

2 February 2012
EMA/84457/2012

Dear Mr Kikura and Dr Kondo,

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 (EMA) on the other side have exchanged letters establishing a Confidentiality 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 without affecting the Arrangement.

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

Considering that all parties have assessed the effectiveness of the Arrangement and found it to be a useful tool in regulatory cooperation, it is hereby agreed to extend the Arrangement for a period of one year as from 2 February 2012.

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

Andrzej Rys
Director - Health systems and products
European Commission
Health and Consumers Directorate General

Guido Rasi
Executive Director
European Medicines Agency