



Health  
Canada

Santé  
Canada

Health Products  
and Food Branch

Direction générale des produits  
de santé et des aliments

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Mr. Guido Rasi  
Executive Director  
European Medicines Agency  
7 Westferry Circus  
Canary Wharf  
London, E14 4HB  
United Kingdom

Mr. Andrzej Rys  
Director  
Health and Consumers Directorate General  
European Commission  
4 Rue Breydel  
B - 1049 Brussels  
Belgium

Dear Messrs. Rasi and Rys:

On 7 December 2007, 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, the arrangement in annex is maintaining all provisions of the agreed Arrangement and is concluded for a new period of five years with tacit renewal.

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

Sincerely,

Paul Glover  
Assistant Deputy Minister