EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brussels, 2 February 2013
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Dear Mr Ebata 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 European Commission's Directorate General Health and Consumers (DG SANCO) and the European Medicines Agency (EMA) on the other side (collectively "the Participants") 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, the International Conference on Harmonisation (ICH) and the previous information sharing arrangement signed in February 2007.

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

In this context, DG SANCO together with the EMA and the MHLW together with the PMDA see value in establishing an administrative 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 accept 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 does not intend to compromise each Participant's ability to carry out its responsibilities neither does it intend to result in creating rights or obligations under international law on the part of the Participants.

Therefore DG SANCO and the EMA 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 Union 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/health/human-use/index_en.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 EMA or DG SANCO.

5. Information Technology systems supporting regulatory processes.

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

This arrangement does not affect the Participants' 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 EMA or DG SANCO'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 is treated as such.

On each occasion where there is a request for disclosure to third parties of non-public information received from EMA or DG SANCO, MHLW and PMDA will consult with the EMA or DG SANCO. Likewise, on each occasion where there is a request for disclosure of non-public information received from MHLW or PMDA, the EMA or DG SANCO will consult with the MHLW and PMDA.

The EMA and DG SANCO 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 EMA and DG SANCO 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 affirm that they have the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the EMA or DG SANCO and will protect such information as information not to be disclosed. MHLW and PMDA understand that the EMA and DG SANCO consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. The EMA and DG SANCO understand 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 applicable for a period of five years with tacit renewal for subsequent periods of five years.

DG SANCO and the EMA 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.

This arrangement does not intend to create rights or obligations under international law.

We look forward to furthering cooperation on the basis of this arrangement allowing for the sharing of non-public information and to continuing cooperative activities to further enhance the relationship between MHLW, PMDA, the EMA, and DG SANCO, in the best interests of public health.

Paola Testori Coggi
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