Tokyo; 13th September, 2016

Dear Dr. Takeda

Dear Dr. Kondo

The Pharmaceutical Safety and Environmental Health Bureau of the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan on the one side, and the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe on the other side, the respective authorities involved with and responsible for the regulation on therapeutic products in Europe and Japan (hereinafter collectively referred to 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 Participants recognise that each Participant regulates specific products and may define 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 to 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 the populations of their respective country/region 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/region of the Participant providing the information. The Participants note that it is essential that confidential information 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.

Information will not be considered to be confidential if it:

(i) is generally available to the public other than as a result of unauthorised disclosure by the receiving Participant.
(ii) was already lawfully in possession of the receiving Participant before the signatures of this exchange of letters, or is obtained by the receiving Participant from another source that has the legal right to use and disclose such information.
(iii) is independently developed or created by or on behalf of the receiving Participant.

Confidential information may be shared with or used by the other Participant, or shared with the non-participants set out in the paragraph below, without the prior written consent of the individual or entity to whom the information relates as 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 their procedures permitted by those laws and regulations.

Information provided by one Participant to the other may be shared on a “need-to-know” basis 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 applicable to the Participant who receives the information.

Each Participant 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 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 applicable laws and regulations as well as their procedures that may affect their treatment of confidential information obtained from the other Participant.

The Participants consider it crucial for the sustainability of this exchange of letters and future cooperation that confidential information shared between their respective organisation/agencies or branches be protected in accordance with the applicable laws and regulations as well as their procedures 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 organisation/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 the EDQM, the Director of the EDQM, and (b) for MHLW, the Director of Office of International Regulatory Affairs; and for PMDA, the Director of Division of Regulatory Cooperation, Office of International Programs.

The cooperation commences upon the date of the last letter exchanged. This cooperation will continue unless it is terminated by either Participant, in writing, on 30 days' prior 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 applicable laws and regulations as well as the procedures permitted by those laws and regulations.

The MHLW and PMDA are informed and give an authorisation of

disclosure of all relevant terms of this exchange of letters for the purposes of internal and external audit and to the Committee of Ministers and to the Parliamentary Assembly of the Council with a view to these latter discharging their statutory functions, as well as for the purpose of meeting the publication and transparency requirements of the Council of Europe or its donors.

Each Participant will make all reasonable efforts to settle conflicts between the Participants arising from the interpretation or implementation of the cooperation under this exchange of letters through consultations and negotiations.

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

Yours sincerely,

Dr Susanne Keitel
Director
European Directorate for the Quality of Medicines & HealthCare
Council of Europe