MEMORANDUM OF UNDERSTANDING

BETWEEN THE

FEDERAL DEPARTMENT OF HOME AFFAIRS
ACTING ON BEHALF OF THE FEDERAL COUNCIL OF THE SWISS CONFEDERATION

AND THE

THERAPEUTIC GOODS ADMINISTRATION
DEPARTMENT OF HEALTH OF AUSTRALIA

REGARDING

THERAPEUTIC PRODUCTS

I. BACKGROUND

1. The Therapeutic Goods Administration, Department of Health, Australia (TGA), 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 TGA 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 TGA and Swissmedic (the Swiss Agency for Therapeutic Products), acting in the name of FDHA, hereafter referred to as "the Participants", will:

   a. facilitate the exchange of information and documentation relating to the regulation of Therapeutic Products, and

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

2. Information and documentation that is exchanged under this MOU will 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. 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 (a) and (b) of the Swiss *Federal Act on Medicinal Products and Medical Devices 2000,* as amended from time to time (Act on Therapeutic Products); and

b. Therapeutic goods as defined in Section 3 of the Australian *Therapeutic Goods Act 1989*, as amended from time to time.

"Vigilance Information" means information relating to the monitoring for, 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, or 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 Australia 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.

o. 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.

p. 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.

2. Collaborative activities may include the exchange of personnel, collaborative research relating to the quality, safety or efficacy of Therapeutic Products, and the planning of joint workshops, conferences, seminars or meetings.

V. ACKNOWLEDGMENT

1. The Participants acknowledge that the information and documentation described in Section IV, Scope, will, other than in the case of information exchanged to avoid serious health risks, 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 TGA is authorized to exchange information and documentation in accordance with Section 61(5) of the *Therapeutic Goods Act 1989*.

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 TGA 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 TGA in accordance with this MOU. When seeking such consent, Swissmedic will inform any Concerned Person of the purposes for which the TGA might use the information, and that the TGA has consented to treat the information as confidential in so far as it is not already in the public domain in Australia.

1.2 Swissmedic will inform the TGA 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 TGA 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 TGA or written confirmation from the TGA that the information has been made public in Australia.

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. TGA

2.1 Before releasing any Non-public Information to Swissmedic relating to Therapeutic Products, the TGA will obtain the consent of any Concerned Person – if required by Australian legislation – to the provision of such information to Swissmedic in accordance with this MOU. When seeking such consent, the TGA 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 TGA will inform Swissmedic of the response from any Concerned Person in cases where consent is sought, or notification is given under clause 2.1.

2.3 Unless otherwise required by law, the TGA 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 TGA 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 between identified contact points in each organization.

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

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

4. 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. ADMINISTRATION

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

   a. for the TGA, the person holding the position of Head, Office of Parliamentary and Strategic Support; and

   b. for Swissmedic, the person holding the position of Head of Networking.

2. The Participants will 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 commitments or serve as a basis for expenditure. Each Participant will be solely responsible for the administration and expenditure of its own resources.

IX. 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 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 the Memorandum by either of the Participants.

X. ENHANCEMENT OF COOPERATION

1. It is the mutual understanding of the Participants that this MOU will be the basis for building confidence in each other's regulatory system with the goal of establishing a mutual recognition agreement in areas to be defined by the Participants over time.

XI. RELATION TO EARLIER MOU

1. This Memorandum of Understanding terminates and replaces the Memorandum of Understanding of 29 March 2006 between the Federal Department of Home Affairs acting in the name of the Federal Council of the Swiss Confederation and the Therapeutic Goods Administration Department of Health and Ageing of Australia regarding therapeutic products, as amended by exchange of notes of 28 February/5 March 2007.

2. This MOU does not preclude entering into separate arrangements for specific activities that can be handled more efficiently by special arrangements.

Signed in duplicate in the English language.

FOR THE FEDERAL DEPARTMENT OF HOME AFFAIRS
SWITZERLAND

27 July 2015

Jürg H. Schnetzer
Executive Director Swissmedic

FOR THE THERAPEUTIC GOODS ADMINISTRATION
DEPARTMENT OF HEALTH
AUSTRALIA

22 July 2015

Adjunct Professor John Skerritt
Deputy Secretary for Regulatory Services