COUNCIL GUIDELINES REGARDING PRESCRIBING, DISPENSING, COMPOUNDING AND SELLING PHARMACEUTICALS

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INTRODUCTION

Alberta veterinarians are dedicated to the health and welfare of all animals through diagnosis, treatment and prevention of disease. Veterinarians also play a principal role in ensuring a safe food supply for Canadians by promoting the responsible use of pharmaceuticals, biologicals and agricultural chemicals by animal owners and animal caretakers.

These guidelines are intended to promote the appropriate delivery of veterinary services and safe, responsible drug use by veterinarians and their clients, and to address public concerns regarding food safety and use of pharmaceuticals in animal production.

In addition, adherence to these guidelines will help maintain the highest quality and purity standards in Alberta's agri-food industry, and safeguard export markets.

The ABVMA supports the development of regulations that encourage the prudent use of animal medications in all areas of animal management. The Association believes that such regulations are essential to the long-term viability of food animal production in Alberta.

Federal Food and Drug Regulation amendments announced in 2016 and policy changes relating to veterinary oversight of antimicrobials have been considered in the drafting of these guidelines. The professional responsibilities of veterinarians registered in Alberta who are engaged in the prescribing, dispensing, selling, and compounding antimicrobials, including those administered through feed and water, are explained in this guideline.

The professional obligations of registered veterinarians engaged in the prescribing, dispensing, compounding and selling pharmaceuticals described in this guideline are consistent with the Canadian Veterinary Medical Association Veterinary Pharmaceutical Stewardship Advisory Group (CVMA – VPSAG) and the Canadian Council of Veterinary Registrars (CCVR) collaboration on the document: *Veterinary Oversight of Antimicrobial Use: A Framework of Professional Standards for Veterinarians.*

PART A - ABVMA COUNCIL GUIDELINES FOR VETERINARIANS PRESCRIBING DRUGS

APPLICATION

The Guidelines set out in this part with respect to required professional responsibilities of veterinarians related to prescribing apply to the following categories of drugs and substances:

- All drugs or substances listed in the *Prescription Drug List* http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_list_fin_ord-eng.php#a2
- Any antimicrobials not listed in the *Prescription Drug List* administered by any route of administration including in feed and water, regardless of their designation by Health Canada
- Any modified live virus vaccine;
- Any drug or medication used in an extra-label manner;
- Any drug which has been removed from its original packaging;
- Any drug or substance listed in the Schedules to the Controlled Drugs and Substances Act in which case additional conditions will apply.

These professional responsibilities apply to prescribing of antimicrobials administered by all routes of administration including feed or water.

The issuing of prescriptions for administration of antimicrobials via feed must be in accordance with the Compendium Medicating Ingredient Brochures (MIB).

Notwithstanding the above, members are reminded of the substances prohibited for sale for administration to food-producing animals in Canada (Banned Substances). Currently these include:

- Chloramphenicol or its salts or derivatives;
- 5-nitrofuran compound;
- Clenbuterol or its salts or derivatives;
- 5-nitroimidazole compound;
- Diethylstilbestrol or other stilbene compounds.

PROFESSIONAL OBLIGATIONS - PRESCRIBING

The prescribing veterinarian must be registered with the ABVMA and be working out of or in conjunction with an ABVMA certified and inspected veterinary practice entity where medical records are maintained.

Requirements to be met by the registered veterinarian in order to appropriately prescribe a drug include:

1. Establish and meet conditions of a valid Veterinary Client Patient Relationship (VCPR) in regards to a specific animal or group of animals
2. Make an evidence-based determination of medical need
3. Complete appropriate documentation in the medical record
4. Provide oversight of use and follow up

1. Establish a Valid VCPR

Veterinarians are required to establish a valid VCPR prior to the provision of veterinary medical services including ordering treatment by virtue of issuing a prescription.

The term "Veterinary-Client-Relationship" is defined in s. 21.2 of the *Veterinary Profession General Regulation.*

For the purpose of this document the following definition is accepted as an interpretation of the Veterinary Profession General Regulation.

Veterinary-Client-Patient Relationship (VCPR) - A VCPR exists when all of the following conditions have been met:

1. The veterinarian has assumed responsibility for making clinical assessments and recommendations regarding the health of the animal(s) and need for medical treatment,

2. The veterinarian has sufficient knowledge of the animal(s) on which to base the assessment, diagnosis and treatment of the medical condition of the animal(s). This means that the veterinarian:

- *is professionally acquainted with the keeping and care of the animal(s), and*
- *has documented relevant and timely interaction between the veterinarian, animal owner or caretaker and animal patients, and*
- *has documented medically appropriate information and knowledge about the animal(s)*

3. The client has agreed to follow the veterinarian's recommendations and prescription.
4. The veterinarian is available or has arranged for follow-up evaluation, especially in the event of adverse reactions or failure of the treatment regimen.

The medical record must clearly demonstrate the establishment of a legitimate Veterinary Client Patient Relationship.

2. Make an Evidence-Based Determination of Medical Need

It is the responsibility of the registered veterinarian to make an informed decision that a particular drug will be prescribed. The veterinarian must have established the medical needs of the patient, either on an individual or herd basis, prior to prescribing treatment

It is expected that the establishment of need and the decision to prescribe a particular drug is evidence based or informed. The evidence results from some appropriate form of investigation that results in the veterinarian having collected or received significant and relevant information with respect to the health of the animal or animals.

The most common investigation used when prescribing drugs in veterinary medicine is receiving a pertinent medical history and conducting a physical examination of an animal or group of animals.

A registered veterinarian may use other forms of investigation and information related to the particular case at hand to make or support an evidence-based diagnosis and decision on treatment. These include culture and sensitivity testing, laboratory reports, production data, necropsy results, histology, bacteriology and virology results.

It is not necessary that an individual animal is examined in every instance that a veterinarian issues a prescription. Veterinarians may appropriately prescribe drugs based on examination and/or relevant knowledge of a group of animals.

It is required in every instance when a prescription is issued that the veterinarian has relevant medical knowledge to support the establishment of medical need.

The prescribing veterinarian when prescribing an antimicrobial should consider the contribution of all antimicrobial use to development of AMR. Veterinarians should consider the importance of the prescribed antimicrobial to human health. Veterinarians must prescribe the right antimicrobial at the right dose for the right duration. Prescribing veterinarians are required to follow the CVMA Prudent Use Guidelines.

ANIMAL HEALTH PROTOCOL

Veterinarians may establish animal health protocol(s) for an animal or group of animals in advance or anticipation of the animal health event (illness, vaccination, processing etc.).

The documented animal health protocol established by the veterinarian is considered to establish the medical need for issuing a prescription.

An animal health protocol is not a prescription and does not authorize dispensing of pharmaceuticals.

An animal health protocol is a specific direction or series of steps to be undertaken following a specific scenario or indication.

When an animal health protocol includes a direction that a pharmaceutical be administered to an animal or group of animals, a legitimate prescription must be issued before pharmaceuticals are dispensed.

3. Complete Appropriate Documentation in the Medical Record

The investigation conducted and the information upon which the registered veterinarian relies to determine the medical need must be documented in the medical record. The medical record must also document the elements of each specific prescription issued.

Medical records for all practice types (companion animal, equine and production animal) shall contain sufficient information entered into the record regarding the history, consultations, laboratory investigations and physical examination findings to justify the prescription and use of the pharmaceutical. A precise diagnosis or purpose for use of the pharmaceutical must be recorded.

Specifically, medical records shall be maintained by the veterinary practice and document:

- All prescriptions generated for the specific animal or group of animals (including in feed and water prescriptions), supported with specific evidence of establishment of medical need.

- All prescriptions must be specific to drug, quantity, indication, route of administration, duration of administration, withdrawal time (if relevant) and number of refills available.

- The prescribing veterinarian must clearly document the intention to prescribe a specific product (trade name) with no substitution or the chemical name of the drug which would allow the dispenser to dispense the product (trade name) of their choice.
- All medication dispensed or sold for the animal or group of animals and evidence that a valid prescription is on file.

- Medical records shall document the diagnosis or purpose of use, and communication regarding progress of care, patient response to treatment including treatment failures and any adverse reactions.

Records that are maintained on any farm, production or other group unit are only in addition to the medical records maintained by the veterinarian.

A prescription or order for treatment that is to be dispensed at a facility other than the VPE at which the prescribing veterinarian is employed, the prescription may be transcribed in a portable format and must include the following information:

- Prescribing veterinarian and certified veterinary facility, and contact information
- Patient owner/agent (client)
- Date of prescription
- Identification of individual animal or group of animals

- Name of drug prescribed and concentration
- Quantity of drug
- Directions for use, including dose, frequency, and duration
- Route of administration
- Substitution (yes or no) of same drug (different brand name)
- Number of refills (implies zero if not indicated)
- Withdrawal time
- Signature of the veterinarian

In addition, prescriptions for pharmaceuticals to be administered via feed must be consistent with federal legislation and minimally include the following:

- Animal production type
- Weight or age
- Type of feed
- Total amount of feed or feeding period
- Amount of drug used per tonne
- Manufacturing instructions
- Cautions
- CgFARAD # if applicable

4. Provide Oversight of Use and Follow Up

The accepted definition of VCPR specifically dictates that the registered veterinarian who is responsible for making medical decisions with regards to an animal or group of animals must be available for follow up or have arranged a designated alternate. This obligation extends to the prescription of any pharmaceuticals including antimicrobials.

It is the responsibility of the prescribing veterinarian to ensure that prescribed pharmaceuticals are used properly. This includes client training and education on appropriate use, handling and storage, withdrawal time (if applicable), and being available in event of treatment failure or adverse reactions.

Regardless of where a client gets a prescription filled, the prescribing veterinarian is responsible for oversight of appropriate use of prescribed medications.

EXTRA LABEL DRUG USE (ELDU)

In the interest of protecting animal health and welfare, veterinarians' right to prescribe extra-label drug use (ELDU) must be maintained.

ELDU (also referred to as "off-label use") is defined as the use in animals of:

i) A pharmaceutical product in a manner that is not in accordance with Health Canada's approved label, package insert, or registration by the Canadian Food Inspection Agency or Health Canada.

ii) Any approved drug that is administered in a manner not explicitly stated on the approved label in regard to indication, dosage regimen, route or frequency of administration, duration of treatment, or target species.

iii) Any drug approved for human but not veterinary use, active pharmaceutical ingredients (API's), and compounded drugs.

Extra label drug use by veterinarians is guided by the CVMA "Extra-Label Drug Use (ELDU) – Position Statement" June 30, 2015:

> *The CVMA holds that Extra-Label Drug Use (ELDU) is an important and legal strategy in the effective and efficient treatment of animals by licensed veterinarians when an approved veterinary product is not available or suitable.*
>
> *The CVMA supports ELDU when the prescribing veterinarian has evidence to support efficacy, dosage regimen, or indication for the disease and species being treated, and the circumstances of the use are in accordance with the provincial veterinary regulatory authority's policy or guidelines.*
>
> *The CVMA holds that only veterinarians are qualified to prescribe ELDU in animals and it must only be performed within the confines of a valid veterinary-client-patient relationship.*

A prescription for a medically important antimicrobial to be administered via feed must be issued in accordance with the indications, species, dosage, treatment durations and withdrawal times specified in the Compendium of Medicating Ingredient Brochures (CMIB) and / or drug label.

However, in exceptional circumstances, a feed prescription issued for an antimicrobial or other medications not listed in the Compendium of Medicating Ingredient Brochures (CMIB) or for a species, dosage, duration or withdrawal time not listed in the specified CMIB or on the label, is considered extra-label drug use. The veterinarian issuing any ELDU prescription for food producing animals is required to comply with the CVMA Antimicrobial Prudent Use Guidelines (2008) which state:

> *"If an antimicrobial is selected that is an extra-label use, the veterinarian must provide, in writing, the appropriate information on dose, route, frequency, duration and withdrawal time to avoid a risk to food safety. The Canadian Global Food Animal Residue Avoidance Database (www.cgfarad.usask.ca) should be consulted for its recommended residue avoidance information when antimicrobials are used in an extra-label manner".*

The veterinarian may also rely on other relevant information and advice.

Drugs or classes of Very High Importance in human medicine which are listed as class I Antimicrobials by Health Canada should not be used in an extra-label manner in animals destined for the food chain and should only be used in other animals if all alternatives have been exhausted, there is culture and sensitivity supporting their use, and the animal is determined to have a reasonable chance of survival.

Veterinarians may prescribe a Health Canada approved product (veterinary or human) for a species, at a dose or for an indication not on the label, provided there is no suitable on-label product available.

When prescribing extra-label drug use, the veterinarian has the responsibility to ensure safety, efficacy and, if appropriate, food safety.

Veterinarians must obtain informed consent from the owner when prescribing extra-label drug use.

Veterinarians must adhere to Health Canada regulations and guidelines on drugs prohibited for use in food producing animals or other situations.

PART B – ABVMA COUNCIL GUIDELINES FOR VETERINARIANS DISPENSING PRESCRIPTION DRUGS

> *NOTE: Guidelines set out in this part apply to dispensing of types or categories of drugs or substances set out in Part A of these Guidelines. Members should note additional requirements for drugs covered in Part E of this Guideline regarding Prescribing Narcotic, Controlled and Targeted Substances.*

Dispensing is the act of supplying prescription medication(s) on the specific direction (prescription) of a registered veterinarian, for a specific animal or group of animals.

Dispensing or filling a prescription is a unique activity, under provincial and territorial authority and may only be performed by a registered veterinarian or a registered pharmacist in accordance with provincial legislation.

In Alberta, the *Veterinary Profession Act* includes the activity of “dispensing” within the scope of activities that a registered veterinarian may undertake as part of the practice of veterinary medicine.

Dispensing is the act of supplying prescription medication(s) on the specific order of a practitioner, who has determined the need or anticipated need of a patient (either individual animal or group of animals with a similar need) and who is responsible to treat or address this specific need.

A veterinarian who undertakes the dispensing of a medication pursuant to their own or another veterinarian’s prescription is considered to be a dispensing veterinarian.

Federal legislation defines a "practitioner" as a person authorized by the law of a province of Canada to treat patients with any drug listed or described in the Prescription Drug List of the Food and Drug Act.

In Alberta, medical treatment of animal patients is restricted to registered veterinarians. There is a requirement that all veterinary practice entities offering veterinary services in Alberta be inspected and certified by the ABVMA in accordance with the *Practice Inspection Practice Standards Bylaw.*

The acts of prescribing and dispensing are separate and distinct professional activities and may appropriately each be performed by different veterinarians in different veterinary practices. However, in many circumstances where an animal is examined and treatment is ordered, the prescribing veterinarian also acts as the dispensing veterinarian and the acts of prescribing and dispensing are performed as an integrated activity.

This separation of prescribing and dispensing activities is recognized by the ABVMA as acceptable practice.

TRANSPARENCY

Prescribing and dispensing are separate veterinary medical activities. The authority for a veterinarian to undertake each of these activities is established by legislation.

Recognizing a potential conflict of interest exists, the process of prescribing and dispensing of pharmaceuticals must be transparent.

The establishment of medical need and prescribing of a particular pharmaceutical must be transparent to the client and is an evidence based decision.

The client's choice to have a prescription filled wherever they may legally do so must be maintained and respected. Any action that would result in a client being forced to purchase pharmaceuticals from a particular location would justify claims of conflict of interest.

A registered veterinarian who has determined the medical need and appropriately issued a prescription must provide a transcribed copy of this prescription to a client at the clients' requests. Such a transcribed prescription permits a client to access medication from a source other than the prescribing veterinarian.

PROFESSIONAL OBLIGATIONS - DISPENSING

A registered veterinarian may dispense drugs only through an ABVMA certified veterinary practice entity, and only for animals located within Alberta.

Notwithstanding the above, a veterinarian registered and practicing out of, or in conjunction with an ABVMA certified veterinary practice entity located in Alberta may dispense pharmaceuticals

for animals located in another jurisdiction with which the ABVMA has an established agreement (Appendix B) provided the following conditions are met:

a. The dispensing veterinarian is also registered by the professional regulatory organization in the jurisdiction where the animal(s) are located,

b. The veterinary practice entity in Alberta is certified and inspected by the ABVMA and the professional regulatory organization of the jurisdiction where the animals are located or alternatively, the practice certification and inspection undertaken by the ABVMA is recognized by the other regulatory organization,

c. The veterinarian dispensing the pharmaceuticals does so in accordance with the minimum practice standards of the ABVMA and regulatory organization of the jurisdiction where the animal(s) are located,

d. The veterinary practice entity from which the pharmaceuticals are dispensed agrees that the practice may be audited or inspected (at the cost of the veterinary practice entity) by the ABVMA and the regulatory organization of the jurisdiction where the animal(s) are located, and

e. The veterinarian may only dispense pharmaceuticals pursuant to a prescription issued by a veterinarian working out of, or in conjunction with the same ABVMA certified veterinary practice entity.

A veterinarian who elects to dispense medication (pursuant to a prescription issued by a veterinarian in the same VPE, or to fill a prescription written by another veterinarian) must meet the following requirements:

Establish the identity of client and create medical record

- The dispensing veterinarian must confirm the identification of the client and establish and maintain an appropriate medical record for each client/patient.

Establish the identity of prescriber

- The dispensing veterinarian must confirm the registration of a prescribing veterinarian as well as the fact that the prescribing veterinarian is practicing in conjunction with an appropriately certified veterinary facility or practice in Alberta.

Determine the validity of the prescription

- The dispensing veterinarian must confirm the validity or reasonableness of a prescription; if a prescription is not valid, not reasonable, or improperly written, the dispensing veterinarian **must** reject the prescription and not dispense any medications. The situation may be rectified by calling the prescribing veterinarian for clarification and confirmation of the prescription.
- A prescription may only be filled within 12 months from the date it is written (after this time, a new prescription is required);

- A prescription, including refill, can only facilitate treatment for up to 18 months from when the prescription was written.

Maintain prescriptions on file

- The dispensing veterinarian must maintain original prescriptions in the medical record. Copies (marked as such) may be provided to the client as required. These copies must be marked such that another veterinarian will not fill them. A specific prescription may only be maintained at ***one*** dispensing location at a time.

Manage available refills

- The dispensing veterinarian must obtain and confirm accuracy of an original prescription and refill information, and must forward available or remaining totals to other dispensing locations if requested by the client.
- A declining balance of refills must be maintained, and when the final refill is performed, a prescription is finished. No more refills may be made, and a new prescription must be generated by a prescribing veterinarian.

Appropriate delegation of dispensing

- While only a registered veterinarian may prescribe drugs (prescribing veterinarian) under Part A, a registered veterinarian (dispensing veterinarian) may delegate the task of dispensing to a Registered Veterinary Technologist (RVT) who is employed by the dispensing veterinarian's practice and under that veterinarian's indirect, direct or immediate supervision. The dispensing veterinarian remains ultimately responsible for the dispensing process.
- Dispensing pursuant to a prescription may delegated to an RVT under immediate supervision or must be reviewed by the dispensing veterinarian within 24 hours.
- Dispensing refills may be delegated to an RVT under indirect supervision; such dispensing does not require review by the dispensing veterinarian.
- Certain logistical services may be delegated to other non-registered staff (i.e. picking inventory, counting pills, printing and affixing labels), but the responsibility for labeling and final check of the dispensed pharmaceuticals must be performed by an RVT or dispensing veterinarian.

Provide Information to client

- The dispensing veterinarian must provide a client with all necessary information regarding use, storage and safety of a product.

In addition:

- Any substitution by the dispensing veterinarian of a specific prescribed medication for a generic medication, compounded medication, different formulation, strength or drug from the same or not the same drug class, must be confirmed with the prescribing veterinarian prior to dispensing.

- Prescriptions taken over the phone must be immediately transcribed to a written prescription by the dispensing veterinarian or an RVT to which the veterinarian delegates the activity. This may NOT be delegated to an unregistered individual.

- All pharmaceuticals must be stored and displayed in accordance with the *Practice Inspection Practice Standards Bylaw*. Specifically, the types or categories of drugs or substances set out in Part A of these Guidelines must be stored in such a manner as to prevent physical access to products by the public.

LABELING OF DISPENSED PHARMACEUTICAL

All products dispensed under Part B must be appropriately labeled.

In all cases, a dispensing label generated and affixed by the dispensing veterinarian is required in addition to the manufacturer's label.

Medication that is dispensed in the original manufacturer's packaging will provide the client with only part of the required labelling information.

In these cases, a dispensing veterinarian is not required to duplicate information from the manufacturers label on the veterinary dispensing label.

Labels Applied to 'Using Unit'

Each 'using unit' of product must be labeled by the dispensing facility. A using unit is defined as the amount of the medication in the manufacturer's packaging that is expected to be used as a unit when dispensed.

For example, if units of medication are dispensed by the bottle, each bottle must have a dispensing label. If units are dispensed in a case, each case must display the dispensing label.

"For Veterinary Use Only"

The *Food and Drugs Regulations* require that the words *"For Veterinary Use Only" or "Veterinary Use Only"* must appear on the main panel of both inner and outer package labels of approved veterinary pharmaceuticals. These words must appear immediately following or proceeding the proprietary or brand name, proper name or common name, in type not less than one half as large as the largest type on the label. When a pharmaceutical is dispensed in a container other than its original, the dispensing veterinarian must include *"For Veterinary Use Only" or "Veterinary Use Only"* on the dispensing label.

Dispensing Label Information

A dispensing label that includes information specific to the prescription (and therefore will not appear on manufacturer's label information) must be affixed or confirmed by a registered member working at the dispensing VPE. The dispensing label must include:

- Name of client or owner,
- Name of prescribing veterinarian and veterinary practice entity where prescribing veterinarian is employed,
- Name of dispensing veterinarian and veterinary practice entity where dispensing veterinarian is employed,
- Identification of specified animal or group of animals for which medication is dispensed,
- Total quantity of drug dispensed, and
- Directions for use in the animals for which drug is prescribed, including dose, frequency, and duration of treatment.

Manufacturer's Label Information

The following information will appear on the manufacturer's label. If medication is dispensed in packaging other than the manufacturers' original packaging then the following information must appear on the dispensing label.

- Name of drug dispensed and its concentration,
- Drug Identification Number (DIN),
- Minimal withdrawal time (where applicable) as prescribed, and
- Storage precautions and any toxic warnings or other precautions appearing on the manufacturers' label.

DISPENSING RECORD AUDIT

All veterinary practice entities (VPEs) must create and maintain medical records of dispensing undertake by veterinarians working in that VPE.

The ABVMA will undertake practice inspections and may audit pharmaceutical sales from veterinary practice entities.

All pharmaceuticals that are sold from an ABVMA certified and inspected veterinary practice entity must have a recorded audit trail. The sale of any prescription pharmaceutical that is recorded by an invoice will require as part of the audit trail:

- A record of the appropriate dispensing, including the labeling of the dispensed pharmaceutical,
- A record of the prescription, either:

  - medical record documentation of the required elements of the prescription as described in Part A if prescribed by a veterinarian in the same veterinary practice entity from which the pharmaceutical was dispensed, or
  - the original prescription issued by another ABVMA registered veterinarian
- A medical record that documents the investigation that was undertaken by the prescribing veterinarian to determine the medical need if the prescribing veterinarian is working in the veterinary practice entity that dispensed the pharmaceutical.

Veterinarians dispensing drugs may have their purchase and sales records audited by the ABVMA.

SHIPPING PHARMACEUTICALS

Veterinary practice entities may ship appropriately prescribed and dispensed pharmaceuticals.

Appropriately prescribed and dispensed pharmaceuticals may only be shipped by a veterinary practice. Drop shipping, or shipping of pharmaceuticals from the distributor or manufacturer directly to a client's place of residence or business, does not constitute appropriate dispensing.

A dispensed pharmaceutical may be shipped to the client's place of residence or business in the following manner:

All pharmaceuticals are dispensed and labeled in accordance with Part B of this Guideline before leaving the dispensing VPE.

The properly dispensed and labeled pharmaceuticals assembled for shipment are packaged in a sealed box(es) or shipping container(s) intended to be opened by the client only.

All boxes are clearly identified with the client's name and destination address and the dispensing VPE name and contact phone number

Pharmaceuticals may be delivered directly to the client or client's residence or business location by dispensing practice staff.

Pharmaceuticals may be shipped by a veterinary practice through the mail or by a commercial carrier directly to the client or client's residence or business address.

In cases where a commercial carrier is unable to deliver directly to the client or client's residence or business, a 'drop location' or 'depot' may be used. This drop location or depot must be a recognized shipping location of a commercial carrier. The shipped pharmaceutical may not be opened or repackaged prior to being received by the client.

The dispensing veterinarian is ultimately responsible to maintain the integrity of pharmaceuticals through transit, including:

Protection from extreme heat or freezing, and maintaining proper temperature of pharmaceuticals that require refrigeration. Pharmaceuticals must be shipped in containers that are well insulated.

Protection against breakage during normal handling – pharmaceuticals must be appropriately secured against breakage.

Application of appropriate warning labels to the shipping container (Protect from Freezing, Protect from Heat, Refrigerate on Arrival, Do Not Drop, etc.)

Shipping must comply with all applicable federal and provincial legislation.

PART C – ABVMA COUNCIL GUIDELINES ON VETERINARIANS SELLING NON-PRESCRIPTION DRUGS

The Guidelines set out in this Part C apply to sales of drugs other than those of categories or types set out in Parts A.

They will typically apply to:

Drugs that are *not* on the Prescription Drug List and are *not* antimicrobials;
Certain pesticide products;
Certain parasiticides
Killed vaccines.

These drugs are referred to in this Part as “Non-Prescription Drugs”.

The sale of Non-Prescription Drugs is a recognized activity of veterinary practice entities in Alberta. Such sales may be carried out under the following conditions:

Sales of non-prescription drugs are within the scope of practice of veterinary medicine. Notwithstanding, a veterinarian may delegate sales of non-prescription drugs to a registered veterinary technologist or an appropriately trained and qualified unregistered auxiliary employed by the veterinarian.

Sale of non-prescription drugs do not require a prescription issued by a veterinarian and do not require the presence of a Veterinary Client Patient Relationship as defined in the Veterinary Profession General Regulation.

Notwithstanding, the veterinarian has a responsibility to ensure clients are provided with and / or have adequate information about safe use of products, including: dosage, storage, withdrawal times, and any relevant precautions to be taken when using the product(s).

Non-prescription products may only be sold as such in the manufacturer's original container and packaging. Re-packaging of non-prescription products require that the product is prescribed and dispensed in accordance with Parts A and B.

Veterinarians must consider all antimicrobials as prescription only. All medically important antimicrobials, regardless of their route of administration, must be appropriately prescribed and dispensed in accordance with Parts A and B. Medically important antimicrobials must not be sold as non-prescription or over-the-counter, regardless of their designation as prescription by Health Canada.

Veterinarians must consider all modified live vaccines as prescription only and they must be appropriately prescribed and dispensed in accordance with Parts A and B. Modified live vaccines must not be sold as non-prescription or over-the-counter.

Veterinarians are reminded of s. 21.2 of the *Veterinary Profession General Regulation* (as below), which prohibits the sale of any pharmaceutical or biological product to a warehouse, pharmacy, Authorized Medicine Sales Outlet or any other individual who intends to re–sell the drug.

Prohibited sales and supplies
21.1(1) *No registered veterinarian or permit holder shall sell or supply a pharmaceutical or biological product to any person or entity that intends to resell the product, including but not limited to a wholesaler, a pharmacy and a person who holds a license under the Production Animal Medicine Regulation (AR 299/2003).*

(2) *Subsection (1) does not apply where*

(a) the sale or supply is to a registered veterinarian,

(b) the veterinary practices of the vendor and purchaser or the supplier and recipient are recognized by, or have been inspected and certified by, the Council, and

(c) all statutory requirements that apply to the product and to the veterinary practices of the vendor and purchaser or the supplier and recipient have been met.

PART D – ABVMA COUNCIL GUIDELINES ON VETERINARIANS COMPOUNDING DRUGS

The ABVMA recognizes that the procedure of compounding pharmaceuticals is within the scope of practice of veterinarians.

Compounding is defined in the *Canadian Veterinary Medical Association Antimicrobial Prudent Use Guidelines 2008 for Beef Cattle, Dairy Cattle, Poultry and Swine* as: "compounding is the combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing".

If a veterinarian participates in this field of practice, he or she must be knowledgeable about the activity and must do so within the standards of good practice required for this field. This scope of practice must be carried out in accordance with Health Canada, Health Products and Food Branch Inspectorate, "Policy on Manufacturing and Compounding Drug Products in Canada."

When no approved products (veterinary or human) exist, veterinarians may prescribe that a drug be compounded for a specific animal or group of animals. Compounding pharmacies or veterinary practices that compound quantities of drugs for which no prescription has been received for purpose of maintaining an inventory for subsequent sale is considered manufacturing and not in compliance with Health Canada regulations and consequently is not permitted.

Compounding does not include mixing drugs with feed in accordance with label directions for approved products.

Compounding of drugs is considered extra-label drug use.

Drugs may only be compounded by a veterinarian or pharmacist pursuant to a veterinary prescription in accordance with provincial legislation.

A veterinarian may compound under the following conditions:

> Veterinarians prescribing medications requiring compounding must adhere to the Canadian Veterinary Medical Association*, "Guidelines for the Legitimate Use of Compounded Drugs in Veterinary Practice";*
>
> Drugs may only be compounded by a veterinarian or pharmacist pursuant to a veterinary prescription in accordance with provincial legislation.
>
> When no appropriate approved products (veterinary or human) exist, veterinarians may prescribe drugs to be compounded for use for a specific animal or group of animals provided the veterinarian has adequate medical justification for the prescription. Notwithstanding, a veterinarian may issue a prescription for a quantity of a compounded drug in the absence of an identified need in a patient and for the purpose of maintaining

an inventory of the compounded drug for dispensing that is reasonably expected to be used within 30 days.

When dispensing any compounded drug, the veterinarian is responsible for the quality of the ingredients used.

Veterinarians must use veterinary or human approved pharmaceutical products as the basis for compounding when available.

The prescribing veterinarian remains responsible for outcomes including adverse reactions, which may include lack of efficacy.

A veterinarian shall not use cost as the sole reason for prescribing a compounded antimicrobial drug.

Cost shall not be used as a basis for using an API instead of an approved pharmaceutical product when compounding.

Veterinarians must not prescribe, dispense or administer APIs in dose form.

Veterinarians must not prescribe, dispense or administer active pharmaceutical ingredients (API) of medically important antimicrobials that is not a Health Canada approved product (Drug Identification Number) for use in food animals.

PART E – ABVMA COUNCIL GUIDELINES ON VETERINARIANS PRESCRIBING NARCOTIC, CONTROLLED AND TARGETED SUBSTANCES

NOTE: The following Guidelines apply to prescribing of narcotic, controlled and targeted substances, and are in addition to requirements of the Guidelines set out in Part A and B.

Veterinarians are unique in that they are defined in Federal legislation as a practitioner who has the authority to prescribe and are entitled through Alberta legislation (the Veterinary Profession Act) to dispense. With this privilege comes significant risks with regards to the accessibility of narcotic controlled and targeted substances. The nature of these pharmaceuticals in these categories carry a risk of diversion and addiction. This risk extends well beyond the patient being treated and can impact the patient's owner and general public as well as veterinary practitioner, allied professionals and staff.

Incidents of addiction, self-medication, drug diversion, theft, fraud and other illegal activities are all too common. It is the veterinary profession's responsibility to ensure that continued access to these necessary products is maintained through processes that guarantee their safe use in all situations.

The Alberta Veterinary Medical Association is committed to protection of public and member wellness. Accordingly, the Council directive for prescribing narcotic, controlled and other targeted substances is that the ABVMA participates fully in the College of Physicians and Surgeons of Alberta Triplicate Prescription Program (TPP).

Veterinarians in Alberta are not permitted to authorize the purchase of marijuana for the treatment of animals.

Council directs that it is mandatory for veterinary practitioners to record all prescribing and dispensing of narcotic, controlled and other targeted medications through the use of a triplicate prescription form.

TRIPLICATE PRESCRIPTION PROGRAM (TPP)

The TPP is a program administered by the College of Physicians and Surgeons of Alberta (CPSA) that monitors prescribing and dispensing of TPP listed medications. This program allows for recording and traceability of all transactions involving substances of concern. Physicians, dentists, nurse practitioners, pharmacists and veterinarians from Alberta must register with the TPP and use a special three part prescription form to prescribe TPP medications. On receipt of the CPSA copy of a TPP prescription or through the capture of digital Patient Information Network (PIN) data, information regarding the prescription is entered into a database. The CPSA generates and analyzes reports to monitor prescribing rates for the TPP medications. Prescriber prescribing patterns are monitored and statistical reports are also maintained. The CPSA publishes an annual Triplicate Prescription Program Atlas.

The TPP is administered by:

College of Physicians and Surgeons of Alberta
Telus Plaza, South Tower
2700-10020 100 St NW
Edmonton, Alberta T5J 0N3
Phone: (780) 423-4764
Toll Free: 1-800-320-8624
Fax: (780) 420-0651
Email: TPPinfo@cpsa.ab.ca

Eligible Veterinarians

Active General Licensed Veterinarians and Time Limited General Licensed Veterinarians are eligible to participate in the program.

Locum veterinarians require their own TPP pad if they wish to prescribe TPP medications.

Veterinarians with Limited Licensure - Unsupervised with advance credentials *may* be granted permission by ABVMA Council to participate in the TPP.

Ineligible Veterinarians

Veterinarians who are registered as a Temporary Registered Member or a Limited Licensee – Supervised are not eligible to participate in the TPP.

Veterinarians identified with addictions, or who have been found to be incapacitated, or have a history of narcotic or controlled substances abuse *may* not be eligible for the TPP.

TPP Medications

A complete expandable list of TPP medications can be found at:

http://www.cpsa.ca/triplicate-prescription-program-tpp/tpp-medication-list/

Buprenorphine
Butalbital Preparations
Butorphanol
Detropoxyphene
Fentanyl/Sufentanil/Alfentanil
Hydrocodone-Dihydrocodeinone
Hydromorphone-Dihydromorphinone
Ketamine
Meperidine-Pethidine
Methadone (may be prescribed only by physicians authorized by Health Canada for opioid dependency or pain management and veterinarians authorized by Health Canada)

Methylphenidate (exception is Concerta brand of methylphenidate - excluded from TPP)
Morphine
Normethadone
Oxycodone
Pentazocine
Tapentadol

NOTE: Codeine containing preparations and benzodiazepines are being captured through PIN data for human prescriptions.

Additional Veterinary Specific Medications

Type 2 Medications consistent with the CPSA and including:

All Barbiturate preparations (Phenobarbital, etc.)
All codeine containing preparations
Benzodiazepines
Tramadol
Anabolic Steroids

It is **mandatory** that a Veterinarians use a TPP form to prescribe any of the above listed medications.

TPP Forms and Pads

Upon enrollment in the TPP with the CPSA, a veterinarian is provided with their own TPP prescription pad. The 3-part TPP prescription forms are personalized with the veterinarian's individual information and veterinary practice location. The unique prescriber identification number is NOT the prescribers' registration or license number. Prescribers can only use their own personalized TPP pad. Pads must not be shared, and must not be lent to a co-worker or any other prescriber. Each prescriber must register and obtain their own pad in order to have the privilege of prescribing these products. ***There can be no exceptions!*** Verbal orders for TPP medications are NOT permitted.

Security

Security of TPP prescription pads is essential and is the responsibility of each prescriber. TPP prescription pads need to be kept in a locked environment with access only by the prescriber. Allowing anyone else to have access to a prescription pad may allow an unauthorized person to illegally access dangerous, life threatening products. It is each veterinarian's professional responsibility to prevent this from happening. **Should a triplicate prescription pad be lost or stolen, the prescriber must contact the police and notify the CPSA immediately.**

If a TPP pad is lost or stolen, the prescriber must provide the following information to the CPSA:
Date of loss or theft,
Serial number(s) of missing pad(s),
Name of the last patient prescribed a triplicate prescription, and

The police file number and the investigating Constable's name and phone number.

When a veterinarian retires, leaves practice, or leaves the province, unused portions of the pads must be returned to the CPSA for proper destruction. Spoiled prescription forms or prescription pads no longer required must be returned to the CPSA, or reported and appropriately destroyed.

Using a TPP Form

A TPP form must be used to prescribe all TPP medications, except for:

- TPP medications that are to be dispensed from the same veterinary practice where prescribed for a usage period of less than 96 hours, or
- TPP medications that are used for animals in-clinic.

However, these medications must be recorded in the clinic logs.

TPP pads shall not be used to prescribe non-triplicate prescription medications.

Pharmacists and veterinarians are NOT to fill prescriptions for triplicate prescription medications issued on regular prescription pads.

Please refer to Appendix A, Figure 1, Prescribing and Dispensing Information for Veterinarians, which provides detail on filling out a TPP form.

All fields must be filled out appropriately in a legible manner and must include:

- the clinic name that the TPP form originates from on every form,
- the identification of the animal, (the animal name followed by the owner's name in brackets)
- the client/owner's full name,
- the client's address
- the total quantity of the prescription indicted both numerically and written (to deter forgery),
- directions for use that are as complete as possible to assist in verifying quantities,
- The Personal Health Number (PHN) box is not completed on the form for veterinary prescriptions.

Once the TPP form is completed:

- one copy is retained by the prescriber,
- two copies are sent with the client to be filled at a pharmacy or dispensing veterinary practice.

Faxing TPP Forms

A TPP prescription may be faxed to a pharmacy or dispensing practice provided the TPP form is used. Data is entered in the TPP database based on the prescriber and unique prescription number assigned to each triplicate prescription form.

Once faxed, the original copy of the TPP form must be destroyed or marked VOID and must not be given to the owner or client.

The pharmacy or dispensing practice must submit a copy of the faxed prescription to the CPSA.

Dispensing TPP medications

Prescriptions for triplicate prescription medications must be filled within three days (72 hours) of the prescribing date.

Prescriptions not filled within this time become void.

All other requirements for dispensing as described in Part B of this Guideline apply to dispensing of TPP medications

Dispensing veterinarians must have clients sign the TPP forms at the time medication is provided.

The pharmacist (or dispensing veterinary practice) will keep one copy for their records and submit the third copy to the program (CPSA).

Refills and Part Fills

No refills are allowed with TPP medications. Part-fills are not allowed for compounded TPP medications dispensed from a pharmacy.

The CPSA discourages part-fills as a method to provide owners with large quantities of a drug over extended periods of time. Part-fills will **only** be accepted if the following information is specified:

total quantity,
amount to be dispensed each time, and
time interval between fills.

Dispensing TPP Medications from the Veterinary Practice where prescription is issued

Veterinarians may dispense triplicate prescription medications based on their own prescription generated from within the practice provided each prescription is first transcribed to a TPP form. In this situation:

- one copy is retained by the prescribing veterinarian,
- one copy is retained with the clinic narcotic log (as the dispensing practice),
- one copy is submitted to the CPSA by the veterinary practice.

In Addition

Veterinarians may obtain CPSA envelopes from WDDC and should ensure that CPSA copies of TPP forms are submitted to the CPSA weekly.

TPP medications that are prescribed and dispensed from a veterinary practice for a usage period longer than 96 hours require completion and submission of a TPP form to the CPSA.

Clients are required to sign TPP forms at the time of dispensing in all cases.

Compounded TPP Medications

A completed TPP form is required to prescribe and obtain TPP medications from a compounding pharmacy. This includes a prescription for a specific patient, as well as any small volume of compounded TPP medications ordered for in-clinic use that the practice anticipates dispensing within an appropriate time frame (1 month). This time frame must be consistent with the stability of the product.

As with all TPP prescription, two copies of the TPP are sent to the compounding pharmacy. For out of province compounding pharmacies, the veterinarian must complete a TPP form and fax a copy to the CPSA before providing the TPP to the out of province pharmacy.

As with all TPP medications, a TPP form must be completed if compounded TPP medications are dispensed from a veterinary practice for use by the client for a time period greater than 96 hours.

Other

A Health Canada training program (methadone exemption) is ***not*** required for veterinarians prescribing buprenorphine.

More detailed information and an application form can be obtained from the College of Physicians and Surgeons of Alberta, www.cpsa.ab.ca 780-423-4764.

ABVMA RESTRICTED MEDICATIONS

Despite the above requirements for prescribing and dispensing TPP medications, the following medications cannot be dispensed under any circumstances:

- Ketamine
- Euthanasia Solution
- Sodium Pentobarbital
- General Anesthetics (Propofol, Halothane, Isoflurane)
- Injectable alpha-2 agonists

Notwithstanding the above, it may be appropriate for a veterinarian to prescribe and dispense an injectable alpha-2 agonist with the following limitations:

- the prescription is for a specific single animal;
- the prescription is for a specific single purpose;
- the prescription is for a specific single incident use; and
- the client is made aware of the inherent dangers associated with the use of injectable alpha-2 agonists.

It is considered unethical conduct to prescribe and dispense ***any* quantity outside of these limitations.**

Alpha 2 agonists administered orally require a prescription as described in Part A of these Guidelines.

APPENDIX A

The following information must appear on all three copies of the TPP form:

When the patient is an animal, the Health Care Number field is left blank.

When the prescription is written by a veterinarian for an animal, the form should include the animal name followed by the owner's name in brackets.

The patient's address provides further verification of their identity within the TPP database.

The total quantity of the prescription must be indicated both numerically and alphabetically to deter forgery. Refills are not permitted and part-fills are discouraged.

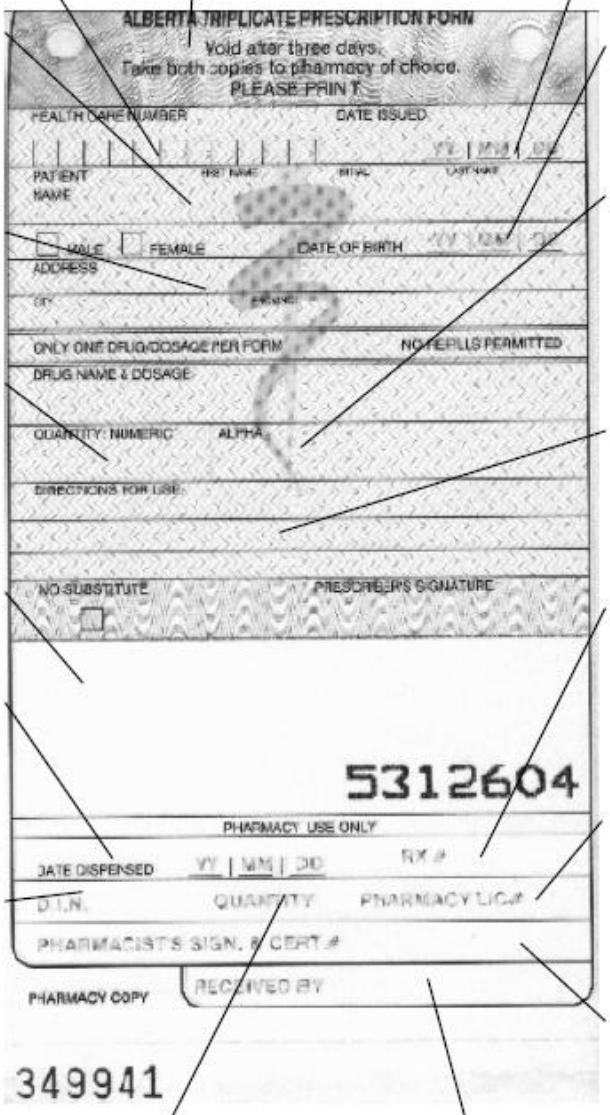
Prescribers must only use their own personalized TPP forms.

The dispenser compares the date dispensed to the date issued. If the prescription is to be put on hold, it should be documented as "deferred".

The DIN(s) of the drug(s) dispensed is (are) indicated here. If the prescription is compounded, the DIN of the TPP medication component is identified here. If the compounding agent does not have a DIN number, indicate the agent here (do not use pseudo DIN 999999)

The quantity dispensed is verified against the quantity ordered. Part fills are accepted if the total quantity, the amount dispensed each time, and the time interval between fills is specified. Document part fills as the amount dispensed over the total quantity (30/90).

The dispenser (pharmacist or veterinary practice) must be presented with the top two copies of the TPP form.



Prescriptions are only valid for 72 hours. The prescription cannot be honoured after midnight of the third day.

When the prescription is written by a veterinarian for an animal, the animal's date of birth must appear here.

A separate form is required for each TPP medication. Different strengths of the same medication are permitted on the same form provided the orders are legible and clearly indicate the prescribed dosage and quantity.

The directions for use must be as complete as possible as this assists in verifying quantities. An interval must be noted here for part-fills.

Pharmacy assigned prescription number (Not applicable when the dispenser is a veterinary practice. Reference to the TPP number on the form must be indicated in the client's chart).

Pharmacy license number is used to identify the pharmacy in the database. When the dispenser is a veterinary practice, the veterinary clinic identification number should be recorded here.

The pharmacist responsible for dispensing the medication is identified by their practice permit number. When the dispenser is a veterinary practice, the license number of the veterinarian should be indicated here.

The animal's owner should sign for the TPP medication upon the receipt of the medication. Dispensers should NOT ask the owner to sign for the medication before it is dispensed.

APPENDIX B

Memorandum of Understanding between the Alberta Veterinary Medical Association (ABVMA) and the Saskatchewan Veterinary Medical Association (SVMA)

BACKGROUND:
The practice of veterinary medicine is regulated in each province under the authority of enabling legislation.

Each professional regulatory organization has the responsibility to develop and enforce bylaws or guidelines regarding the practice of veterinary medicine in each jurisdiction. The authority to regulate veterinary medicine does not extend past provincial borders.

Veterinarians that provide services to animal agriculture enterprises are often registered to practice veterinary medicine in more than one jurisdiction. Commonly these are neighboring jurisdictions separated by a provincial border.

Veterinarians that practice out of or in conjunction with a veterinary practice entity located geographically near provincial borders provide veterinary medical services to clients in more than one jurisdiction on a daily basis.

Modern animal agriculture enterprises rely on herd veterinarians to provide production medicine services on operations that span provincial borders.

Veterinarians are under increased scrutiny to provide oversight of the appropriate use of pharmaceuticals, particularly antimicrobials.

PURPOSE:
This MOU is intended to facilitate cooperation, coordination and information sharing between the participants, namely the Saskatchewan Veterinary Medical Association (SVMA) and the Alberta Veterinary Medical Association (ABVMA) where the participants may engage in potentially overlapping enforcement activities under their respective legislative mandates, based on each participant's distinct provincial enforcement powers and processes.

AGREEMENT:
This agreement recognizes the authority and accountability established by provincial legislation relating to the regulation of veterinary medicine by the Alberta Veterinary Medical Association in Alberta and the Saskatchewan Veterinary Medical Association in Saskatchewan.
This agreement will in no way hinder the authority of the professional regulatory organization in regulating the practice of veterinary medicine within their respective jurisdictions.

The ABVMA and SVMA agree that:

1) Dispensing of pharmaceuticals by a registered veterinarian must only be performed out of or associated with a certified and inspected veterinary practice entity and for animals located within the jurisdiction where the veterinarian is registered and the veterinary practice is located.

2) Notwithstanding (1) above, a veterinarian registered and practicing out of, or in conjunction with a veterinary practice entity located in one jurisdiction may dispense pharmaceuticals for animals located in another jurisdiction provided the following conditions are met:

a. The dispensing veterinarian is also registered by the professional regulatory organization in the jurisdiction where the animals are located,

b. The veterinary practice entity is certified and inspected by the professional regulatory organizations of both jurisdictions or alternatively, the practice certification and inspection undertaken by the regulatory organization in which the practice is located is recognized by the other regulatory organization,

c. The veterinarian dispensing the pharmaceuticals does so in accordance with the minimum practice standards of the regulatory organization of both jurisdictions (medical records, labelling, shipping etc.),

d. The veterinary practice entity from which the pharmaceuticals are dispensed agrees that the practice may be audited or inspected (at the cost of the veterinary practice entity) by the professional regulatory organization of both jurisdictions, and

e. The veterinarian may only dispense pharmaceuticals pursuant to a prescription issued by a veterinarian working out of, or in conjunction with the same veterinary practice entity.

ABVMA Representative	SVMA Representative
May 8, 2017	March 30, 2017
DATE	DATE

REFERENCES

1) Veterinary Oversight of Antimicrobial Use: A Pan Canadian Framework of Professional Standards for Veterinarians *https://www.canadianveterinarians.net/documents/pan-canadian-framework*

2) CVMA Antimicrobial Prudent Use Guidelines 2008 for beef cattle, dairy cattle, poultry and swine *https://www.canadianveterinarians.net/documents/cvma-antimicrobial-prudent-use-guidelines-2008-for-beef-dairy-poultry-swine*

3) CVMA Guidelines for the legitimate Use of Compounded Drugs in Veterinary Practice 2006 *https://www.canadianveterinarians.net/documents/cvma-guidelines-for-legitimate-use-of-compounded-drugs-in-veterinary-practice-2006*

4) Compendium of Medicating Ingredient Brochures *http://www.inspection.gc.ca/animals/feeds/medicating-ingredients/mib/eng/1330705207970/1330714849837*

5) *Prescription Drug List* *http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_list_fin_ord-eng.php#a2*

6) CgFARAD *https://cgfarad.usask.ca/home.html*

7) CVMA Extra-Label Drug Use (ELDU) – Position Statement, June 30, 2015 *https://www.canadianveterinarians.net/documents/extra-label-drug-use-eldu*

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