MEMORANDUM OF UNDERSTANDING
BETWEEN
THE FOOD AND DRUG ORGANIZATION OF THE ISLAMIC REPUBLIC OF IRAN
AND
THE MINISTRY OF FOOD AND DRUG SAFETY OF THE REPUBLIC OF KOREA
ON COOPERATION IN THE FIELD OF THE SAFETY OF FOOD, PHARMACEUTICALS, COSMETICS AND MEDICAL DEVICES

The Food and Drug Organization of the Islamic Republic of Iran and the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (hereinafter referred to as "the Sides"),

Desiring to cooperate in the regulation, approval, standards, specifications, import and export, and safety of foods, pharmaceuticals (including biological products), cosmetics, and medical devices (hereinafter referred to as "subject of cooperation"), based on the principles of equality, reciprocity and mutual benefit.

Have reached the following understanding:

Paragraph 1

Basic Principles

The Sides hereby confirm their intention to promote cooperation in accordance with Memorandum of Understanding (hereinafter referred to as "MOU") and the relevant laws and regulations of each country.

Paragraph 2

Scope of Cooperation

This MOU will be applied to the following areas controlled by the Sides, including:

1. Food, including:

(a) Exchange of information on the laws, regulation and standards regarding food safety and quality standards;

(b) Safety requirements and technical regulations relating to processed food (including agricultural, forest, meat, dairy and fishery products under the control of the Sides);

(c) Safety, standards and specifications for the food and health supplements, medical food and food for special dietary uses, food additives and processing aids, food utensils, containers, packages and food contact materials that come into contact with food;

(d) Food safety management, including inspection, post-market surveillance and laboratory testing;

(e) Food safety communication; and

(f) Active provision of information regarding the other Side's relevant systems such as officially recognized inspection agencies and registration procedures for imported and exported foods (including types of certificate of hygiene, certificate of free sale and certificates of analysis).

2. Pharmaceuticals, including:

(a) Pharmaceutical registration regulations;

(b) Pharmaceutical quality management;

(c) Pharmaceutical safety management policy; and

(d) Science and research in the field of the regulation of pharmaceuticals.

3. Cosmetics, including:

(a) Cosmetics management policy and registration regulations;

(b) Cosmetics safety surveillance; and

(c) Cosmetic quality management, including current Good Manufacturing Practices (cGMP), sampling and testing, and material substance management

4. Medical devices, including:

(a) Medical devices safety management policy;

(b) Administrative processes for the regulation of medical devices;

(c) Post-marketing vigilance;

(d) Medical devices manufacturing and quality control (cGMP); and

(e) Science and research in the field of the regulation of medical devices; and

5. 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 MOU, may include, but not are limited to:

1. Exchange of the following Information:

(a) Information on the relevant systems, laws, regulations and regulatory approval processes, registered products, and other relevant policies of the subject of cooperation;

(b) Information on counterfeit or substandard, food products, pharmaceuticals, medical devices, cosmetics and medical devices; adverse reactions to pharmaceuticals and medical devices; and products recall situations

(c) Prompt notification to the exporting Side of safety problems detected in imported food products, upon the receipt of the notification from the importing Side, the exporting Side will promptly conduct an investigation, take corrective measures, and notify the importing Side of the results, including the name of the product, risk detected, name and address of exporter, importer and manufacturer and other relevant information; and

(d) Information on international harmonization activities of the subject of cooperation.

2. Active utilization of "Officially Authorized Inspection Agencies in Foreign Countries", and the Prior Inspection Completion System to ensure the safety of food imports and vitalize food trade by preemptively identifying any food safety hazards at production facilities. Where either Side designates Officially Authorized Inspection Agencies in

the other country, the designating Side will provide the other Side with a list of such agencies;

3. Cooperation to expedite onsite inspections of exporters' food production facilities;
4. Holding of joint symposiums, workshops and conferences and/or offering joint training courses, subject to the availability of funds of each Side; and
5. Any other forms of cooperation that may be jointly decided upon by the Sides

Paragraph 4

Organizing and Operation of Working Group

1. The Sides may establish a working-level group (hereinafter referred to as the "WG") to review the progress of the cooperative activities and projects under this MOU and discuss other issues related to this MOU.
2. Director general-level official from each side will be designated as a representative in each Side.
3. Meetings of the WG will be held as jointly decided by the Sides, and will be carried out alternately in the Republic of Korea and the Islamic Republic of Iran, as often as deemed necessary.
4. The composition and agenda of each meeting of the WG will be decided by the Sides in advance.
5. The Sides will designate their respective contact points to ensure the efficient operation of the WG.

Paragraph 5

Contact Points

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

(a) For the MFDS : The International Cooperation Office

(b) For the FDO: The Department of International Cooperation

Paragraph 6

Financial Arrangements

1. The Sides will bear their own costs in relation to the cooperative activities under this MOU.
2. Cost of any assistance provided by either Side at the request of the other Sidel be borne by the requesting Side, unless otherwise jointly by the Sides.

Paragraph 7

Release of Information

Neither Side may disclose or distribute to any third party any confidential information transmitted by the other Side in the process of the cooperative activities under this MOU, except as and to the extend authorized in writing to do so by that other Side.

Paragraph 8

Resolution of Disputes

Any disputes arising from the interpretation and/or implementation of this MOU will be resolved amicably through consultations between the Sides.

Paragraph 9

Entry into Effect, Duration, Amendment and Termination

1. This MOU will come into effect on the date of its signature and will remain effective for a period of 5 years. It will be automatically renewed for successive periods of 5 years, unless either Side notifies the other in writing of its intention to terminate this MOU 6months in advance.
2. This MOU may be amended with the mutual written consent of the Sides. Any such amendment will take effect on the date of signature of the corresponding amendment instrument.
3. The termination of this MOU will not affect the duration or validity of any cooperative activities under this MOU, which are in progress at the time of the

notification of the termination of this MOU unless otherwise jointly decided by the Sides.

Signed in duplicate in Teheran, on May 3, 2016, in two original copies in English

FOR THE MINISTRY OF FOOD AND DRUG ORGANIZATION REPUBLIC OF IRAN

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