Memorandum of Cooperation
Between
The Ministry of Health, Labour and Welfare of Japan
And
The Saudi Food and Drug Authority
On Medical Products

The Ministry of Health, Labour and Welfare of Japan (MHLW) and the Saudi Food and Drug Authority (SFDA) (hereinafter referred to collectively as **"Both sides"** and individually as a **"side"**);

Believing in the importance of promoting joint cooperation and the exchange of expertise with regard to medical products including pharmaceuticals, biopharmaceuticals, medical devices, regenerative medical products, quasi-drugs (that refers to health products in Saudi Arabia (excluding equipment and instruments etc.) intended for uses related to health and hygiene, etc.), cosmetics and raw materials intended for pharmaceutical use; and

Desiring to develop and benefit from such expertise and capabilities,

in accordance with the laws and regulations applicable in Both sides' countries, have therefore decided the following:

Paragraph 1

Purpose

The purpose of this Memorandum of Cooperation (MOC) is to strengthen cooperation between Both sides with regard to medical products, including pharmaceuticals, biopharmaceuticals, medical devices, regenerative medicines, quasi-drug (that refers to health products in Saudi Arabia (excluding equipment and instruments etc.) intended for uses related to health and hygiene, etc.), cosmetics and raw materials intended for pharmaceutical use, in accordance with the laws and regulations applicable in both countries, and in a manner that serves their mutual interests.

Paragraph 2

Areas of Cooperation

Both sides will encourage cooperation in the areas covered under this MOC, particularly in the following:

1. The priority review and licensing by SFDA for new pharmaceutical products approved by MHLW and marketed in Japan, in accordance with a mechanism determined by Both sides per the applicable laws and regulations.
2. Capacity building by training SFDA's technical staff in the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs of the Pharmaceuticals and Medical Devices Agency (PMDA-ATC) in Japan, in accordance with a decided mechanism.
3. Joint cooperation at international forum such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), International Medical Device Regulators Forum (IMDRF) and Pharmaceutical Inspection Co-operation Scheme (PIC/S).
4. Ad-hoc consultations to Japanese expertise to advise on technical issues of pharmaceutical, biological and biosimilar drug reviews, and regulation of pharmaceuticals and medical devices.
5. Any other means of cooperation decided by Both sides.

Paragraph 3

Implementation Mechanism

1. For the purpose of implementing this MOC, Both sides will establish a technical committee comprising representatives appointed by Both sides. The committee will be tasked with establishing the rules and procedures for the implementation of this MOC.
2. The technical committee will convene upon the request of either side, alternating between the Saudi Arabia and Japan in terms of meeting location.

Paragraph 4

Contact Points

1. For MHLW: The Office of International Regulatory Affairs, General Affairs Division, Pharmaceutical Safety and Environmental Health Bureau.
2. For SFDA: The International Cooperation Department.

Both sides will notify one another upon any change in their contact points.

Paragraph 5

Financial Costs

Implementation of this MOC will be subject to each sides's budget priorities and the availability of funds and resources; and each side will incur the expenses arising from the implementation of its part of the matters of this MOC as per the mechanism to be decided.

Paragraph 6

Confidentiality of Information

Both sides will use the information and documents exchanged between them only within the scope of the decided purposes; and each side will not disclose any exchanged information to a third party without the written consent of the source side.

Paragraph 7

Settlement of Disputes

Any dispute arising between Both sides regarding the interpretation or implementation of this MOC will be resolved amicably to the best of their mutual interest.

Paragraph 8

Commitments

This MOC will not constitute an international agreement and will not result in any financial or legal obligations for either side.

Paragraph 9

General Provisions

1. This MOC will commence on the date of the most recent mutual notice exchanged between Both sides through diplomatic channels that affirms the completion of the necessary internal procedures.
2. This MOC will continue for a term of five years, renewable automatically for the successive period of five years, unless one side notifies the other in writing through diplomatic channels of its desire to discontinue the MOC at least six months prior to the date this MOC ends.
3. Subject to the consent of Both sides, this MOC may be modified by the exchange of written consent through diplomatic channels, in accordance with the necessary procedures in both countries.
4. In case of the discontinuation of the MOC, its matters regarding the projects and programs established will be implemented after the discontinuation, unless otherwise decided.

Signed on December 14, 2020 in two original copies in Arabic, Japanese and English, all text having equal value. In the event of any divergence regarding the interpretation of the MOC, Both sides will refer to the English version.

For **the Ministry of Health, Labour and Welfare** **of Japan**	**For the Saudi Food and Drug Authority** **In Saudi Arabia**
Director General, Pharmaceutical Safety and Environmental Health Bureau	**The CEO of SFDA**
Name: Kamata Mitsuaki	**Name: Prof. Hisham Saad AL Jadhey**
Date: December 14, 2020	**Date: December 14, 2020**