



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brussels, 22nd of February 2013

Dear Mr. Glover,

Subject: Administrative Arrangement to exchange non-public information on medicinal products between DG SANCO/EMA and Health Canada

Thank you for your letter of 21 December confirming the renewal of the arrangement to exchange non-public information on medicinal products between our organizations. The first arrangement was concluded in December 2007. At that time, the Health Products and Food Branch of Health Canada, on the one side, and the European Medicines Agency (EMA) and the European Commission's Directorate General Enterprise and Industry, on the other side, concluded an exchange of letters establishing a Confidentiality Arrangement to exchange regulatory information including position papers concerning the development of new legislation or modifications to existing legislation and/or draft regulatory guidance documents as well as information related to the authorisation and supervision of medicinal products for human and animal 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 and benefits of the Arrangement and found it to be a useful tool in regulatory cooperation, we concur to renew such Arrangement for a new period of five years with tacit renewal for subsequent periods of five years.

We would be grateful if you could confirm your concurrence with the terms of the renewed Arrangement in annex.

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