Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Director-General

Pharmaceutical and Food Safety Bureau

Ministry of Health, Labour and Welfare

Chief Executive

Pharmaceuticals and Medical Devices Agency

Dear Mr. Yoshiyuki Kikura and Dr Tatsuya Kondo,

The **Ministry of Health, Labour and Welfare (MHLW)'s Pharmaceutical and Food Safety Bureau** and the **Pharmaceuticals and Medical Devices Agency (PMDA)** of Japan on the one side, and the **Therapeutic Goods Administration (TGA)** of Australia on the other side, the respective authorities responsible for the regulation of therapeutic products in Australia and Japan (hereinafter referred as "the Participants"), have recognised the need to enhance their relationship with increased cooperation, by means of an exchange of letters, in respect of the sharing of information.

The purpose of this exchange of letters is to facilitate the exchange of information and documentation relating to the regulation of therapeutic products, and to allow for the exchanged information and documentation to be used by the Participants to assist them in carrying out their regulatory functions and duties. It will provide improved regulatory

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

performance and safety of therapeutic products as a result of the involvement of the best regulatory expertise from each of the Participants, strengthen communication between the Participants, and enhance their ability to protect and promote the health and safety of the populations of their respective countries in carrying out their respective functions and responsibilities.

The Participants recognise that each Participant has jurisdiction over specific products, and defines those products differently. Collaboration under this exchange of letters is intended to cover all types of therapeutic products regulated by the Participants, and to permit meaningful collaboration between them. As such, this could include an expansion of scope by any participant in the future.

The TGA is therefore pleased to co-operate with the MHLW and PMDA to facilitate the sharing of information related to the safety, quality and efficacy or performance of:

- 'therapeutic goods' as defined by the Australian *Therapeutic Goods Act 1989*, as amended from time to time; and
- 'drugs', 'medical devices', 'quasi-drugs' and 'cosmetics' as defined by the *Pharmaceutical Affairs Law of Japan (Law No. 145, 1960)*

This exchange of letters does not compromise the regulatory authority of any of the Participants to carry out their respective regulatory responsibilities and programs, nor does it create legally binding obligations on any of the Participants or amongst them to share information with each other. It will not modify existing cooperative activities, or preclude the Participants from entering into separate arrangements for specific activities that could be handled more efficiently by special arrangements.

Each Participant will be solely responsible for the administration and expenditure of its

own resources associated with activities conducted under this exchange of letters.

Each Participant recognises that information exchanged between them may include confidential information that is not in the public domain in the country of the Participant providing the information. The Participants share the recognition that it is essential that confidential information emanating from one Participant will be treated as such by the other Participant.

The types of information or documents that may be shared include, but are not limited to:

- guidance documents, policies, procedures and other technical documents for which the Participants have responsibility, including draft and final documents;
- post-market vigilance data, particularly those of an urgent nature as well as safety concerns arising from periodic safety update reports and post-authorisation responsibilities and commitments;
- risk management plans;
- information contained in applications for scientific advice, orphan designation, marketing authorisation, post-authorisation activities and activities of significant public health interest ;
- information related to the regulation of manufacturers;
- information relating to laboratory testing of therapeutic products, including testing methodologies or algorithms, and test results;
- information relating to any cases, or possible cases, of counterfeit therapeutic products;
- information relating to administrative arrangements including fees and charges; and
- information technology systems supporting regulatory processes.

The Participants are permitted to limit the information that may be shared, should its dissemination or exchange undermine any government policy, specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of Japan or Australia, or the protection of the Participants' interests in the confidentiality of their proceedings. In some cases, exchange of information under this exchange of letters may be subject to prior authorisation from third parties concerned, including the companies responsible for the supply of the therapeutic products in the Participant's jurisdiction.

Each Participant will make every reasonable effort to prevent: (a) the public release of confidential information that has been shared for the purposes set out in this exchange of letters; and (b) any other release of this information for purposes not set out in this exchange of letters.

Confidential information may be used by the other Participant, or shared with the non-participants set out in the next paragraph below, without the prior written consent of the individual or entity to whom the information relates, so long as it is only for the purposes contemplated in this exchange of letters, and provided that such disclosure or use is in accordance with the laws and regulations as well as the policies of their respective countries and their procedures permitted by those laws and regulations.

Information provided by one Participant to another may be shared with the receiving Participant's employees, agents or contractors who: (a) require the information solely for work related to the delivering of the functions and responsibilities of the Participant, who will only use that information for purposes contemplated by this exchange of letters; and (b) will have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, confidentiality contract or other document that permits

those persons to use the information for the purposes of this exchange of letters, and requires them to protect the confidentiality of the information in accordance with the laws and regulations of the country of the Participant who receives the information.

The Participants will consult with each other on each occasion where there is a request for public disclosure or disclosure to non-participants other than those set out in the preceding paragraph, of confidential information received from any of the Participants.

Each Participant will make all reasonable efforts to inform the other of any effort made pursuant to a judicial, legislative or other authority to obtain confidential information that has been provided by one Participant to the other Participant. If public disclosure is required by such authorities, the other Participant will consult with the Participant which provided the information before disclosing any information.

Each Participant will make all reasonable efforts to inform the other Participant of any changes to the laws and regulations as well as the policies of their respective countries or their procedures that may affect their treatment of confidential information obtained from the other Participant.

The Participants consider it crucial to the sustainability of this exchange of letters, and future cooperation, that confidential information shared between their respective agencies be protected in accordance with the laws and regulations as well as the policies of their respective countries, from unauthorised use and disclosure.

The Participants acknowledge that requests for information will be made to designated officers responsible for the administration of this exchange of letters within their own agency. Unless otherwise notified in writing, the contact points for matters relating to this exchange of letters are as follows: (a) for MHLW, the International Planning Director; and for PMDA, the Director, Division of Regulatory Cooperation, Office of International

Programs; and (b) for TGA, the Head, Office of Parliamentary and Strategic Support.

The cooperation set out in this exchange of letters commences upon the date of the last letter of the exchange. This cooperation will continue unless it is terminated by either Participant, in writing, on 30 days notice to the other Participant. Upon termination of this cooperation, the Participants will continue to treat confidential information that has been shared under this cooperation as such, and to protect it from unauthorised disclosure and use in accordance with the laws and regulations of their respective countries, as well as the practices and procedures permitted by those laws and regulations.

This exchange of letters embodies the common recognition of the participants. It does not create legal relations and is not governed by international law.

We look forward to implementing the cooperative relationship allowing for the sharing of information, and to continuing cooperative activities to further enhance the relationship between the MHLW, the PMDA, and TGA in the best interests of public health.

Yours sincerely,

Dr Rohan Hammett

National Manager

Therapeutic Goods Administration

6 September, 2011