식품의약품안전처
MINISTRY OF FOOD AND DRUG SAFETY

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

MEMORANDUM OF UNDERSTANDING IN THE FIELD OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICES, BETWEEN THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA AND THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES

The Ministry of Food and Drug Safety of the Republic of Korea (MFDS) 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";

Considering the provisions of the Memorandum of Understanding in the field of Pharmaceuticals, Cosmetics and Medical Devices between the Ministry of Health of the United Mexican States through the Federal Commission for the Protection against Sanitary Risks and the Ministry of Food and Drug Safety of the Republic of Korea, signed in Osong, Korea,

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on May 27th, 2014;

Desiring to address and strengthen cooperation between the Sides in the field of pharmaceutical Good Manufacturing Practices (hereinafter referred to as the "GMP") (including biological products);

Have reached the following understanding:

Paragraph 1. Objective

The objective of this Memorandum of Understanding (MOU) is to facilitate cooperation between the Sides, in accordance with their respective national laws, regulations and any other provisions applicable of each country, in the field of pharmaceutical GMP, based on the principles of reciprocity and mutual benefit, in order to look to improve the applicable regulatory processes in the pharmaceutical field.

Paragraph 2. Cooperation Activities

The Sides will promote mutual cooperation as the following:

1. Once the accession to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) of COFEPRIS is effective, both Sides will mutually

recognize pharmaceutical GMP after the period of preparation within six (6) months from the effective date.

2. Both Sides, even prior to the mutual recognition of referred to above, will have five (5) years of the site inspection exemption period of approved pharmaceuticals. The exemption is exceptional in case of necessity for the public health of the Sides including occurrence of risk information, increase of the risk level according to risk evaluation in a maximum period of 30 months or for the addition of manufacturing sites.
3. Both Sides will begin mutual discussion for fast approval of pharmaceuticals e.g. new molecular entities, incrementally modified drugs, biosimilars and gene therapy products, among others, originally authorized in each country. Also, both Sides want to intensify mutual discussion and exchange of information on these and similar mechanisms with a view to facilitating for fast approval/clearance procedures of medical devices so that those already authorized in each country could be authorized in the other country.
4. The Sides will designate the persons in charge of regulation in pharmaceutical field of both Sides as contact points, for the sake of prompt exchange of regulation information such as pharmaceuticals permission and approval. Furthermore, for the cooperation promotion in medical device sector in the future, persons in charge of regulation in medical device field of both Sides would be designated additionally as contact points.

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5. Especially, for the strengthening of technological cooperation in biological products field, the experts exchange, joint training and symposium will be managed.

Paragraph 3. Contact Points

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

- For the "MFDS": the Director of International Cooperation Office, and
- For the "COFEPRIS": the Executive Director of International Affairs.

Paragraph 4. Operation of Working-Level Consultation

1. The Sides may establish a working-level group (hereinafter referred to as the "WG") to discuss the cooperative activities under this MOU.
2. The WG will consist of equal number of representatives designated by each Side.
3. Meetings of the WG will be held as jointly decided by the Sides, and will be carried out in the Republic of Korea or the United Mexican

States, by turns, or by telecommunication media, as often as deemed necessary.

4. The two Sides make a decision on the WG's agenda through the prior consultation.
5. The two Sides can invite the related associations and the related representatives of corporations to the WG pursuant to the two Sides' request and written agreement.

Paragraph 5. Confidentiality

1. Neither Side may disclose information received or generated under this MOU 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 MOU will be protected from disclosure according to the applicable national laws and regulations of each Side.

Paragraph 6. Legal Obligations

1. This MOU is not intended to create any legally binding obligations between the Sides under national or international law.
2. The provisions of this MOU will not to be interpreted to create any right or obligation for the two countries.

3. Nothing in this MOU imposes an obligation on one Side to release information, either public or non-public, to other Side.

Paragraph 7. Consults

The Sides may hold consultations at any time, in order to attend any issue related to the interpretation, application and/or implementation of this MOU.

Paragraph 8. Final Provisions

1. This MOU will come into effect on the date of its signature, and 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 decision to terminate it one hundred and eighty (180) days, in advance.
2. This MOU may be amended by mutual written consent of the Sides. Any such amendment will take effect on the date of the signature of the corresponding amendment instrument.
3. The termination of this MOU will not affect the conclusion of the cooperation activities that may had been formalized while it was effective, unless the Sides agree otherwise.

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Signed in duplicate, at Mexico City, Mexico, on April 4th, 2016, in Korean, Spanish and English languages, all texts being equally valid. In case of any divergence on the interpretation, the English text will prevail.

FOR THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA

Sohn Mun-gi

Minister of the Ministry of Food and Drug Safety

FOR THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES

Julio Salvador Sánchez y Tépoz

Federal Commissioner for the Protection against Sanitary Risks