MEMORANDUM OF UNDERSTANDING

BETWEEN THE

HEALTH SCIENCES AUTHORITY
OF SINGAPORE

AND

THE FEDERAL DEPARTMENT OF HOME AFFAIRS
ACTING IN THE NAME OF THE FEDERAL COUNCIL
OF THE SWISS CONFEDERATION

REGARDING THERAPEUTIC PRODUCTS

I. BACKGROUND

1. The Health Sciences Authority of Singapore (HSA), and the Federal Department of Home Affairs, Switzerland (FDHA), share the common goal of protecting the health and safety of their respective populations by ensuring the safety, quality and efficacy of Therapeutic Products, manufactured in, imported into, and exported from, their respective countries.

2. The HSA and FDHA share a high regard for each other's regulatory practices and systems.

II. PURPOSE

1. On the basis of this Memorandum of Understanding (MOU) the HSA and Swissmedic, Swiss Agency for Therapeutic Products (Swissmedic), acting in the name of FDHA, hereafter referred to as "the Participants", will:

a. facilitate the exchange of information and sharing of documentation relating to the regulation of Therapeutic Products, to advance and improve policy and operational regulatory affairs from the pre-market to the post-market lifecycle of Therapeutic Products and to enable the Participants to acquire reciprocal knowledge and understanding of each other's regulatory requirements and processes and to improve the safety, quality and efficacy of Therapeutic Products marketed in each country.

b. encourage the development of collaborative activities relating to the regulation of Therapeutic Products.

2. Information and documentation that may be exchanged under this MOU may only be used for the purposes of this MOU.

3. The circumstances under which information and documentation may be exchanged include:

a. where either Participant has already completed a particular regulatory activity, and the other Participant requires insight into issues that arose during that activity, and how those issues were dealt with during the final decision-making process, or

b. where the Participants are carrying out a particular regulatory activity synchronously, and would like to share information about their process(es) and/or issues that have been identified.

4. This MOU does not modify existing cooperative activities nor does it preclude entering into separate arrangements for specific activities that can be handled more efficiently by special arrangements.

5. Nothing in this MOU is intended to diminish or otherwise affect the authority of either Participant in carrying out its regulatory responsibilities.

III. DEFINITIONS

1. In this MOU:

"Concerned Person" in relation to Non-public Information, means any individual or other legal person to whom the Non-public Information relates.

"Non-public Information" means any information not in the public domain that is held by a Participant and is treated as confidential by that Participant in accordance with laws applicable to the Participant.

"Therapeutic Products" means:

a. medicinal products and medical devices as defined in Article 4.1 (a) and (b) of the Swiss *Federal Law on Medicinal Products and Medical Devices 2000* as amended from time to time (Law on Therapeutic Products); and

b. Therapeutic goods as defined in Section 2(1) of the Health Products Act 2007 and its First Schedule, and in Section 3 of the Medicines Act (Chapter 176), as amended from time to time.

"Vigilance Information" means information relating to the monitoring and study of the effects and other safety-related aspects of Therapeutic Products that have been approved and/or are marketed to the public, e.g., product safety assessments, individual adverse event reports, adverse event trend information, health hazard evaluations and alert system notifications as appropriate.

IV. SCOPE

1. The types of information and documentation that may be exchanged include:

   a. Guidance documents, policies, procedures, and other technical documents for which the Participants have responsibility.

   b. Information related to the categorization of Therapeutic Products pre-market applications, e.g., priority review status, orphan drug designation, etc.

   c. Information contained in, and about, clinical trial or investigational applications for Therapeutic Products, including adverse event reports or evaluation reports from the various discipline reviews, e.g., chemistry and manufacturing, clinical, etc.

   d. Information about ongoing clinical trials for Therapeutic Products, including information related to clinical trial site inspections directed at determining compliance with good clinical practice.

   e. Information contained in, or about, Therapeutic Products marketing applications, including evaluation reports from the various discipline reviews, e.g., chemistry and manufacturing, clinical, etc., and results from any on-site evaluations.

   f. Information that supports the conformity of Therapeutic Products with applicable regulatory requirements, including the results from pre-approval consistency testing, post-approval lot release testing and information on testing methodologies or algorithms for biological pharmaceuticals, or product sample test results for chemical pharmaceuticals.

   g. Information related to compliance and completed enforcement activities, e.g., product or establishment investigations.

   h. Information regarding the suppliers of Therapeutic Products that are the subject of specific shortage situations in either jurisdiction.

   i. Inspection reports, or other information, that supports the compliance of facilities that manufacture, wholesale, test or import Therapeutic

Products, with applicable regulatory requirements.

j. Information on facilities licensed, registered or authorized in each Participant's country that then market Therapeutic Products in the other Participant's country.

k. Information related to import refusals for reasons related to the safety, quality, or integrity of a shipment.

l. Post-market surveillance information having potential impact on public health, including Vigilance Information, and information about impending regulatory actions, e.g., proposed market withdrawals and product recalls.

m. Information on safety and quality defects reported for, and product recalls effected for, Therapeutic Products manufactured and/or supplied in Singapore or Switzerland.

n. Information on practices and procedures relating to the development of policy, regulation or legislation, including strategies designed to ensure that regulatory processes are transparent and open. Information regarding risk management, risk communication, or public involvement strategies, and consideration for ethical or other socio-economic issues in the development of new regulatory frameworks.

o. Information on technology, e.g., information management systems, database systems, and other related computer applications that support the evaluation, testing and investigation of Therapeutic Products, the tracking of Therapeutic Products applications, or the inspection of facilities in which Therapeutic Products are manufactured.

p. Any other information technology or systems that may be mutually agreed upon from time to time.

2. Collaborative activities may include the exchange, training and development of professional competence in the evaluation, assessment or regulation of specific Therapeutic Products, collaborative research relating to the quality, safety or efficacy of Therapeutic Products, and the planning of joint workshops, conferences, seminars or meetings for the mutual benefit of each other.

   The Participating Parties will collaborate, where appropriate, (and where necessary, establish joint working groups) to assess new and emerging technologies and the risk management strategies associated with such innovations. This may include, but will not be limited to :

   - Laboratory testing and validation methodologies
   - Laboratory proficiency testing programs
   - Information collection and sharing; and
   - Consideration of regulatory guidelines for Therapeutic Products.

V. ACKNOWLEDGMENT

1. The Participants acknowledge that the information and documentation described in Section IV, Scope, will only be exchanged at the request of either Participant.

2. The purpose of exchanging information and documentation is to enhance each Participant's regulatory processes and decision-making practices.

3. The HSA is authorized to exchange information and documentation in accordance with Section 19B(1)(c) (iii) of the Medicines Act.

4. Swissmedic is authorised to exchange information and documentation in accordance with Article 64 of the *Law on Therapeutic* Products and within the scope of the *Swiss legislation on Data Protection.*

VI. CONFIDENTIALITY

1. SWISSMEDIC

   1.1 Before releasing any Non-public Information to the HSA regarding Therapeutic Products, Swissmedic will obtain the consent of any Concerned Person – if required by Swiss legislation - to the provision of such information to the HSA in accordance with this MOU. When seeking such consent, Swissmedic will inform any Concerned Person of the purposes for which the HSA might use the information, and that the HSA has consented to treat the information as confidential in so far as it is not already in the public domain in Singapore.

   1.2 Swissmedic will inform the HSA of the response from any Concerned Person to a request for consent under clause 1.1.

   1.3 Unless otherwise required by law, Swissmedic will make all reasonable efforts to protect the confidentiality of any information it receives from the HSA from disclosure to any third parties, and will not release it to any persons other than Swissmedic staff or contractors who need to know the information for work purposes, except with written consent from the HSA or written confirmation from the HSA that the information has been made public in Singapore.

   1.4 Refusal of a Concerned Person to share information as outlined in this MOU will not affect the regulatory processes for which purposes it was originally prepared.

2. HSA

   2.1 Before releasing any Non-public Information to Swissmedic relating Therapeutic Products, the HSA will obtain the consent of any Concerned Person. When seeking such consent, the HSA will inform any Concerned

Person of the purposes for which Swissmedic might use the information and that Swissmedic has consented to treat the information as confidential in so far as it is not already in the public domain in Switzerland.

2.2 The HSA will inform Swissmedic of the response from any Concerned Person to a request for consent under clause 2.1.

2.3 Unless otherwise required by law, the HSA will make all reasonable efforts to protect the confidentiality of any information it receives from Swissmedic from disclosure to any third parties, and will not release it to any persons other than HSA staff or contractors who need to know the information for work purposes, except with written consent from Swissmedic or written confirmation from Swissmedic that the information has been made public in Switzerland.

2.4 Refusal of a Concerned Person to share information as outlined in this MOU will not affect the regulatory processes for which purposes it was originally prepared.

VII. ROLES AND RESPONSIBILITIES

1. The Participants note that the exchange of information and documentation, if any, should be made by written request between identified contact points in each organization.

2. The Participants will provide any information or documentation free of charge.

3. The Participants will establish a steering committee for regular bilateral meetings (in person or by teleconference/ videoconference) as a means of facilitating the development of collaborative activities (refer to Section VIII, Steering Committee).

4. The Participants acknowledge that, where appropriate, certain collaborative activities may need to be carried out under a separate arrangement.

5. For the purposes of strengthening the relationship between their respective organizations, the Participants will endeavour to invite each other to their scientific meetings and/or regulatory training events.

VIII. STEERING COMMITTEE

1. The steering committee will be comprised of representatives from both Participants.

2. The steering committee will meet at least once annually either in person or by video/teleconferencing or at a mutually agreed opportunity.

The role of the steering committee will include regular:

a. reviewing of the scope and operation of the MOU;
b. monitoring of the activities performed under this MOU; and
c. reporting to the Participants.

3. The steering committee will be co-chaired by the Participants of this MOU or as mutually agreed upon.

4. Working parties may be established on topics agreed by the steering committee.

IX. ADMINISTRATION

1. The officers responsible for the administration of this MOU are:

   a. for the HSA, the person holding the position of Administrator, Health Products Regulation Group, or any person designated by the CEO of HSA; and

   b. for Swissmedic, the person holding the position of Head of Management Services and Networking, or any person designated by the Executive Director of Swissmedic.

2. The Participants will promptly notify each other of changes in their respective legislation, operational policies, practices and procedures relating to matters covered by this MOU, and which might impact on their ability to cooperate as intended by this MOU.

3. Either Participant may propose variations to the provisions of this MOU, but such variations must be subject to consultation between the Participants, and must be consented to in the form of a written amendment to this MOU by both Participants.

4. This MOU defines, in general terms, the basis on which the Participants intend to cooperate, and does not constitute a financial obligation or serve as a basis for expenditure. Each Participant will be solely responsible for the administration and expenditure of its own resources.

X. COMMENCEMENT AND TERMINATION

1. This MOU will commence on the day on which it is signed by the last Participant.

2. Either Participant may terminate this MOU by giving written notice to the other Participant. The MOU will then terminate 30 calendar days after the date of receipt of the intention to terminate.

3. Section VI, Confidentiality, will continue to apply between the Participants notwithstanding termination of, or withdrawal from, the Memorandum from either of the Participants.

4. The Participants may evaluate this MOU at any time, and may amend it by written consent of both Participants, and any such amendments would come into effect on a date determined by the Participants.

XI. GENERAL

1. All activities of FDHA and the HSA undertaken pursuant to this MOU are to be conducted in accordance with the laws and regulations of Switzerland and Singapore respectively. These activities are also subject to the availability of personnel, resources and funds.

Signed in duplicate, Singapore, on this 12 May, 2008.

FOR THE HEALTH SCIENCES AUTHORITY
OF SINGAPORE

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Dr. John C. W. Lim
Chief Executive Officer

Signed in duplicate, Singapore, on this 12 May, 2008.

FOR THE
FEDERAL DEPARTMENT OF HOME AFFAIRS
ACTING IN THE NAME OF THE SWISS FEDERAL COUNCIL
OF THE SWISS CONFEDERATION

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Mr. Rolf Frei
Chargé d'Affaires of Switzerland a.i.