Ministry of Health Labour and Welfare

Pharmaceuticals and Medical Devices Agency

Tokyo; 2 February 2012

Mr Andrzej Rys
Director, Health and Consumers Directorate-General
European Commission
Rue Breydel 4, B-1040 Brussels
Belgium

Dr Guido Rasi
Executive Director
European Medical Agency
7 Westferry Circus, Canary Wharf
London, E14 4HB
United Kingdom

Dear Mr Rys and Dr Rasi,

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 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.

Yoshiyuki Kikura
Director General
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

Tatsuya Kondo
Chief Executive
Pharmaceuticals and Medical Devices Agency