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Subject: Exchange of Letters constituting an Arrangement between Health Products and Food Branch and the Healthy Environments and Consumer Safety Branch of Health Canada and the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária) in respect of the sharing of confidential information

Dear Dr. Dirceu Raposo de Melo and Dr. José Agenor Álvares da Silva,

The Health Products and Food Branch of Health Canada (HPFB), along with the Healthy Environments and Consumer Safety Branch (HECSB) and the Brazilian Health Surveillance Agency (ANVISA), as the respective authorities responsible for the regulation of tobacco, health products and food in Canada and Brazil (hereinafter referred to as “the Participants”), have recognized the need to enhance their relationship with increased cooperation, by means of an exchange of letters (also referred to as the “Arrangement”), in respect of the sharing of confidential information.

This Arrangement recognizes that each Participant has jurisdiction over specific products and defines those products differently. Collaboration under this Arrangement is intended to cover all products regulated by, and common to, the Participants and to permit meaningful collaboration between them.

This Arrangement strengthens communication between the Participants and enhance their ability to protect and promote the health and safety of their respective populations in carrying out their respective mandates. The purpose of this Arrangement is to facilitate increased access to safe, effective and high quality food and health products, and share information related to these products. The goal is also to facilitate the exchange of information regarding tobacco products, particularly technical cooperation and provision of related expertise, to establish and implement effective tobacco control programmes. Consequently, it should provide improved regulatory performance and safety as a result of the involvement of the best regulatory expertise from both countries.

This Arrangement does not compromise the regulatory authority of either Participant to carry out their respective responsibilities, nor does it create legally binding obligations on either Participant or between them to share information with each other.

Each Participant understands that information exchanged between them may include confidential information that is not in the public domain in the country of the Participant providing the information. Participants will advise one another of the confidential status of the information at the time it is shared. As such, each Participant understands that confidential information will be shared in confidence, and will be shared in accordance with the laws as well as the policies and procedures permitted by those laws applicable to the respective Participant. Each Participant will make every reasonable effort to prevent: (a) the public release of confidential information that has been shared for the purposes set out in this Arrangement; and (b) any other release of this information for purposes not set out in this Arrangement.

Confidential information may be shared with or used by the other Participant, or shared with the third parties set out in the next paragraph below without the prior written consent of the individual or entity to whom the information relates so long as this relates to the purposes contemplated in this Arrangement, and provided that such disclosure or use is in accordance with the laws as well as the policies and procedures permitted by those laws applicable to the respective Participant.

Information provided by one Participant to the other may be shared with that Participant's employees, agents or contractors who require the information solely for work purposes in respect of this Arrangement, who will only use that information for purposes contemplated by this Arrangement, and who will have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, confidentiality contract or other document that permits those persons to use the

information only for the purposes of this Arrangement and requires them to protect the confidentiality of the information in accordance with the laws that are applicable to the Participant who receives the information.

The Participants will consult with each other on each occasion where there is a request for public disclosure or disclosure to third parties other than those set out in the preceding paragraph of confidential information received from either Participant.

Each Participant will make all reasonable efforts to inform the other of any effort made pursuant to a judicial, legislative or other authority to obtain confidential information that has been provided by one Participant to the other Participant. If public disclosure is required pursuant to such authority, the other Participant will make all reasonable efforts to ensure that the information is disclosed in a manner that protects the information from any subsequent disclosure that is not authorized by the judicial, legislative or other authority.

Each Participant will make all reasonable efforts to inform the other Participant of any changes to their respective laws, policies or procedures that may affect their treatment of confidential information obtained from the other Participant.

Each Participant will protect the confidentiality of information in accordance with their respective laws as well as the policies and procedures permitted by those laws. The Participants consider it crucial to the sustainability of this Arrangement and future cooperation that confidential information shared between their respective agencies or branches be protected according to the respective laws of Brazil and Canada from unauthorized use and disclosure.

The Participants acknowledge that requests for information will be made to designated officers responsible for the administration of this Arrangement within their own agency or branch. Unless otherwise notified in writing by one Participant to the other, the contact points for matters relating to this Arrangement are as follows: (a) for HPFB, the Director of International Affairs of the Policy, Planning and International Affairs Directorate and for HECSB, the Director of Tobacco Policy and Strategic Planning, Controlled Substances and Tobacco Directorate; and (b) for ANVISA, the Head of the International Affairs Office.

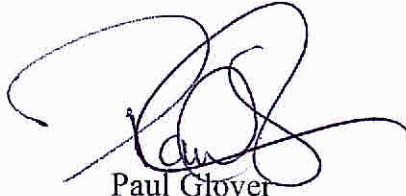
We confirm that our respective letter, once signed by each of us, sets out our Arrangement in respect of the sharing of confidential information and will become effective at the date of the last letter from one Participant to another setting out this Arrangement. This Arrangement will continue unless it is terminated by either Participant, in writing, on 30 days notice to the other Participant, or it is terminated at such other time upon the mutual consent of the Participants. This Arrangement may be amended at any time, in writing, with the mutual consent of the Participants. Upon termination of this Arrangement, the Participants will continue to protect confidential information from unauthorized disclosure and use in accordance with their respective laws as well as the practices and procedures permitted by those laws.

We look forward to adopting this Arrangement and allowing for the sharing of confidential information and to continuing cooperation between HPFB, HECSB and ANVISA, in the best interests of public health.

Yours sincerely,



Meena Ballantyne  
Assistant Deputy Minister  
Health Products and Food Branch  
Branch



Paul Glover  
Assistant Deputy Minister  
Healthy Environments and Consumer Safety  
Branch