

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA
OF CANADA

AND THE

THERAPEUTIC GOODS ADMINISTRATION
DEPARTMENT OF HEALTH AND AGEING
OF AUSTRALIA

REGARDING THERAPEUTIC PRODUCTS

I. PREAMBLE

The Health Products and Food Branch, Health Canada, Canada, and the Therapeutic Goods Administration, Department of Health and Ageing, Australia 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.

The Health Products and Food Branch and the Therapeutic Goods Administration share a high regard for each other's regulatory practices and systems.

II. PURPOSE

1. This Memorandum of Understanding (MOU) establishes an arrangement between the Health Products and Foods Branch (HPFB) and the Therapeutic Goods Administration (TGA), hereafter referred to as "the Participants", that 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 that may be exchanged under this MOU may only be used for the purposes of this MOU.
3. The circumstances under which information or documentation may be exchanged include:
 - a. where either Participant has already completed a particular regulatory activity, and 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:

“Biological” means of human, animal, plant or microbial origin;

“Drug” means substance or mixture of substances sold, manufactured or represented:

- for use in diagnosis, mitigation, treatment or prevention of a disease, disorder or abnormal physical state in humans or animals
- for use in restoring, correcting or modifying organic functions in humans or animals
- for use in disinfection of premises where food is manufactured or kept;

“Medicine” means

- therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and
- any other therapeutic goods declared by the Secretary, for the purpose of the definition of *therapeutic device*, not to be therapeutic devices.

“Pharmacovigilance Information” means information relating to the monitoring for, and study of, effects and other safety-related aspects of drugs and/or medicines that have been approved and 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;

“Supply” means

- supply by way of sale, exchange, gift, lease, loan, hire or hire purchase; and
- supply, whether free of charge or otherwise, by way of sample or advertisement; and
- supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons or animals; and
- supply by way of administration to, or application in the treatment of, a person or animal;

“Therapeutic Products” means pharmaceutical products of chemical or biological origin (including active pharmaceutical ingredients, bulk drug and/or medicinal substances and finished dosage forms), medical devices, disinfectants, natural health products/ complementary medicines, radiopharmaceutical products intended for human use, human blood and blood components intended for transfusion, xenografts, and human cells, tissues and organs intended for transplantation;

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 Product 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 Product 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 Pharmacovigilance 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 Canada or Australia.
 - 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 Product 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 Biological pharmaceuticals, 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 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. The Participants acknowledge that information provided in support of applications filed with the TGA will be treated as confidential information for the purposes of the *Freedom of Information Act 1997*. The TGA will therefore seek the written consent of the applicant prior to providing any information contained in said applications to HPFB.
5. The Participants acknowledge that it is the policy of HPFB to treat all information provided in support of applications to HPFB as confidential information. Likewise, all of HPFB's evaluation reports are also considered confidential information. In addition, HPFB treats all information received as if it were confidential information for the purposes of the Access to Information Act and the Privacy Act. HPFB will therefore seek the written consent of the applicant prior to providing any information contained in said applications to the TGA.

VI. CONFIDENTIALITY

1. HPFB
 - 1.1 Before releasing any information to the TGA regarding Therapeutic Product applications, HPFB will obtain the consent of the applicant to the provision of such information to the TGA in accordance with this MOU. When seeking such consent, HPFB will inform the applicant of the purposes for which the TGA might use the information, and that the TGA has agreed to treat the information as confidential in so far as it is not already in the public domain in Australia.
 - 1.2 HPFB agrees to inform the TGA of the applicant's response to a request under clause 1.1.
 - 1.3 Unless otherwise required by law, HPFB 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 HPFB 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 the applicant to share information as outlined in this MOU will not affect the regulatory processes for which purposes it was originally submitted.

2. TGA

- 2.1 Before releasing any information to HPFB regarding Therapeutic Product applications, the TGA will obtain the consent of the applicant to the provision of such information in accordance with this MOU. When seeking such consent, the TGA will inform the applicant of the purposes for which HPFB might use the information, and that HPFB has agreed to treat the information as confidential in so far as it is not already in the public domain in Canada.
- 2.2 The TGA agrees to inform HPFB of the applicant's response to a request 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 HPFB 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 HPFB or written confirmation from HPFB that the information has been made public in Canada.
- 2.4 Refusal of the applicant to share information as outlined in this MOU will not affect the regulatory processes for which purposes it was originally submitted.

VII. ROLES AND RESPONSIBILITIES

1. The Participants agree 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 agree to provide any information or documentation free of charge.
3. The Participants agree to establish a mechanism for regular bilateral meetings (in person or by teleconference/ videoconference) as a means of facilitating the development of collaborative activities. The Participants acknowledge that, where appropriate, certain collaborative activities may need to be carried out under a separate agreement.

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 Executive Director, Trans Tasman and Business Management Group, and
 - b. for HPFB, the person holding the position of Director General, Office of Regulatory and International Affairs, HPFB.
2. The Participants agree to 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 agreed to in writing 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.

IX. COMMENCEMENT, REVIEW AND TERMINATION

1. This MOU will commence on the day on which it is signed by the last participant.
2. On the first anniversary of this MOU, the officers responsible for this MOU will review the flow of information between the Participants and the scope of the arrangements, and determine if amendment(s) are required.
3. 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.

Signed in duplicate, at Ottawa, Canada on this fourteenth day of April, 2004.

FOR THE HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA
CANADA

Diane C. Gorman,
Assistant Deputy Minister

Signed in duplicate, at Ottawa, Canada, on this fourteenth day of April, 2004.

FOR THE THERAPEUTIC GOODS ADMINISTRATION
DEPARTMENT OF HEALTH AND AGEING
AUSTRALIA

Terry Slater,
National Manager