European Commission

European Medicines Agency

7 December 2007

Dear Ms Ballantyne

The Health Products and Food Branch of Health Canada on the one side and European Commission's Directorate General Enterprise and Industry and the European Medicines Agency (EMEA) (collectively "the Participants") on the other side have recognised the need to further improve their relationship including the need for increased co-operation as a means to better protect health and to address technical barriers to trade in goods.

There is already considerable experience in the field of regulatory and administrative co-operation between the participants in the pharmaceutical sector. To date, this has been in the context of, mutual recognition agreements, bilateral meetings, through the International Conference on Harmonisation (ICH) and the International Conference on Harmonization of Technical Requirements for Registration of Veterinary Products (VICH).

The success of existing regulatory co-operative measures on harmonisation of technical requirements and an agreement on a common format for the submission of certain regulatory information to the respective pharmaceutical regulatory authorities has led to the desire from both sides to increase the range of information that can be shared in the interests of better regulatory co-operation.

In this context, the European Commission together with the EMEA and Health Canada see value in establishing an arrangement to exchange more 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. Because this type of information may include information of a non-public nature, both sides agree, to the extent permitted by their respective laws, to keep the information exchanged confidential.

The potential benefits of this exercise are expected to include accelerated access of patients and animals to new and innovative medicines; resource savings due to reduced duplication of assessment and improved performance and safety as a result of the involvement of the best regulatory expertise from both sides. This co-operation shall not compromise each

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Participant's ability to carry out its responsibilities and shall not create any kind of legal obligation on the part of the Participants.

Therefore the European Commission and the EMEA are pleased to cooperate with Health Canada to facilitate the sharing of documents and/or information related to ensuring the safety, quality, and efficacy of medicinal products for human and veterinary use, authorised or under review both in Canada and in the European Union (EU).

This arrangement covers therapeutic products (Canada) and medicinal products (EU) for either human or animal use regulated by the Participants. In the context of this arrangement, the term therapeutic product includes pharmaceuticals, radiopharmaceuticals, biologics and natural health products. Also in the context of this arrangement, the term 'medicinal product authorised in the European Union' refers to products subject to evaluation or authorised under the centralised procedure as well as medicinal products authorised at national level by the EU Member States that are subject to official European Community arbitration and referrals.

This cooperation activity will strengthen communication between public authorities involved in these activities and reinforce public health protection.

The type of information that may be shared includes, but is not limited to:

1. All legislation and guidance documents available under the rules and regulations governing medicinal products in the EU (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm). This also includes all position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation.

2. Post-authorisation pharmacovigilance data, particularly those of an urgent nature related to EU or non-EU originating adverse drug reactions as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments.

3. Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and applications for agreement of paediatric investigation plans.

4. Good Clinical Practices (GCP) inspections for specific products and GCP Inspection reports available to the EMEA or the European Commission.

5. Information Technology systems supporting regulatory processes.

At the EMEA, the information may be shared with national experts on secondment from the EU Member States, EEA countries, or EU candidate countries. These individuals will be required to sign a confidentiality undertaking with the EMEA.

The Participants reserve the right to limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of the EU or the protection of the European Commission or the EMEA's interests in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the companies concerned.

Participants note that it is an essential element of this international arrangement on regulatory cooperation that confidential information emanating from the other Participant will be treated as such.

On each occasion where there is a request for disclosure to third parties of non-public information received from the European Commission or the EMEA, Health Canada shall consult with the European Commission or the EMEA. Likewise, on each occasion where there is a request for disclosure of non-public information received from Health Canada, the European Commission or the EMEA shall consult with Health Canada.

The European Commission and the EMEA affirm that they have the authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by Health Canada, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001. The European Commission and the EMEA understand that Health Canada considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants.

Similarly, Health Canada affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the European Commission or the EMEA, and will protect such information as information not to be disclosed. Health Canada understands that the European Commission and the EMEA consider it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants.

This arrangement is concluded for a period of five years after which we will assess its effectiveness.

The European Commission and the EMEA should be obliged if Health Canada would acknowledge receipt of this letter and confirm that this letter and your reply constitute the arrangement set out above between our services.

We look forward to implementing this arrangement allowing for the sharing of non-public information and to continuing cooperative activities to further enhance the relationship between Health Canada, the European Commission, and the EMEA in the best interests of public health.

Signature on file

Georgette Lalis

Director, DG Enterprise and Industry
European Commission

Signature on file

Thomas Lönngren

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