EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brussels, 2 February 2013

Dear Mr Ebata and Dr Kondo,

Subject: **Administrative arrangement to exchange non-public information on medicinal products between DG SANCO/EMA and MHLW/PMDA**

On 2 February 2007, 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) on the other side have exchanged letters establishing an administrative arrangement to exchange regulatory information including advanced drafts of legislation and/or regulatory guidance documents as well as information related to the authorisation and supervision of medicinal products for human use. This Arrangement was concluded for a period of five years.

In the meantime the European Commission transferred the responsibility related to the EU legislation on medicinal products from Directorate General Enterprise and Industry to Directorate General Health and Consumers (DG SANCO) without affecting the Arrangement.

It should also be noted that in December 2009, the European Medicines Agency's acronym was changed to EMA.

The administrative arrangement was extended for a period of one year on 2 February 2012.

Considering that all parties have assessed the effectiveness of the Arrangement and continued to find it to be a useful tool in regulatory cooperation, the arrangement in annex is maintaining the provisions of the current arrangement and is concluded for a new period of five years with tacit renewal for subsequent periods of five years.

We look forward to continuing cooperative activities to further enhance our relationship in the best interests of public health.

Paola Testori Coggi
European Commission
Health and Consumers Directorate General
Director General

Guido Rasi
European Medicines Agency
Executive Director