Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Home Affairs FDHA

ARRANGEMENT

BETWEEN THE

NEW ZEALAND MINISTRY OF HEALTH

AND

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

REGARDING THERAPEUTIC PRODUCTS

The New Zealand Ministry of Health, acting for and on behalf of the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) and the Federal Department of Home Affairs, Switzerland acting for and on behalf of the Swiss Agency for Therapeutic Products (Swissmedic), hereinafter referred to as "the Participants" have reached the following understandings regarding therapeutic products:

I. BACKGROUND

1. The Participants share the common goal of protecting the health and safety of their respective populations by ensuring the safety, quality and efficacy or performance of Therapeutic Products, manufactured in, imported into, and exported from, their respective countries.

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

II. PURPOSE

1. This Arrangement is intended to enhance the ability of the Participants in protecting and promoting health in their respective countries.

2. The Participants have mutually decided that on the basis of this Arrangement they may:

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

improve regulatory 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.

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

4. 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 would like information about the 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.

5. This Arrangement 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.

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

III. DEFINITIONS

In this Arrangement:

"Affected 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 Law on Medicinal Products and Medical Devices 2000* as amended from time to time (Law on Therapeutic Products); or

b. medicines and medical devices as defined in sections 3 and 4 of the Medicines Act 1981 of New Zealand 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. AREAS OF VOLUNTARY COOPERATION

1. The types of information and documentation that may be exchanged on a voluntary basis 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 New Zealand or Switzerland.

n. Information on practices and procedures relating to the development of regulatory 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.

q. Any other information technology or systems as mutually decided from time to time by the Participants.

2. Voluntary 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 Participants may 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 Paragraph IV should only be exchanged at the request of either Participant.

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

3. Medsafe has the general authority to exchange information and documentation under the Medicines Act 1981, subject to the requirements of the data protection provisions in this Act or any other legislation.

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. Transmission of confidential information may be made in accordance with the following confidentiality guidelines.

1.1 SWISSMEDIC

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

b. Swissmedic will inform Medsafe of the response from any Affected Person to a request for consent under sub-paragraph 1.1 (a).

c. Swissmedic will make all reasonable efforts to protect the confidentiality of any information it receives from Medsafe from disclosure to any third parties and persons other than Swissmedic staff or contractors who need to know the information for work purposes according to the applicable Swiss legislation.

d. Refusal of an Affected Person to share information as outlined in this Arrangement will not affect the regulatory processes for which purposes it was originally prepared.

1.2 MEDSAFE

a. Before releasing any Non-public Information to Swissmedic relating to Therapeutic Products, Medsafe will obtain the consent of any Affected Person and give effect to any applicable New Zealand legal requirements, including the Official Information Act 1982 and the Privacy Act 1993. When seeking such consent, Medsafe will inform any Affected 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.

b. Medsafe will inform Swissmedic of the response from any Affected Person to a request for consent under sub-paragraph 1.2(a).

c. Medsafe will make all reasonable efforts to protect the confidentiality of any information it receives from Swissmedic from disclosure to any third parties and persons other than Medsafe staff or contractors who need to know the information for work purposes according to the applicable New Zealand legislation.

d. Refusal of an Affected Person to share information as outlined in this Arrangement will not affect the regulatory processes for which purposes it was originally prepared.

2. The Participants understand that some of the information they receive from each other may include confidential information protected from public disclosure under the New Zealand/Swiss laws and regulations.

Therefore, the Participants

a. will endeavour to protect from public disclosure the confidential information provided to each other in confidence, subject to the applicable New Zealand/Swiss legislation;
b. may inform each other within two working days of any effort made to obtain confidentially-provided information by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of confidentially-provided information, the Participants may take all legally possible measures to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and
c. will endeavour to inform each other as soon as possible of any changes to New Zealand/Swiss laws, policies or procedures that would affect the Participant´s ability to honour the provisions in this document.

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. No charge should be connected to the provision of any information or documentation.

3. In order to ensure smooth implementation of this Arrangement the Participants may establish a steering committee for regular bilateral meetings (in person or by teleconference/ videoconference) as a means of facilitating the development of collaborative activities (as provided for in paragraph VIII).

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 should be comprised of representatives from both Participants.

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

   The role of the steering committee may include:
   a. reviewing of the scope and operation of the Arrangement;
   b. monitoring of the activities performed under this Arrangement; and
   c. reporting to the Participants.

3. The steering committee may be co-chaired by the Participants or otherwise as mutually decided by the Participants.

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

IX. ADMINISTRATION

1. Each Participant may identify an officer responsible for the administration of this Arrangement. These should be:

   a. for Medsafe, the person holding the position of Principal Advisor Regulation, or any person designated by the Group Manager of Medsafe; 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 endeavour to notify each other as soon as possible of changes in their respective legislation, operational policies, practices and

procedures relating to matters covered by this Arrangement, and which might impact on their ability to cooperate as intended by this Arrangement.

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

X. COMMENCEMENT, REVIEW AND AMENDMENT

1. The Arrangement will enter into effect on the day on which it is signed by the last Participant.

2. The Participants may evaluate this Arrangement at any time and propose amendments to it. Any proposed amendments will be subject to consultations between the Participants. Amendments may be made to the Arrangement with the mutual written consent of the Participants and will enter into effect on a date as determined by the Participants in the circumstances of the particular amendment.

XI. GENERAL

All activities of the Participants undertaken pursuant to this Arrangement should be conducted in accordance with the national laws and regulations of the respective Participants. These activities should also be subject to the availability of personnel, resources and funds.

Signed in duplicate, at Ottawa, Canada, on this 15 October 2009.

FOR the New ZEALAND MINISTRY OF HEALTH

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Dr Stewart Jessamine
Group Manager Medsafe

Signed in duplicate, at Ottawa, Canada, on this 15 October 2009.

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

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Jürg H. Schnetzer
Director, Swiss Agency for Therapeutic Products