



Ministry of Health, Labour and Welfare Pharmaceuticals and Medical Devices Agency

26, November, 2012

Subject Confidentiality arrangement

The Pharmaceutical and Food 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 Agenzia Italiana del Farmaco (AIFA) on the other side, the respective authorities involved with and responsible for the regulation of therapeutic products in Italy 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 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 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 Participants. 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.

Each Participant will advise the other(s) of the public or confidential status of the information at the time that the information is shared. When documents are shared, Participants will mark each document clearly with its public or confidential status.

Confidential information may be shared with or used by the other Participants, 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 laws and regulations as well as 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 or provides the information.

The Participants 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 any of the Participants.

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 Participants 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 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 accordance with the laws and regulations as well as the policies of their respective countries, 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 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 MHLW, the International Planning Director; and for PMDA, the Director, Division of Regulatory Cooperation, Office of International Programs; and (b) for AIFA, the International Relation Director.

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 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 and the PMDA, and the AIFA, in the best interests of public health.

Yours sincerely,

Jun Ebata
Director General
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

Tatsuya Kondo
Chief Executive
Pharmaceuticals and Medical Devices
Agency