MEMORANDUM OF UNDERSTANDING

between

The Federal Department of Home Affairs of the Swiss Confederation

and

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

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

INTRODUCTION

The Federal Department of Home Affairs (FDHA) of the Swiss Confederation and the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (hereinafter referred to as the “Participants”);

Desiring to establish a framework for cooperation in the area of the regulation of therapeutic products;

Have reached the following understanding:

1. OBJECTIVES

(1) The objectives of this Memorandum of Understanding (hereinafter referred to as the "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 and conformity assessment of therapeutic products;

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

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

(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;

b. that this MOU is intended to cover all types of therapeutic products regulated by the Participants and permit meaningful collaboration between them; and

c. that some information may be classified as non-public/confidential information exempt from public disclosure under the laws and regulations of each Participant, such as confidential commercial information, trade secret information, personal privacy information, law enforcement information, or internal pre-decisional information.

2. DEFINITIONS

In this MOU, the term “therapeutic products” means:

a. medicinal products and medical devices as defined in Article 4 (a) and (b) of the Swiss Federal Act on Medicinal Products and Medical Devices 2000 as amended from time to time (Therapeutic Products Act, TPA); and

b. medicinal products (including herbal medicinal products), medical devices or other products or devices related to the regulatory functions of MFDS according to the Pharmaceutical Affairs Act and the Medical Devices Act.

3. AREAS OF COOPERATION

The Participants will:

a. establish avenues of communication to facilitate the exchange of information about the regulation and conformity assessment of therapeutic products by each Participant, including 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, including, where practical, the exchange of personnel.

4. CONFIDENTIALITY

(1) Each Participant may release information, either public or non-public, to the other Participant, subject to each Participants' own applicable laws, policies and procedures.

(2) Any information the Participants received under this MOU will be protected from disclosure according to the applicable national laws of each Participant.

(3) The Participants understand that some information they receive from each other may include confidential information protected from public disclosure under each Participants' laws and regulations.

(4) The Participants understand that any non-public information is shared in confidence, and consider it critical that the other Participant maintains the confidentiality of the information. Public disclosure of this information by one of the Participants could seriously jeopardize any further scientific and regulatory interactions between the Participants.

(5) Each Participant should advise the other of the non-public status of the information at the time that the information is shared. Both Participants state that they have the authority to protect the non-public information provided to each other in confidence from public disclosure.

5. FINANCIAL ASPECTS

Each Participant is responsible for the administration and expenditure of its own resources associated with activities conducted under this MOU.

6. STATUS OF THE MEMORANDUM OF UNDERSTANDING

(1) This MOU is not intended to create any legally binding obligations between the Participants.

(2) Nothing in this MOU will impose an obligation on either Participant to release information, either public or non-public, to the other. It will be a

matter for each Participant to determine if they will release information based on its own applicable laws and policies.

7. LIAISON OFFICERS

The liaison officers responsible for the administration of this MOU are:

a. for Swissmedic, the person holding the position of Head of Networking; and

b. for the MFDS, the person holding the position of Director of International Cooperation Office.

8. ENTRY INTO EFFECT

This MOU will enter into effect on the day on which it is signed by the last Participant.

Signed in duplicate in Berne, on the 20th of January 2014 in the French, Korean and English languages, each text being equally valid. In case of any divergence of interpretation, the English text will prevail.

For the Federal Department of Home Affairs of the Swiss Confederation	For the Ministry of Food and Drug Safety of the Republic of Korea
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