



***MEMORANDUM OF UNDERSTANDING BETWEEN THE VETERINARY DRUGS  
DIRECTORATE OF THE DEPARTMENT OF HEALTH OF CANADA AND THE  
AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY OF AUSTRALIA***

The Veterinary Drugs Directorate (VDD) of the Department of Health of Canada and the Australian Pesticides and Veterinary Medicines Authority (APVMA), hereinafter referred to as the Participants,

Taking into account that they are responsible for the regulation of veterinary medicines in their respective countries;

Noting that they have a strong record of cooperation in various international forums to advance the effective regulation of veterinary medicines and a history of ad hoc direct cooperation on technical regulatory matters from time to time;

Recognising that they have similar approaches to regulation of veterinary medicines in the broad sense and at the practical level in relation to the type of data they required;

Recognising that there is mutual advantage to increasing the scope of and strengthening the framework for such cooperation;

Have come to the following understanding:

***1. PURPOSES AND OVERVIEW***

- 1.1. The Participants intend to strengthen exchange of knowledge and expertise to enhance the efficiency and effectiveness of their respective roles.
- 1.2. This Memorandum of Understanding (MOU) will focus on cooperation in relation to the operational aspects of veterinary medicine regulation and will not cover broader government regulatory policy.
- 1.3. Subject to the confidentiality provisions outlined in paragraph 3, the Participants will exchange information on risk assessment and risk management options in respect of veterinary medicines that they jointly cover.

1.4. The exchange of information and cooperative action between the Participants will relate to veterinary medicines regulatory matters of mutual interest, with focus on the following elements:

- (i) A system for early information exchange on upcoming veterinary medicines regulatory issues that may impact on Australia and Canada.

This would involve, but not be limited to, exchange of information on routine veterinary medicine issues and organizations initiatives that may be of mutual interest such as veterinary medicine quality, issues of public concern, risk reduction, minor uses, animal health issues, cost recovery and efficiency measures;

- (ii) Information and experience in relation to information technology, particularly in the area of electronic data submission and templates;
- (iii) A mechanism to routinely exchange lists of new veterinary medicines under evaluation and existing veterinary medicines under re-evaluation as well as a mechanism to exchange assessment reports prepared for veterinary medicines of common interest, subject to sponsor permission;
- (iv) Scientific exchange and staff involvement in cooperative efforts to the fullest extent possible;
- (v) A mutual commitment to take advantage of international fora, such as the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), VICH and other international meetings as appropriate, for face-to-face meetings between staff, as an important mechanism for advancing the work program that the Participants will mutually determine;
- (vi) The development of a joint work program with a set of defined milestones over a three (3) year period. The work program will aim towards achieving common approaches to risk assessment methods and processes and conducting a concurrent assessment of applications for approval/registration of veterinary medicines;
- (vii) As further elements of the work program are developed and mutually determined by officers responsible for the implementation of this MOU, these will be exchanged in writing.

## **2. ROLES AND RESPONSIBILITIES**

### **2.1. APVMA**

2.1.1. Subject to paragraph 3.1, APVMA will notify VDD of applications received or proposals initiated relating to, but not limited to, those areas listed under paragraph 1.3. Notification will involve APVMA providing an information summary to VDD describing the nature of the application or proposal.

2.1.2. At the request of VDD, and subject to paragraph 3.1 APVMA will provide further information to VDD regarding APVMA's assessment of any application or proposal formally notified under paragraph 2.1.1. Further information may include the following:

- (i) full copies of APVMA's assessment reports,
- (ii) information about the type and scope of data submitted with the application, including copies of specific study reports; and
- (iii) discussions with the assessing officers regarding issues of concern that arose during an assessment.

2.1.3. APVMA will inform VDD of the outcome of APVMA's final assessment in relation to draft standards and variations, and the APVMA's final decision made in respect of any application not under paragraph 2.1.1.

2.1.4. APVMA will provide information under paragraph 2.1.2 free of charge.

### **2.2. VDD**

2.2.1. Subject to paragraph 3.2, VDD will notify APVMA of any applications received relating to, but not limited to, those areas listed under paragraph 1.3. Notification will involve VDD providing an information summary to APVMA describing the nature of the application.

- 2.2.2. At the request of APVMA, and subject to paragraph 3.2, VDD will provide further information to APVMA regarding VDD's assessment of an application notified under paragraph 2.2.1. Further information may include the following:
- (i) full copies of VDD's assessment reports;
  - (ii) information about the type and scope of data submitted with the application, including copies of specific study reports; and
  - (iii) discussions with the assessing officers regarding issues of concern that arose during an assessment.
- 2.2.3. VDD will inform APVMA of VDD's final decision made in respect of any application notified to APVMA under paragraph 2.2.1.
- 2.2.4. VDD will provide such information under paragraph 2.2.2 free of charge.

### **3. CONFIDENTIALITY**

#### **3.1. APVMA**

- 3.1.1. APVMA will not disclose to VDD confidential commercial information without first obtaining the consent of the person whose information it is to the provision of such information in accordance with this MOU. When seeking such consent to provide the information to VDD, APVMA will inform the person of the purposes for which VDD might use the information and that VDD will take all reasonable efforts to protect confidential information, in so far as the information is not already in the public domain in Canada.
- 3.1.2. APVMA will consider that all information provided by an applicant in support of an application to it, except for confidential commercial information, will be, once the application has been disclosed by the APVMA, a matter of public record and will be subject to requests under Australian Law. Similarly, all of APVMA's assessment reports, including the safety assessment reports, will also be a matter of public record. APVMA is acting in accordance with its legislative framework in committing to provide such information to VDD and is not committed to inform the applicant about the provision of such information. However, as a matter of good practice, it will generally do so.
- 3.1.3. APVMA will inform VDD of the person's response to a request under paragraph 3.1.1.

- 3.1.4. Unless otherwise required by law, APVMA will take all reasonable efforts to protect the confidentiality of any information provided to it by VDD from disclosure to any third party and will not release it to any person other than APVMA staff members or contractors who need to know the information for work purposes, except with written consent from VDD or written confirmation from VDD that the information has been made public in Canada. APVMA will take all reasonable efforts to ensure that staff members and contractors receiving access to such information will protect its confidentiality.
- 3.1.5. Refusal of an applicant to share information as outlined in this MOU will not preclude APVMA from evaluating its application.

### 3.2. VDD

- 3.2.1. Before releasing any information, including confidential information to APVMA, VDD will obtain the consent of the applicant to the provision of such information to APVMA in accordance with this MOU. When seeking the consent of the applicant, VDD will inform the applicant of the purposes for which APVMA might use the information and APVMA will take all reasonable efforts to keep any such information confidential, in so far that the information is not already in the public domain.
- 3.2.2. VDD will treat all information provided in support of applications to it as confidential information. Likewise, all of VDD's evaluation reports will also be considered confidential information. In addition, VDD will treat all information received as if it were confidential information. VDD will therefore seek the written consent of the applicant prior to providing any information contained in said applications to the APVMA.
- 3.2.3. VDD will inform APVMA of the applicant's response to a request under paragraph 3.2.1.
- 3.2.4. Unless otherwise required by law, VDD will take all reasonable efforts to protect the confidentiality of any information provided to it by APVMA from disclosure to any third party and will not release it to any other person other than VDD members or contractors who need to know the information for work purposes, except with the written consent from APVMA or written confirmation from APVMA that the information has been made public. VDD will take all reasonable efforts to ensure that staff members and contractors receiving access to such information will protect its confidentiality.

3.2.5. Refusal of the applicant to share information as outlined in this MOU will not preclude VDD from evaluating its application.

#### **4. ADMINISTRATIVE ARRANGEMENTS**

- 4.1. Changes by either Participant in legislation, operational policies, practices and procedures which relate to matters covered by the MOU, and which would impact on the operations of the MOU, will be notified to the other Participant and any consequential changes necessary to the MOU will be subject to consultation between the Participants.
- 4.2. The officers responsible for the administration of this MOU are:
  - 4.2.1. the person holding the position of Chief Executive Officer, APVMA; and
  - 4.2.2. the person holding the position of Director General, VDD.
- 4.3. The officers responsible for the day-to-day operations under this MOU are:
  - (i) The person holding the position of Program Manager Veterinary Medicines, APVMA; and
  - (ii) Persons holding the position of Directors / Chiefs, VDD
- 4.4. Changes to contact officers will be notified within 10 working days and transitional arrangements put in place to deal with correspondence received in the interim. The Participants will assist each other when requested to identify sources of expertise to review applications or to review or provide other information.

#### **5. REVIEW OF THIS MOU**

- 5.1. On, or shortly after, the first anniversary of the date of this MOU, representatives of the Participants will review the flow of information between the Participants, the costs incurred by each Participant in providing information, and the scope of the MOU and consider, if appropriate, amendment of this MOU. Thereafter, periodic review of this MOU may take place on request from either Participant.
- 5.2. Nothing in paragraph 6.1 precludes the Participants from mutually determining to amend this MOU at any time.
- 5.3. This Memorandum of Understanding is comprised of this document and its amendments and schedules, as amended from time to time.

**6. EFFECTIVE DATE AND TERMINATION OF THIS MOU**

- 6.1. The MOU will commence on the day on which it is signed by both Participants or if signed on separate days, the day on which it is signed by the last Participant.
- 6.2. Any disagreement regarding the interpretation or implementation of this MOU will be resolved by consultation between the Participants.
- 6.3. Either Participant may terminate this MOU by written notice to the other Participant. The MOU will terminate 30 calendar days after the provision of the written notice from the other Participant of its intention to terminate.

Signed in duplicate in Ottawa, this 29<sup>th</sup> day of April 2005, in the English and French languages, each version being equally valid.

*D. C. Kirpatrick*

FOR THE VETERINARY DRUGS DIRECTORATE  
DEPARTMENT OF HEALTH  
OF THE GOVERNMENT OF CANADA

Signed in duplicate in Barton, this 16<sup>th</sup> of May 2005, in the English and French languages, each version being equally valid.

*R. J. Smith*

FOR THE  
AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY