Spanish Agency of Medicines and Medical Devices

19 December, 2025

Dear Mr Miyamoto Naoki and Dr Fujiwara Yasuhiro,

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 Spanish Agency of Medicines and Medical Devices (AEMPS) of Spain on the other side, the respective authorities involved with and responsible for the regulation of therapeutic products in Japan and Spain (hereinafter individually referred to as "Participant" and 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 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 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 legally binding obligations on any of the Participants or amongst them to share information with each other.

Each Participant recognises that the 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.

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 not only the laws and regulations but also the policies of their respective countries and their procedures permitted by those laws and regulations.

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 of the country of the Participant who receives the information.

Each Participant will consult with the other Participant 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 Participant of any attempt by a judicial, legislative or other authority to obtain confidential information that has been provided by one Participant to the other Participant. If such authorities require public disclosure, the other Participant will consult with the Participant who provided the information before disclosing it.

Each Participant will make all reasonable efforts to inform the other Participant of any changes to the laws, regulations and policies of their respective countries, as well as any 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 not only the laws and regulations but also 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 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 AEMPS, the Head of EU and International Affairs Division; and (b) 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.

The cooperation commences upon the date of the last letter of the exchange. This cooperation will continue unless either Participant discontinues it in writing, with 30 days' notice to the other Participant. Upon discontinuation of this cooperation, the Participants will continue to treat

confidential information shared within the framework of this cooperation as such and will protect it from unauthorised disclosure and use, in accordance with not only the laws and regulations of their respective countries, but also the practices and procedures permitted by such laws and regulations.

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

Yours sincerely,

María J Lamas

Executive Director

Spanish Agency of Medicines and Medical Devices (AEMPS)