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Arrangement for the Sharing of Confidential Information between the Veterinary Drugs Directorate of the Department of Health Canada and France's Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail – Agence nationale du médicament vétérinaire

The Veterinary Drugs Directorate (VDD) of the Department of Health Canada and the Agence nationale sécurité sanitaire de l'alimentation (Anses) of France's Agence nationale du médicament vétérinaire (ANMV) as, respectively, the regulatory authorities for veterinary drugs and drug products in Canada and France, hereinafter referred to as "the Participants",

Considering the Participants' need to improve their relations through greater cooperation in the sharing of confidential information;

Considering that each Participant has authority to regulate specific products, that each Participant defines these products differently, and that cooperation for the purposes of this Arrangement applies to all regulated products common to the Participants, this productive collaboration may include but not be limited to veterinary drugs,

Considering that the Participants deem it vital, both to the sustainability of this Arrangement and to their future cooperation, that confidential information shared between them be protected from unauthorized use or disclosure under the applicable law of their respective countries,

Have come to the following:

Provision of Information

1. The goal of this Arrangement is to improve communication between Participants, and enhance their ability to protect and promote population health and safety in their respective countries. It is also to ensure greater and faster access to safe, effective and high quality products, and improve regulatory performance and safety by using the best regulatory experts from both countries.

2. a) The Participants understand that information shared between them may include confidential information that is not in the public domain of the country of the Participant providing it. Participants will inform each other of the confidential nature of information at the time it is shared.

b) Participants will endeavour to ensure the confidential information they share remains confidential under the applicable law, and with the policies and procedures covered by said laws they apply to the Participants in their respective countries.

c) Participants will make every reasonable effort to prevent:

i) the public disclosure of confidential information shared for the purposes of this Arrangement; and

ii) any other disclosure of said information for purposes other than those set out in this Arrangement.

3. a) The Participants understand that the provision of documents and other information under this Arrangement is subject to the applicable access to information laws of France and Canada. To the extent that these laws so permit, Participants may provide all confidential information or documents to the requesting Participant (who in turn will disclose them only to staff members who require them to fulfill obligations under the laws and regulations on veterinary drugs, and will use said documents or information in full confidentiality).

b) The Participants understand that the preceding sub-paragraph will not apply if the Participant providing the documents or information has consented to their disclosure.

4. a) Participants will consult each other each time an application for disclosure concerns confidential documents or information received from one of the participants. Public or third-party disclosure may not occur without the express written consent of the party providing the information to the disclosing party.

b) Participants will inform each other of any request by legislative or judicial authorities to obtain confidential documents or information already provided by one Participant to the other. When such interventions require public disclosure, the other Participant will ensure the information and documents are disclosed in a manner that protects them from breaches of industrial or trade secrecy.

5. Participants will inform each other of changes made to laws, policies or procedures that may affect the treatment of confidential information or documents obtained from the other Participant.

6. Participants will protect the confidentiality of documents and information in accordance with applicable laws, and with the policies and procedures covered by said laws as they apply in their respective countries.

7. a) The Participants understand that document and information requests will be directed to those tasked with administering this Arrangement. Unless the other Participant is otherwise notified in writing, the points of contact for all matters concerning this Arrangement will be:

- i) for VDD, the Branch's international liaison officer; and
- ii) for Anses, the ANMV director of international affairs.

b) Participants may change their point of contact by giving written notice to the other Participant.

8. This Arrangement affects neither the regulatory authority nor the responsibilities of Participants, and creates no legally binding obligations.

9. This Arrangement will be implemented at no cost or charge to the Participant requesting the documents or information.

10. Participants will collaborate on a broader scale, including but not limited to:

- i) the pursuit of concurrent veterinary drug evaluation opportunities;
- ii) the sharing of information on veterinary drug marketing authorization requests;
- iii) cooperation in the control or review of existing veterinary drugs;
- iv) the sharing of information on marketing authorization for veterinary drugs and licensing for veterinary drug manufacturers;
- v) the sharing of information on electronic application submission and management procedures.

11. a) This Arrangement will come into force on the date of the Participants' last signature, for a tacitly renewable period of 5 (five) years.

b) Participants may terminate this Arrangement by giving 30 days' written notice to the other Participant, or by mutual consent. Upon termination of the Arrangement, Participants will continue to protect confidential information from unauthorized disclosure or use in accordance with the applicable law and the practices and procedures covered by and deriving from said law.

c) The Participants may amend this Arrangement at any time by mutual written consent.

Signed in duplicate at Maisons-Alfort on this April day of 30th, 2012
and at Ottawa on this 1st day of May, 2012 in both English and French, each
version being equally valid.

For the Agence nationale sécurité sanitaire
de l'alimentation of France's Agence
nationale du médicament vétérinaire

For the Veterinary Drugs Directorate of the
Department of Health Canada

Le Directeur Général



Marc MORTUREUX



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