Ministry of Health Labour and Welfare Pharmaceuticals and Medical Devices Agency

Chicago; 20 June 2017

Dear Dr. Jaap Venema

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, the authority involved with and responsible for the regulation of therapeutic products in Japan, and the United States Pharmacopeial Convention (USP), a scientific non-profit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide (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.

The Participants recognize that each Participant has jurisdiction or standards-setting authority over specific products and defines those products differently. Collaboration under this exchange of letters is intended to cover products 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. This exchange of letters will also 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 mandates.

This exchange of letters does not compromise the authority of any of the Participants to carry out their respective 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 Participant. 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.

The aforementioned information may include confidential product and/or commercial and financial confidential information; trade secret information, personal privacy information; law enforcement information, and/or internal, pre-decisional information and rules.

The principles of confidentiality and restricted use mentioned above do not apply to information for which the receiving Participant can clearly indicate and provide concrete evidence to the disclosing Participant that:

A. the information was legally in its possession and was already known (without any confidentiality commitment) prior to the disclosure by the disclosing Participant (as verified by written reports or other acceptable evidence); or

B. the information was already in the public domain or publicly known at the time of the disclosure by the disclosing Participant; or

C. the information came into the public domain or was brought to public attention in the absence of any fault of the receiving Participant; or

D. the information was made available to the receiving Participant by a third party without breach of any legal confidentiality commitment; or

E. the information is the result of activities carried out independently by or on behalf of the receiving Participant without having access to the information of the disclosing Participant.

Confidential information may be shared with or 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 applicable laws and regulations as well as the policies of their respective countries and their procedures permitted by those laws and regulations, or in the case of USP, consistent with its internal rules and procedures.

Information provided by one Participant to the other may be shared with the receiving Participant's employees, agents, volunteers 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 applicable laws and regulations of the country of the Participant who receives the information, or consistent with the Participant's internal rules and procedures.

Each Participant will, consistent with its internal policies and procedures, consult with the 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 the other Participant.

Each Participant will make all reasonable efforts to inform the other of any effort made by 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 or branches be protected in accordance with the applicable laws and regulations as well as the policies of their respective countries, and as well, their internal rules and procedures, 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 organization. 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 The USP, the Senior Manager, Pharmacopeial Collaboration and (b) for MHLW, the Office Director, Office of International Regulatory Affairs, General Affairs Division, Pharmaceutical Safety and Environmental Health Bureau; and (c) for PMDA, the Director, Division of Regulatory Cooperation, Office of International Programs.

The cooperation 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 unauthorized disclosure and use in accordance with the applicable laws and regulations of their respective countries, their internal rules and procedures, 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 the USP, the MHLW, and the PMDA in the best interests of public health.

Yours sincerely,

<<Signature>>

Toshihiko Takeda

Director General

Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare

<<Signature>>

Tatsuya Kondo

Chief Executive

Pharmaceuticals and Medical Devices Agency