EUROPEAN COMMISSION
DIRECTORATE-GENERAL ENTERPRISE AND INDUSTRY

Consumer Goods
The Director

Brussels, 19 -10- 2009
ENTR/F/3/LSE/cr D(2009) 32920

Dear Mr. Takai and Dr. Kondo,

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 Commission's Directorate General Enterprise and Industry on the other side, (collectively "the Participants"), have recognised the need to further improve their working relationship, including the need for increased cooperation in the field of regulations of medical devices as a means to better protect health and safety and to reduce technical barriers to trade affecting these products.

This exchange of letters should further enhance and strengthen the cooperation between the Japanese and the European authorities, notably in the framework of the Global Harmonisation Task Force (GHTF). We expect this cooperative activity to further enhance and strengthen communication between our respective organizations and further enhance public health promotion and protection in Japan and the European Union (EU). In this context, the Participants see value in exchanging more regulatory information including advance drafts of legislation and/or regulatory guidance documents as well as information related to regulatory policies and practices in their respective regions.

Because this type of information may include information of a non-public nature, both sides should, to the extent permitted by their respective national and regional laws and regulations, keep the information exchanged confidential.

The information sharing based on this exchange of letters is intended, among other things, to help regulators on both sides to take informed decisions with regard to regulatory policies and practices in their respective regions. This cooperation should not compromise each Participant's ability to carry out its responsibilities and should not create any kind of legal obligation on the both sides of the Participants.

Therefore, the European Commission is pleased to cooperate with the MHLW and the PMDA to facilitate the sharing of documents and/or information related to ensuring the quality, safety and efficacy, as appropriate, of medical devices.

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This cooperation activity will strengthen communication between public authorities involved in these activities and reinforce public health protection.

The language for the exchange of information will be English and the type of information that may be shared includes, but is not limited to:

- Advanced drafts of pending laws, regulations, guidance documents, procedures and other technical documents available to the individual Participants related to medical devices.

- As far as known to the Participants, post-marketing data and information that could have an impact on the public health, or information about impending regulatory actions.

- As far as known to the Participants, information on quality defect or product recalls of these products known by the EU to have been manufactured or distributed in Japan, and vice versa.

The Participants can limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of EU or the European Commission's interest in the confidentiality of their proceedings. In some cases, exchange of information based on this exchange of letters may be subject to prior authorisation from the companies concerned.

The Participants note that it is an essential element of this exchange of letters on regulatory cooperation that confidential information emanated from one Participant will be treated as such by the other Participant.

On each occasion where there is a request for disclosure to third parties of non-public information received from the European Commission, the MHLW or the PMDA should consult with the European Commission. Likewise, on each occasion where there is a request for disclosure of non-public information received from the MHLW or the PMDA, the European Commission should consult with the MHLW or the PMDA.

The European Commission affirms that it has the authority to maintain the confidentiality of non-public information, including confidential commercial information, provided to their officials or representatives by the MHLW and/or the PMDA, and will protect such information as information not to be disclosed under Article 4 of Regulation (EC) 1049/2001, and in particular paragraph 1(a) thereof, which protects non-public information from further disclosure. The European Commission recognises that the MHLW and the PMDA consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the relations between the Participants. The European Commission recognises that "confidential commercial information" includes information referred to in the Japanese Act on Access to Information Held by Administrative Organs (Act No.42 of 1999) and in Regulation (EC) No. 1049/2001.

Similarly, the MHLW and the PMDA should affirm that they have the authority to maintain the confidentiality of non-public information, including confidential commercial information, provided to their officials or representatives by the European Commission, and will protect such information as information not to be disclosed under Article 5 of Act on Access to Information Held by Administrative Organs (Act No.42 of 1999).

This cooperation does not include classified information within the meaning of Commission Decision 2001/844/ regarding the Commission's provisions on security.

Each Participant will promptly inform the other of any changes to relevant laws, regulations, policies, or procedures that would affect the ability of the Participant to honour the recognitions in this exchange of letters.

This letter, together with your letter on behalf of the MHLW and the PMDA, will constitute mutual intent for cooperation between the Participants, and the cooperative relationships proposed and defined in this exchange of letters will commence on the date of this letter, for an initial period of five years after which the Participants will consult about the cooperation thereafter.

We look forward to implementing this exchange of letters allowing for the sharing of non-public information in accordance with our respective national and regional laws and regulations, including the Japanese Act on Access to Information Held by Administrative Organs (Act No.42 of 1999) and Regulation (EC) No 1049/2001, and to continuing cooperative activities, to further enhance the relationship between the European Commission and the MHLW and the PMDA, in the best interests of public health.

Sincerely,

Georgette Lalis