korea ("MFDS") and the National Administration of Drugs, Foods and Medical Devices ("ANMAT"), hereinafter jointly referred to as the "Parties");

CONSIDERING:

That the MFDS was originally established as a governmental agency for monitoring food and drug safety in 1996, it was later upgraded to the status of administration in 1998 —Korean Administration of Food and Drug Safety— and to the status of Ministry in 2013, adopting its current name, and that the MFDS has grown in importance and broadened the scope of its functions, promoting public health by guaranteeing the safety of food, drugs, medical products and cosmetics for human consumption;

That ANMAT is a decentralized agency —established through Decree No. 1490 of 20 August 1992 within the Secretariat for Policies, Regulation and Institutions of the Ministry of Health of the Argentine Republic— responsible for monitoring and supervising the safety and quality of drugs, chemical products, reagents, pharmaceutical forms, medicines, diagnosis elements, biomedical materials and technology and any other products used in and applied to human medicine; preserved foods, including specific supplies, additives, colorants, sweeteners and ingredients used for human consumption, domestic use products and food contact materials; hygiene and cosmetic products for human use and the drugs and raw materials of which they are composed, and that ANMAT is also responsible for supervising the effectiveness and for detecting the adverse effects resulting from the consumption and use of the abovementioned products, elements and materials and the presence of any kind of substance or residues —whether organic or not— that may affect the health of the population;

That it is within the functions of ANMAT to evaluate clinical pharmacology tests and tests conducted on medical products;

That ANMAT adopts timely and appropriate measures to protect the health of the population upon detecting any risk factor related to the quality and safety of the abovementioned products, substances, elements or materials;

The desire to promote bilateral relations and build mutual trust between the authorities of the Republic of Korea and the Argentine Republic in order to contribute to the performance of their institutional functions; and

The importance of cooperation between the authorities of the Republic of Korea and the Argentine Republic to improve their respective regulatory powers in order to protect and promote the health standards of their respective populations pursuant to the health and quality standards of their respective countries;

Have agreed as follows:

Article 1

Purpose

The purpose of this Memorandum is

a. to promote mutual understanding between the Parties of their respective regulatory frameworks, requirements and procedures;
b. to facilitate the exchange of information and documents on the regulation of drugs and health materials;
c. to promote cooperation activities between the Parties and improve their capacity to provide services related to their functions, in keeping with their respective legislations, in order to satisfy the needs of their respective populations.

Article 2

Implementation

1. Cooperation activities and the tools to implement them shall be determined through specific cooperation projects or work plans, which shall be prepared by mutual consent and reviewed annually, subject to the available financial, material and human resources of each Party.

2. The Parties shall

   a. establish communication channels to facilitate the exchange of information on regulatory and health practices concerning drugs and health materials of each Party, including policies, practices, standards, regulations for producers, regulation of clinical tests, and requirements for the regulation of drugs and health materials; and
   b. carry out cooperation activities and, where possible, personnel exchange programmes.

3. The cooperation projects or work plans shall include the following information:

   a. the cooperation activities to be carried out, the expected results, the time frame, and the personnel responsible for execution;
   b. the human resources to be made available by each Party; and
   c. the necessary financial resources to carry out the jointly agreed-upon activities.

4. the cooperation projects or work plans shall be valid only after express approval by the Parties.

Article 3

Financing

1. The financing of the cooperation activities under this Memorandum of Understanding shall be agreed upon by the Parties and detailed in separate documents, i.e., the cooperation projects or work plans referred to in Article 2 above, taking into consideration the available resources of the Parties.

2. Both Parties agree to search for sources of financing to ensure the implementation of the cooperation activities under this Memorandum, particularly between the institutions promoting cooperation.

Article 4

Monitoring and evaluation

The Parties shall monitor and evaluate the work plans or cooperation projects implemented annually. A final report shall be submitted to the heads of both Parties and to the institutions that support the specific cooperation activity.

Article 5

Confidentiality

1. The implementation of the cooperation activities under this Memorandum may give the Parties and their personnel access to restricted information concerning —among other matters— the effectiveness, safety and quality of the products monitored and regulated by the Parties.

2. Restricted information referred to in paragraph 1 above includes confidential commercial information, trade secrets, private information, information on the application of the law or information concerning decision-making processes of the Parties.

3. The Parties guarantee the strict protection of information pursuant to their respective laws and rules, and they shall not disclose it to the public during the implementation of the cooperation activities.

4. The Parties understand that the exchange of restricted information shall be based on mutual trust. Therefore, they undertake to maintain its confidentiality and not to disclose it to third parties.

5. The Parties shall ensure that their personnel respect the confidentiality of restricted information pursuant to their respective laws and rules.

6. The Parties shall inform each other of any legislative or judicial decision that may give third parties access to restricted information. Should any such legislative or judicial decision order the disclosure of restricted information provided by either Party, the other Party shall adopt any necessary legal measures to ensure that the information is disclosed in such a way as to ensure it does not become available to the public.

7. The Parties shall inform each other, without delay, of any changes in their respective national legislation, policies or procedures which may affect their capacity to fulfil the commitments undertaken under this Memorandum.

8. The commitment to maintaining the confidentiality of the information exchanged under this Memorandum shall not be limited in time and shall continue to be valid regardless of the termination of this Memorandum.

Article 6

Focal Points

For the purpose of guaranteeing the effective implementation of this Memorandum, the Parties shall establish focal points that will serve as bilateral channels of communication. In the case of MFDS, the focal point shall be the Director of the International Cooperation Office. In the case of ANMAT, the focal point shall be the Department of International Relations of the Directorate for Institutional Affairs and Advertising Regulation.

Article 7

Dispute settlement

Any differences in relation to the interpretation or implementation of this Memorandum shall be settled through consultations and negotiations between the Parties.

This Memorandum shall not be construed to create any legal rights or obligations under national or international laws.

Article 8

Amendments

This Memorandum may be amended in writing by mutual consent between the Parties. Any such amendments shall enter into force on the date of their signature by the Parties.

Article 9

Entry into force and term

This Memorandum shall enter into force on the date of its signature and shall be valid for a term of two (2) years. It shall be automatically renewed for consecutive two-year periods unless either Party notifies the other in writing of its intention not to renew it, at least one (1) month prior to the expiration of the relevant period.

Article 10

Termination

The Parties may terminate this Memorandum at any time by means of a two (2)-month written notice.

Article 11

Automatic termination

This Memorandum shall be terminated by operation of law if any new laws or rules adopted in the countries of the Parties hinder or prevent its implementation or render it incompatible with the domestic regulations of the Parties.

As evidence of agreement dual copies in Korean, English and Spanish language of the same tenor and to one purpose only are signed in the Autonomous City of Buenos Aires, December 7th, 2016. In case of any divergence of interpretation, and in accordance with section 3 of the "Vienna Convention on the Law of Treaties", the English text will prevail.

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

Name: _____

Position: _____

For the National Administration of Drugs, Foods and Medical Devices of the Argentine Republic

Name: _____

Position: _____