MEMORANDUM OF UNDERSTANDING

between

Swissmedic, the Swiss Agency for Therapeutic Products (Swissmedic)

and

the Medicines Evaluation Board (MEB)

CONCERNING COOPERATION IN THE REGULATION OF THERAPEUTIC PRODUCTS

1. BACKGROUND

The Swiss Agency for Therapeutic Products (Swissmedic), and the Medicines Evaluation Board (MEB) (hereinafter referred to as the "Participants") wish to establish a framework for cooperation in the area of the regulation of therapeutic products. The respective authorities involved with and responsible for the regulation on therapeutic products including regulatory science, pharmacovigilance, regenerative medicines, pharmacopeia have recognized the need to enhance their relationship with increased cooperation, by means of a Memorandum of Understanding (MoU) with respect to the sharing of information.

2. OBJECTIVES

2.1 The objectives of this 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 share experience in scientific advice and regulatory science.

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 1(b), (b1), (c) and (f) of the Dutch national Act on Pharmaceuticals 2007 as amended from time to time.

4. AREA 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, pre-market assessment, post-market surveillance, pharmacovigilance, scientific advice market compliance, regulation of manufacturers and requirements for the regulation of therapeutic products; and

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

5. CONFIDENTIALITY

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

5.2 The release of information is subject to each Participants' own procedures described in the respective laws and policy guidelines.

5.3 Any information the Participants receive under the terms of this MoU is protected from disclosure according to the applicable national laws of each Participant.

5.4 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.

5.5 The Participants understand that this non-public information is shared in confidence, and that each Participant considers 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. Each Participant should advise the other of the non-public status of the information at the time that the information is shared.

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

6. FINANCIAL ARRANGEMENTS

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

7. STATUS

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

7.2 Nothing in this MoU will impose 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 should release information based on its own applicable laws and policies.

7.3 The MoU will come into effect on the day on which it is signed by the last Participant.

8. AGENCY 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 MEB, the person holding the position of International relations.

Signed in Washington DC, United States of America on 10 September 2018

For Swissmedic, Swiss Agency for Therapeutic Products

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Dr. Raimund T. Bruhin,
Executive Director of Swissmedic, Swiss Agency for Therapeutic Products

Signed in Washington DC, United States of America on 10 September 2018

For the Medicines Evaluation Board

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Hugo Hurts,
Executive Director of the Medicines Evaluation Board

For the Medicines Evaluation Board of the Netherlands

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Dr. A. de Boer
Chair of the Board of the MEB