



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

250 Lanark Avenue
Graham Spry Building
A.L. 2005A
OTTAWA, Ontario
K1A 0K9

12-123293-563

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