MEMORANDUM OF UNDERSTANDING

BETWEEN

THE FEDERAL DEPARTMENT OF HOME AFFAIRS OF THE SWISS CONFEDERATION

AND

THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

The Federal Department of Home Affairs of Switzerland represented by the Swiss Agency for Therapeutic Products (Swissmedic), and the Ministry of Health of the United Mexican States represented by the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS), hereinafter jointly referred to as the "Participants" wish to establish a framework for cooperation in the area of the regulation of therapeutic products.

2. OBJECTIVES

2.1 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;

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 population; and

e. to agree on an arrangement for the reliance on drug Good Manufacturing Practices inspection reports.

2.2 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 the Participants; and

b. 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.

3. DEFINITIONS

In this MoU “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 as defined in Article 194 BIS of the Health General Law and as amended from time to time.

4. AREAS OF COOPERATION

The Participants declare their intention to:

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

b. undertake collaborative activities, including, where practical, the exchange of personnel;

c. take into consideration the results of drug Good Manufacturing Practices (GMP) inspections carried out by the other Participant (i.e. GMP certificate and/or inspection report) in line with international standards (namely those of the Pharmaceuticals Inspection Cooperation Scheme; PIC/S), when establishing the GMP-conformity of manufacturers as long as its national legislation permits; and

d. include in its processes, mechanisms to streamline the granting of sanitary/marketing authorizations for products previously authorized by the other Participant, according to the applicable national regulations.

5. SPECIFIC COOPERATION PROJECTS

For the implementation of this MoU, the Participants may elaborate specific cooperation projects, in which particular aspects for development of cooperation activities would be detailed.

6. CONFIDENTIALITY

5.1 Each Participant may release either public or non-public information to the other Participant based on each Participant's own laws and policies.

5.2 The release of information would be subject to each Participant's own procedures described in their respective laws and policy guidelines.

5.3 The Participants, so far as possible, will make efforts to maintain the confidentiality of the information exchanged as non-public. The Participants understand that disclosure of non-public information by one of the Participants could seriously jeopardize any further scientific and regulatory interactions between the Participants. Each Participant should make an effort to advise the other when the information be classified as non-public information at the time that the information is shared.

5.4 Both Participants state that they have the authority to protect the non-public information provided to each other in confidence from public disclosure.

7. FINANCIAL ARRANGEMENTS

Each Participant is responsible for the administration and expenditure of the resources associated with the participation of this MoU, considering the resources allocated in their respective budgets according to their availability, budget affectation and the provisions of its national laws.

8. LABOUR RELATIONSHIP

The personnel assigned by each of the Participants to carry out cooperation activities under this MoU, would continue under the directive of the institution to which they belong, so that it may not create any labour relations with the other Participant, nor may they be considered as a substitute or solidary employer.

9. ENTRANCE AND DEPARTURE OF OFFICIALS

It is expected that the officials involved in the cooperation activities for which could be required to leave their country of origin comply with the immigration, tax, customs, health and national security laws of the hosting country and do not engage in any activity unrelated to their functions. Official staff are expected to leave the host country, in accordance with the laws and provisions established.

10. INSURANCE

It is expected that each Participant ensure that the officials involved in cooperation activities have medical, personal injury and life insurance, in order that, in case of an accident resulting from its development, which deserves repair or compensation, all costs be covered by the corresponding insurance company.

11. STATUS

11.1 The MoU is not intended to create any legally binding obligation between the Participants.

11.2 Nothing in this MoU imposes an obligation on either Participant to release information, either public or non-public information to the other Participant. It is a matter for either Participant to determine if they release information based on its own applicable laws and policies.

11.3 Any disputes arising from the interpretation and/or implementation of this MoU may be resolved amicably through consultations between the Participants.

11.4 This MoU comes into effect on the day on which it is signed and may be terminated at any time, by either Participant, preferably by notice with two (2) months in advance, with acknowledgment of receipt.

11.5 Any amendment to this MoU may be made at any time, by mutual written consent of the Participants.

12. POINTS OF CONTACT

The liaison officers for the administration of this MoU are:

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

b. for the COFEPRIS, the person holding the position of Executive Director of International Affairs.

Signed in Mexico City, in duplicate on November 4th, 2016, in the English, French and Spanish languages, all versions being equally valid.

FOR THE FEDERAL DEPARTMENT OF HOME AFFAIRS OF THE SWISS CONFEDERATION

Jürg H. Schnetzer
Executive Director Swissmedic

FOR THE MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES

Julio Salvador Sánchez y Tépoz
Federal Commissioner Against Sanitary Risks