식품의약품안전처
Ministry of Food and Drug Safety

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Memorandum of Understanding between the Ministry of Food and Drug Safety of the Republic of Korea and the Health Products Regulatory Authority of Ireland Concerning Cooperation in the Regulation of Therapeutic Products

The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea and the Health Products Regulatory Authority (HPRA) of Ireland (hereinafter referred to individually as a "Participant" and collectively as the "Participants")

Wishing to establish a framework for cooperation in the area of the regulation of therapeutic products.

Have reached the following understanding:

Paragraph 1- Objectives

1. The objectives of this Memorandum of Understanding(MoU) are:

   a. to promote an understanding between the Participants of each other's regulatory framework, requirements and processes;

   b. to facilitate the exchange of information and documentation relating to the regulation of therapeutic products;

   c. to encourage the development of collaborative activities between the Participants; and

d. to enhance the ability of the Participants to provide their services relating to or in connection with public health, in order to meet the needs of their respective population.

2. This MoU represents the understanding reached by the Participants, in particular:

a. that each Participant has jurisdiction over specific therapeutic products and may define those products differently. This MoU is intended to cover all types of therapeutic products regulated by the Participants and permit meaningful collaboration between them. This may include, but is not limited to, medicinal products and medical devices; and

b. that each Participant may limit the scope of disclosure of information particularly if the disclosure may be prejudicial to the commercial interests of a third party, breach the duty of confidence or privacy, disclose a trade secret, is contrary to the public interest or the interests of the Participant concerned, would be in breach or inconsistent with statutory obligations or requirements or other obligations and requirements imposed by the respective laws of the Republic of Korea or Ireland.

Paragraph 2- Definitions

In this MoU "therapeutic products" means:

a. for the MFDS, medicinal products and herbal medicinal products as described in Article 2 of the Pharmaceutical Affairs Act, advanced therapy medicinal products as described in Article 2 of the Advanced Regenerative Medicine and Advanced Biopharmaceuticals Safety and Support Act and medical devices as described in Article 2 of the Medical Devices Act and in vitro diagnostic medical devices as described in Article 2 of the Act on In Vitro Diagnostic Medical Devices; and

b. for the HPRA, medicinal products, herbal medicinal products, advanced therapy medicinal products, medical devices or similar products or devices related to or connected with the functions of the HPRA as described in Section 4 of the Irish Medicines Board Act, 1995 as amended from time to time.

Paragraph 3- Areas of Cooperation

The Participants will:

a. establish avenues of communication to facilitate the exchange of information about the regulation of therapeutic products by each Participant, which may include: policies, practices, standards, laboratory testing, pre-market assessment, post-market vigilance, market compliance, regulation of manufacturers, regulation of clinical trials and requirements for the regulation of therapeutic products; and

b. undertake collaborative activities.

Paragraph 4- Confidentiality

1. MFDS

a. Nothing in this MoU requires MFDS to release confidential information to the HPRA, except in accordance with law.

b. MFDS will make all reasonable efforts to inform the HPRA of any effort made by a judicial, legislative or other authority to obtain confidential information that has been provided by the HPRA to MFDS.

c. Unless otherwise required by law, MFDS will not disclose any information received from the HPRA under this MoU, except with the written consent of the HPRA. If disclosure is required by law, MFDS will consult with the HPRA in advance of releasing such information and will take all reasonable measures to ensure that the information received from the HPRA will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

d. Unless otherwise required by law, MFDS will not use the information disclosed to it under this MoU for any other purpose than the performance of its therapeutic products regulatory activities.

2. HPRA

a. Nothing in this MoU requires the HPRA to release confidential information to MFDS, except in accordance with law.

b. The HPRA will make all reasonable efforts to inform MFDS of any effort made by a judicial, legislative or other authority to obtain confidential information that has been provided by MFDS to the HPRA.

c. Unless otherwise required by law, the HPRA will not disclose any information received-from the MFDS under this MoU, except with the written consent of MFDS. If disclosure is required by law, the HPRA will consult with MFDS in advance of releasing such information and will take all reasonable measures to ensure that the information received from MFDS will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.

d. Unless otherwise required by law, the HPRA will not use the information disclosed to it under this MoU for any other purpose than the performance of its therapeutic products regulatory activities.

Paragraph 5- Financial Arrangements

Each Participant will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MoU.

Paragraph 6- Amendment

Any provision of this MoU may be amended at any time with the mutual written consent of the Participants.

Paragraph 7- Resolution of Differences

Any differences that may arise from the interpretation and/or implementation of this MoU will be resolved amicably through consultations between the Participants

Paragraph 8- General Provision

This MoU reflects the intentions of the Participants and is not intended to create legal obligations of any nature, either in domestic or international law. The Participants consent to make the commitment by the obligation of confidentiality outlined in Paragraph IV in respect of any documents that are released to either party under this MoU.

Paragraph 9- Point of Contact

The liaison offices/officials responsible for the administration of this MoU are:

a. for the MFDS: the International Cooperation Office, e-mail: intmfds@korea.kr

b. for the HPRA: the Deputy Chief Executive: Rita Purcell, e-mail: rita.purcell@hpra.ie

Paragraph 10- Entry into Effect, Duration and Termination

1. This MoU will come into effect upon the date of signature by both Participants and will remain in effect until terminated in accordance with Paragraph 10. Either Participant may, at any time, give written notice of termination to the other Participant. This MoU will terminate six months after the date of receipt of the notice of termination.

2. The termination of this MoU will not affect any commitments given under or as a consequence of this MoU in respect of any arrangement or action taken during the period before the termination takes effect, unless otherwise jointly decided by the Participants.

3. Notwithstanding the termination of this MoU, the commitments of the Participants under Paragraph 4 (Confidentiality) will remain in effect.

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

Kim Ganglip
Minister

Date: 21 October 2021

For the Health Products Regulatory Authority of Ireland

Lorraine Nolan
Chief Executive

Date: 21st October 2021

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