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Tatsuya Kondo
Chief Executive
Pharmaceuticals and Medical
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Tokyo 100-0013 Japan

Dear Mr. Yasuyuki Takai and Dr. Tatsuya Kondo,

The Health Products and Food Branch (HPFB), and the Healthy Environments and Consumer Safety Branch (HECSB) of Health Canada on the one side, and the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan on the other side, the respective authorities involved with and responsible for the regulation of therapeutic products and consumer safety in Canada and Japan (hereinafter collectively referred to as "the Participants"), have recognized the need to enhance their relationship with increased cooperation, by means of an exchange of letters, in respect of the sharing of information.

There is already considerable experience in the field of regulatory and administrative cooperation between the Participants in the pharmaceutical, medical device and cosmetic sector. To date, such cooperation has been done through the International Conference on Harmonization (ICH), the Global Harmonization Task Force (GHTF) and the International Cooperation on Cosmetic Regulations (ICCR).

The success of existing regulatory co-operative measures on harmonization of technical requirements and a common format for the submission of certain regulatory information to the respective pharmaceutical regulatory authorities has led to the desire from the Participants to increase the range of information that can be shared in the interests of better regulatory cooperation.

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

The purpose of this exchange of letters is to facilitate increased access to safe, effective and high quality products, and share information related to these products. Consequently, it will provide improved regulatory performance and safety as a result of the involvement of the best regulatory expertise from both sides. This exchange of letters will also strengthen communication between the Participants and enhance their ability to protect and promote the health and safety of their respective populations in carrying out their respective mandates.

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.

Each Participant understands 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 note that it is essential that confidential information emanated from one Participant will be treated as such by the other Participants. 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.

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Confidential information may be shared with or used by the other Participants, 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 and procedures permitted by those laws and regulations applicable to the respective Participant.

Information provided by one Participant to the other may be shared with the receiving Participant's employees, agents or contractors who require the information solely for work related to the delivering of the mandate of the Participant, who will only use that information for purposes contemplated by this exchange of letters, and who 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 that are applicable to 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 another 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 Participants of any changes to their respective laws, policies or procedures that may affect their treatment of confidential information obtained from the other Participants.

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The Participants consider it crucial to the sustainability of this exchange of letters and future cooperation that confidential information shared between their respective agencies or branches be protected in accordance with their respective laws, regulations and policies, from unauthorized 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 or branch. Unless otherwise notified in writing by one Participant to the other, the contact points for matters relating to this exchange of letters are as follows: (a) for Health Canada, the Director of International Affairs of the Policy, Planning and International Affairs Directorate for HPFB; and the Head of Cosmetics, HECSB; and (b) for MHLW, the International Planning Director; and for PMDA, the Director, Division of Regulatory Cooperation, Office of International Programs.

The sharing of information 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 Participants. 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 unauthorized disclosure and use in accordance with their respective laws and regulations as well as the practices and procedures permitted by those laws and regulations.

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 Health Canada, the MHLW, and the PMDA in the best interests of public health.

Yours sincerely,

Meena Ballantyne
Assistant Deputy Minister
Health Products and Food Branch

Paul Glover
Assistant Deputy Minister
Healthy Environments and
Consumer Safety Branch