Ministry of Health Labour and Welfare

Pharmaceuticals and Medical Devices Agency

Tokyo; 17 July, 2025

Dear Mrs. Lee,

The Pharmaceutical Safety 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 Medical Device Safety Bureau of Ministry of Food and Drug Safety (MFDS) of the Republic of Korea on the other side, the authorities involved with and responsible for the regulation of medical devices in Japan and the Republic of Korea, respectively (hereinafter collectively referred to as the "Participants"), have recognized the need to enhance their relationship through increased cooperation, by means of an exchange of letters, in respect of the sharing of information on Medical Device Single Audit Program (MDSAP) activities.

The Participants recognize that each Participant has jurisdiction over specific products and defines those products differently. Collaboration under this exchange of letters is intended to cover the MDSAP activities which are common to the Participants and to permit meaningful collaboration between them.

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 from the point of the MDSAP. It is intended to lead to 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 countries 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 any legally binding obligations on any of the Participants or amongst them to share information with each other.

Each Participant recognizes 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 emanating from one Participant will be treated as such by the other Participant(s). 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 shared with or used by the other Participants, or shared with the non-participants set out in the next paragraph, 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 line with the laws, regulations and 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 require the information solely for work related to the delivering of the mandate of the receiving Participant, who will only use that information for the purposes contemplated by this exchange of letters, and who has a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, confidentiality contract or other document that permits that person 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 receiving Participant.

Each Participant will consult with the other(s) 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(s).

Each Participant will make all reasonable efforts to inform the other(s) 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(s). If public disclosure is required by such authorities, the other Participant(s) 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 the laws and regulations and the policies of its country or procedures that may affect its treatment of confidential information obtained from the other Participants.

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 line with the laws, regulations and the policies of their respective countries, from unauthorized use and disclosure.

The Participants acknowledge that requests for information will be made to the 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 others, the contact points for matters relating to this exchange of letters are as follows: (a) for MHLW, the Office Director, Office of International Regulatory Affairs, General Affairs Division, Pharmaceutical Safety Bureau, and for PMDA, the Office Director, Office of Asia Training Center and International Cooperation; and (b) for MFDS, the Director, Medical Device Management Division, Medical Safety Bureau.

The cooperation under this exchange of letters commences upon the date of the last letter of the exchange. This cooperation will continue unless it is discontinued by any 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 the laws and regulations of their respective countries, 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 MHLW, the PMDA, and the MFDS in the best interests of public health.

Yours sincerely,

NOMURA Yumiko
Director
Medical Device Evaluation Division
Pharmaceutical Safety Bureau
Ministry of Health, Labour and Welfare

ISHII Kensuke
Associate Executive Director
(Medical Devices and IVD)
Pharmaceuticals and Medical Devices Agency