Health Canada | Santé Canada

Health Products and Food Branch | Direction générale des produits de santé et des aliments

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Mrs. Georgette Lalis
Director
European Commission
Enterprise Directorate-General
Avenue d'Auderghem, 45
1040 Bruxelles
Belgium

Mr. Thomas Lönngren
Executive Director
European Medicines Agency
7 Westferry Circus
Canary Wharf
London, E14 4HB
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Dear Mrs. Lalis and Mr. Lönngren,

Health Canada's Health Products and Food Branch (Health Canada) on the one side the European Commission's Directorate General Enterprise and Industry and the European Medicines Agency (EMEA) on the other side (collectively "the Participants") have recognised the need to further enhance their relationship including the need for increased co-operation as a means to better protect health and facilitate the access to safe and high quality health products.

It is also our view that 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 largely been in the context of the mutual recognition agreements, bilateral meetings, 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 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 interest of enhanced regulatory co-operation.

In this context, the Participants see value in establishing an arrangement to enhance the exchange of regulatory information, including position papers concerning the development of new regulations or modifications to existing regulations, draft regulatory guidance documents as well as information related to authorisation, pharmacovigilance and inspections of therapeutic products/ medicinal products for human and animal use. Unless considered Cabinet

2. Post-authorisation pharmacovigilance data, particularly those of an urgent nature related to Canada and non-Canada 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 Health Canada.

5. Information Technology systems supporting regulatory processes.

All information exchanged between the Participants will be done in confidence and will not be used for purposes other than those envisaged by this arrangement. The Participants note that it is an essential element of this arrangement on regulatory cooperation that confidential information emanating from the other Participant be treated as such.

Information exempt from public disclosure under the laws and regulations of Canada and the European Union will only be shared according to the procedures and policies of the Participants as permitted by their respective laws. Health Canada will not, pursuant to this arrangement, provide the European Commission and/or the EMEA with personal information. In the case of confidential commercial information, including trade secrets, exchange of information, from Health Canada to the European Commission and/or the EMEA, may be subject to prior authorisation from the companies concerned.

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

The Participants reserve the option to limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy the public interests of the EU or Canada, or the protection of the European Commission or the EMEA or Health Canada's interests in the confidentiality of its proceedings.

confidence, this arrangement will also allow for the exchange of information concerning the development of new legislation or modification to existing legislation. Because this type of information may include confidential information of a non-public nature, the Participants agree, to the extent permitted by their respective laws, to keep the information exchanged confidential.

The potential benefits of this exercise are expected to provide accelerated access of patients and animals to new and innovative therapeutic products as well as resource savings and improved regulatory performance and safety as a result of the involvement of the best regulatory expertise from both sides. This co-operation shall not compromise the Participant's ability to carry out their respective responsibilities and shall not create any legal obligation on the part of the Participants.

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

This arrangement covers medicinal products (EU) and therapeutic products (Canada) for either human or animal use regulated by the Participants. In the context of this arrangement, the term therapeutic products include pharmaceuticals, radiopharmaceuticals, biologics and natural health products. Also in the context of this arrangement, the term medicinal product refers to products subject to evaluation or authorised under the EU 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 the Participants involved in these activities and reinforce public health protection. The Participants will exchange information which may include the following, 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) and governing therapeutic products in Canada (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/index_e.html). This also includes all position/discussion papers concerning guidance documents and regulations either in draft, finalised or released for consultation.

Information provided by one Participant to another Participant may be shared with that Participant's employees, agents or contractors who need to know the information for work purposes in respect of this arrangement, which will use that information only for purposes set out in this arrangement and who are legally bound to protect the confidentiality of the information

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.

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 publicly disclosed. Health Canada understands that the European Commission and the EMEA consider it crucial that this non-public information be protected from disclosure.

We confirm that your letter and our letter constitute the collaborative arrangement between Health Canada, the European Commission and the EMEA. This arrangement is concluded for a period of five years after which its effectiveness will be assessed.

I 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 interest of public health.

Yours sincerely,

**Signature on file**

Meena Ballantyne
Assistant Deputy Minister