Ref:523816923

18 December 2024

JO Katsufumi
Director General
Pharmaceutical Safety Bureau
Ministry of Health, Labour and Welfare

FUJIWARA Yasuhiro
Chief Executive
Pharmaceuticals and Medical Devices Agency

Dear Mr. Jo and Dr. Fujiwara,

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 Technology, Health Information, Innovation and Research (MTIIR) Directorate, Ministry of Health (MoH) of Israel on the other side as the respective authorities involved with and responsible for the regulation of medical products in Israel 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.

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 all human health products (i.e. therapeutic products; medical devices; cell, tissue and gene therapy products; cosmetic products) regulated by, and common to, the Participants and to permit meaningful collaboration between them. The collaboration may be expanded in scope in the future, if the Participants reach the mutual consensus of both Participants.

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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 or affect 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 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 that emanates 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, provided that such disclosure or use is in line with the laws, regulations, policies, and procedures of the Participants' respective countries.

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 fulfillment of the mandate of the Participant, who will only use the information for the purposes of this exchange of letters, and will have a legally enforceable obligation, such as, but not limited to, by 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 line with the laws and regulations of the country of the Participant who receives the information.

Each Participant will 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. Any disclosure of the confidential information to the public and/or to non-participants would require the other Participant's consent.

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 or procedures of their respective countries 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 line with not only the laws and regulations but also the policies of their respective countries, from unauthorized use and disclosure.

For the avoidance of doubt, information exchanged hereunder will not include identifiable personal data/information.

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 MTIIR Directorate, the International Regulatory Partnerships Unit, and (b) for MHLW, Director, Office of International Regulatory Affairs, General Affairs

Division, Pharmaceutical Safety Bureau, and for PMDA, Division 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 discontinued by either Participant, in writing, subsequent to a 30 days' notice to the other Participant. Upon discontinuation 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 line with not only the laws and regulations of their respective countries, but also the practices and procedures that are taken in the respective countries.

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 MTIIR at the MoH, Israel, the MHLW, and the PMDA, Japan in the best interests of public health.

Yours sincerely,

Dr. Osnat Luxenburg
Head
The Medical Technology, Health Information, Innovation and Research Directorate
Ministry of Health of Israel

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