European Commission

European Medicines Agency

2 February 2007

Dear Mr Takahashi and Mr Miyajima,

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan on the one side and European Commission's Directorate General Enterprise and Industry and the European Medicines Agency (EMEA) (collectively "the Participants") on the other side have recognised the need to further improve their relationship including the need for increased co-operation as a means to better protect health and to address technical barriers to trade in goods.

There is already considerable experience in the field of regulatory and administrative co-operation between the participants in the pharmaceutical sector. To date, this has been in the context of the EU-Japan mutual recognition agreement (OJ L 284 29.10.2001, p3), bilateral meetings and through the International Conference on Harmonisation (ICH).

The success of existing regulatory co-operative measures on harmonisation of technical requirements and an agreement on a common format for the submission of certain regulatory information to the respective pharmaceutical regulatory authorities has led to the desire from

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both sides to increase the range of information that can be shared in the interests of better regulatory co-operation.

In this context, the European Commission together with the EMEA and the MHLW together with the PMDA see value in establishing an arrangement to exchange more regulatory information including advance drafts of legislation and/or regulatory guidance documents as well as information related to the authorisation and supervision of medicinal products for human use. Because this type of information may include information of a non-public nature, both sides agree, to the extent permitted by their respective laws, to keep the information exchanged confidential.

The potential benefits of this exercise are expected to include accelerated access of patients to new and innovative medicines; resource savings due to reduced duplication of assessment and improved performance and safety as a result of the involvement of the best regulatory expertise from both sides. This co-operation shall not compromise each Participant's ability to carry out its responsibilities and shall not create any kind of legal obligation on the part of the Participants.

Therefore the European Commission and the EMEA are pleased to cooperate with the MHLW and PMDA to facilitate the sharing of documents and/or information related to ensuring the safety, quality, and efficacy of medicinal products for human use, authorised or under review both in Japan and in the European Union (EU).

In this context, the term 'medicinal products authorised in the European Union' refers to products subject to evaluation or authorised under the centralised procedure as well as medicinal products authorised at national level by the EU Member States that are subject to official European Community arbitration and referrals.

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:

1. All legislation and guidance documents available under the rules and regulations governing medicinal products in the EU (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm). This also includes all position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation.

2. Post-authorisation pharmacovigilance data, particularly those of an urgent nature related to adverse drug reactions as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments.

3. Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and applications for agreement of paediatric investigation plans.

4. Good Clinical Practices (GCP) inspections for specific products and GCP Inspection reports available to the EMEA or the European Commission.

5. Information Technology systems supporting regulatory processes.

At the EMEA, the information may be shared with national experts on secondment from the EU Member States, EEA countries, or EU candidate countries. These individuals will be required to sign a confidentiality undertaking with the EMEA.

The Participants reserve the right to 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 the EU or the protection of the EMEA or the European Commission's interests in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the companies concerned.

Participants note that it is an essential element of this international arrangement on regulatory cooperation that confidential information emanating from the other Participant will be treated as such.

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

The EMEA and the European Commission affirm that they have the authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by the MHLW or PMDA, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001. The EMEA and the European Commission understand that the MHLW and PMDA consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants.

Similarly, the MHLW and PMDA shall affirm that they have the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the EMEA or the European Commission, and will protect such information as information not to be disclosed. MHLW and PMDA understand that the EMEA and the European Commission consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. The EMEA and the European Commission agree 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.

This arrangement is concluded for a period of five years after which we will assess its effectiveness.

The European Commission and the EMEA should be obliged if MHLW and PMDA would acknowledge receipt of this letter and confirm that this letter and your reply constitute the arrangement set out above between our services.

We look forward to implementing this arrangement allowing for the sharing of non-public information and to continuing cooperative activities to further enhance the relationship

between MHLW, PMDA, the EMEA, and the European Commission, in the best interests of public health.

Georgette Lalis

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