

#### **Foreword**

ABVMA Council is pleased to present the "ABVMA Prescribing and Dispensing Handbook, 2nd Edition".

This handbook is intended to provide a readily accessible reference for the veterinary practice team. The goal is to provide clarity on the expected professional standards to be met when prescribing and dispensing pharmaceuticals.

The publication of this handbook is undertaken to support ABVMA Council priority to prepare veterinary practice teams for Health Canada's initiatives to strengthen oversight of antimicrobial use in animals.

#### **How to Interpret this Handbook**

This handbook includes the complete ABVMA Council Guidelines Regarding Prescribing, Dispensing, Compounding and Selling Pharmaceuticals. The guidelines are presented in black type on white pages, with sections of particular importance highlighted and emphasized with icons including:



**REMEMBER!** - contents are significant and expected to be frequently encountered in practice



**RESTRICTION** - contents represent a restriction or limitation to be observed



**IMPORTANT!** - contents are noteworthy and should be read carefully



**PARTY** - contents represents directives or guidelines published by other authorities relevant to our current topic

In addition to the approved guidelines the handbook provides additional information to assist in the interpretation of the guidelines. This additional information is provided in various formats including:

**APPLICATION IN PRACTICE** - sections highlighted in blue represent expanded interpretations of the guidelines that precede them, often citing specific industries or applications.

**SCENARIOS** - sections highlighted in orange represent hypothetical scenarios that veterinary professionals will encounter with the purpose of demonstrating how preceding guidelines are to be applied.

**DOCUMENTATION TEMPLATES** - this handbook includes relevant forms and other documentation for demonstration purposes. Each is marked and indexed as a figure.

Council trusts that the handbook will assist veterinary practice team members in educating their clients, prescribing and dispensing pharmaceuticals in compliance with the expected professional standards thereby delivering veterinary medical services in the public interest and protects animal health and welfare.

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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 (FDR) 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 prescribing, dispensing, selling and compounding antimicrobials, including those administered through feed and water, are explained in this Guildeline.

The professional obligations of registered veterinarians engaged in prescribing, dispensing, compounding and selling pharmaceuticals described in this Guidelines 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.



Veterinarians and veterinary technologists are expected to abide by these standards, which are enforceable on members through Practice Inspection Practice Standards (PIPS) and the ABVMA complaints/disciplinary process.

The acts of prescribing and dispensing are separate and distinct professional activities and may appropriately 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.

PART A

## PRESCRIBING DRUGS



#### **Prescribing Drugs**

#### **Guidelines for Veterinarians**

#### **Application**

The Prescribing Guidelines set out in Part A with respect to the required professional responsibilities of veterinarians 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 including feed or water.

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

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:

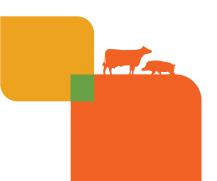
- · Chloramphenicol or its salts or derivatives;
- 5-nitrofuran compound;
- · Clenbuterol or its salts or derivatives;
- 5-nitroimidazole compound;
- Diethylstilbestrol or other stilbene compounds.

## 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 (VPE) where medical records are maintained.

The four professional obligations to be met by the registered veterinarian in order to appropriately prescribe a drug include:

- Establish and meet conditions of a valid veterinarian-client-patient relationship (VCPR) in regards to a specific animal or group of animals
- 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 "veterinarian-client-patient 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.



Veterinarian-client-patient relationship (VCPR) - A VCPR exists when all of the following conditions have been met:

- 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 Veterinarian - Client - Patient - Relationship.

There is no established timeframe for which a VCPR is valid. The conditions above must be met for all instances where a veterinarian is providing care for animals including prescribing pharmaceuticals.

#### **VCPR SCENARIOS**

#### **Hobby Ranch**

A person who recently purchased 60 cows for a hobby ranch about 20 km away drops into a veterinary practice in May to buy some vaccines for his calves for processing before turnout to pasture, and some antimicrobials for treating a lame bull. The VPE has no previous medical record for the producer.

Is there a valid VCPR established to appropriately prescribe and dispense these drugs?

	MLV Vaccines	Any Antimicrobials	Prescribed Antimicrobials
a) The veterinarian is out of the practice on a farm call, the receptionist texts the veterinarian for the OK to sell the antimicrobials and MLV vaccines.	X	X	None prescribed
b) The veterinarian at the practice has not met this person before, though the person would consider himself a client since he and his father before him used this practice for emergencies for their cows and have had their dog neutered at the practice.	X	X	None prescribed
c) The veterinarian is in the practice and has an available appointment to meet with the producer and discuss his operation. The veterinarian establishes an animal health protocol for management of calves prior to pasture turnout which includes the administration of vaccines, documents the consultation and protocol specific for the ranch, and issues written prescriptions for the vaccine	<b>✓</b>	X	None prescribed
d) The producer indicates that he needs a veterinarian for his operation and makes an appointment for the veterinarian to attend at his operation, to discuss calf management and examine the bull. After the herd health visit where the veterinarian develops animal health protocols for the calves and examines the bull and arrives at a diagnosis, the veterinarian issues written prescriptions.		X	<b>✓</b>



#### 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.



When prescribing an antimicrobial, the prescribing veterinarian should consider the contribution of all antimicrobial use to development of antimicrobial resistance (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.

#### **APPLICATION IN PRACTICE**

**Document** - Information about the prescription must be captured in the medical record. If the prescription is to be dispensed at another VPE, pharmacy or commercial feed mill, the information is transcribed to a separate written, portable prescription, either paper or electronic. A specific diagnosis or purpose of use must be documented in the medical record.

Specificity - A prescription may be issued for a specified individual animal ("Stella," "A-241") or a group of animals (Steers in pen 346, 250 mixed breed calves born in 2016, First calf heifers). A prescription issued for a drug for all animals on a farm or operation for all possible indications does not provide the appropriate oversight and is not in compliance with these Guidelines (capped).

Oversight of use and follow-up refers to the prescribing veterinarian's obligation to make sure the users of the product have appropriate training, and to be available in the case of adverse reactions or failure to respond to treatment. This does not mean that the veterinarian must supervise every administration of the drug.

Investigation - The amount and type of investigation necessary to determine medical need for a drug will vary depending on many factors. Investigation typically requires collecting medically relevant history, examination of previous records, examination of the animal or group of animals, undertaking appropriate diagnostic procedures, conducting necropsy or laboratory investigation, and analysis of previous response to treatment. It is recognized that direct examination of animals may not be required in all cases where other documented appropriate information exists.

#### **FAO**

I received a prescription written from another clinic to provide "all the medications needed for a 50-cow dairy herd." Is this a valid prescription, and can I dispense any medications?

**No** – A prescription must be specific for the animal or group of animal(s), and specify a particular drug, at a specific dose for a specific duration for a specific indication. The Guidelines state that "if the prescription is not valid, not reasonable, or improperly written the dispensing veterinarian must reject the prescription and not dispense any medications."

#### Animal Health Protocol

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

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

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. There is some confusion with regards to prescribing for "anticipated need." A veterinarian that issues a prescription and dispenses a pharmaceutical for use in the event the producer or animal owner identifies a need does not provide the necessary oversight on the use of pharmaceuticals, particularly antimicrobials, and is not in compliance with these Guidelines. This differs from the situation where the veterinarian anticipates a need based on the type of facility and previous history of the facility.



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

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



#### **ANIMAL HEALTH PROTOCOL SCENARIOS**

#### **Cow-Calf Operation**

Sample animal health protocol for neonatal scours in a beef cow-calf operation:

- 1. Identify affected calves with hunched back, soiled perineum, failure to get up
- 2. Record tag ID number
- 3. Take temperature
- 4. Assign severity number
- 5. Provide oral electrolytes as per appendix
- 6. If temperature exceeds 39.0°C, administer Nuflor at prescribed dose
- 7. Administer Banamine at prescribed dose
- 8. Move to treatment pen.
- 9. If calf fails to improve, contact veterinarian

Together, the above represent the steps to be taken by a producer upon identification of a case of neonatal scours. Steps 6 and 7 require the administration of a prescription pharmaceutical.

The above animal health protocol does not substitute as a prescription, however it does establish the medical need.

The prescription will need to specify an animal or group of animals; "calves born in the spring of 2018" will suffice. The prescription must consider the expected incidence of disease the expected number of cases to be treated to arrive at a quantity of drug on the prescription.

**Sample Prescription for Nuflor** 

#### **ABC Veterinary Clinic**

555 South Street Anywhere Alberta 780-555-5555

Date: January 28, 2017

Owner: Dun Right Ranching, c/o Mike Dun

Animal(s): 200 calves born spring 2017

**Drug:** Nuflor 300 mg/ml

Amount: 100 ml bottle

**Directions:** For calves identified as scouring calves under animal health protocol "Scouring Calves" administer 6.0 ml per 100 lbs body weight by subcutaneous injection once.

Withdrawal: 36 days for IM, 55 days for SQ

**Precautions/Warnings:** Not for use in breeding animals

Refills: 0

Dr. Jane Jones

The prescription will need to be specific as to volume – calculate 200 cow herd, incidence of scour calves to be treated at 7%, dose rate of the pharmaceutical. Limiting the prescription to a determined amount will result in the veterinarian being required to issue a new prescription if the treatment rate exceeds what is expected. Client education will be necessary to accept that a finite amount of antimicrobial is being prescribed. This is best practice so that the veterinarian is aware if there is more significant illness than expected and can help the producer respond appropriately.

#### **Animal Shelter**

Sample animal health protocol for treatment of animals on arrival at an animal shelter.

Veterinarians are commonly asked to provide care to animals in shelters, rescues and humane societies. The veterinarian that has an established relationship with the shelter may appropriately provide protocols for animals that enter these facilities to provide individual and population-based preventative care where appropriate.

Sample animal health protocol for a group of animals received from a hoarding situation where there is evidence of lice or tapeworms in some of the animals:

- 1. Complete appropriate documentation
- 2. Examine the animal for identifying marks (tattoo, tags) or microchip
- Document identifying marks or microchip number in the medical record.
- 4. In the case identification is found follow protocol "Reunification"
- Examined for external parasites according to the protocol – "Examination for fleas, ticks and lice"
- 6. Perform heartworm test
- 7. Administer a multivalent vaccine for distemper, adenovirus, parainfluenza, parvo virus
- 8. Administer medication for internal parasites including tapeworms at the prescribed dose
- Administer topical medication for lice at the prescribed dose
- 10.Follow animal isolation protocol (see APPENDIX A)

The steps above together represent the steps to be taken by an animal shelter employee for the intake of an identified group of animals. Steps 8 and 9 require the administration of a prescription pharmaceutical.

#### Sample Prescription for Drontal Plus

#### **ABC Veterinary Clinic**

555 South Street Anywhere Alberta 780-555-5555

Date: July 1, 2017

Owner: Smalltown Rescue

**Animal(s):** Small dogs received into shelter in 2017 (estimated to treat on average 75 dogs admitted through the year)

Drug: Drontal Plus 22.7 mg tablets

**Amount:** Drontal Plus 22.7 mg tablets for small dogs – 150 tablets

**Directions:** Administer a single dose of the appropriate tablet by mouth according to the following dosing chart:

Dogs/Puppies (3 weeks of age or older, greater than 1 kg body weight):

Weight	Single Dosage
2-4 lbs	1/2 tablet
5-7 lbs	1 tablet
8-12 lbs	1-1/2 tablets
13-18 lbs	2 tablets
19-25 lbs	2-1/2 tablets

**Precautions/Warnings:** Not for use in dogs weighing less than 1 kg (2.2lbs). Do not administer this drug to breeding animals or to animals kept for breeding purposes.

Refills: 0

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Dr. Jane Jones

### 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.
- 2. 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.
- 4. 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.

When a prescription or order for treatment 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
- "Canadian Global Food Animal Residue Avoidance Databank (CgFARAD) # if applicable

#### **APPLICATION IN PRACTICE**

#### Writing Prescriptions for Medications to be Administered In-Feed

The professional obligations of veterinarians related to prescribing any pharmaceutical are detailed in the CVMA/CCVR Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards for Veterinarians.

Veterinarians are encouraged to consult the Compendium of Medicating Ingredients Brochures (CMIB) for information on appropriate prescription and compatibilities of drugs to be administered in feed.

The prescription for the medicated feed shall contain the information required by the FDR (see Veterinary Prescription Checklist).

Any drugs to be administered in feed in an extra-label-drug-use (ELDU) manner must obtain withdrawal information from CgFARAD.

Veterinarians have the responsibility to ensure that drugs prescribed for food-producing animals will not result in harmful or violative residues in food, and meet other regulatory requirements set out in the Food and Drug Regulations and Feeds Regulations.

## Manufacturing Medicated Feeds by Commercial Feed Mills

A person may sell a medicated feed, pursuant to a written prescription of a veterinary practitioner, if the medicated feed is for the treatment of animals under the direct care of a veterinary practitioner who signed the prescription.

Manufacturing of veterinary feeds must follow the Feeds Regulations and whether the prescriptions are on-label or extra-label does make a difference on the timing of the manufacturing of the feeds. Two scenarios:

- 1. When medications are added to feed 'on-label' as per the CMIB, a feed mill can manufacture and floor stock these medicated feeds. The prescription is needed at the time of sale to a producer/end user.
- When a veterinarian writes a prescription for an ELDU in medicated feed (whether for dosage purpose or non-CMIB approved combinations), these feeds can only be manufactured once the prescription has been sent to the feed mill. They cannot pre-manufacture and floor stock medicated feed that are not made as per the CMIB.

A commercial feed mill cannot manufacture a medicated feed pursuant to a veterinary prescription that includes an ingredient that does not have a DIN. That is, a veterinarian cannot prescribe a vitamin, mineral or feed additives for use in feed.

Additionally, in accordance with the FDR (Page 20):

- 1. The prescription for the medicated feed shall contain the information required by the FDR (see figure A1 Veterinary Prescription Checklist).
- 2. Veterinarians have the responsibility to ensure that drugs prescribed for food-producing animals will not result in harmful or violative residues in food, and meet other regulatory requirements set out in the FDR and Feeds Regulations.
- 3. A person may sell a medicated feed, pursuant to a written prescription of a veterinary practitioner, if the medicated feed is for the treatment of animals under the direct care of a veterinary practitioner who signed the prescription.



#### **Food and Drug Regulations**

#### Sale of Medicated Feeds

- C.08.012 (1) Notwithstanding anything in this Division, a person may sell, pursuant to a written prescription of a veterinary practitioner, a medicated feed if
  - (a) as regards the drug or drugs used as the medicating ingredient of the medicated feed,
    - (i) the Director has assigned a drug identification number pursuant to section C.01.014.2. or
    - (ii) the sale is permitted by section C.08.005, C.08.011 or C.08.013;
  - (b) the medicated feed is for the treatment of animals under the direct care of the veterinary practitioner who signed the prescription;
  - (c) the medicated feed is for therapeutic purposes only; and

- (d) the written prescription contains the following information:
  - (i) the name and address of the person named on the prescription as the person for whom the medicated feed is to be mixed.
  - (ii) the species, production type and age or weight of the animals to be treated with the medicated feed.
  - (iii) the type and amount of medicated feed to be mixed,
  - (iv) the proper name, or the common name if there is no proper name, of the drug or each of the drugs, as the case may be, to be used as medicating ingredients in the preparation of the medicated feed, and the dosage levels of those medicating ingredients,
  - (v) any special mixing instructions, and
  - (vi) labelling instructions including
    - (A) feeding instructions,
    - (B) a warning statement respecting the withdrawal period to be observed following the use of the medicated feed, and
    - (C) where applicable, cautions with respect to animal health or to the handling or storage of the medicated feed.
- (2) For the purpose of this section, medicated feed has the same meaning as in the Feeds Regulations.



#### **VETERINARY PRESCRIPTION CHECKLIST**

(all items are mandatory, otherwise indicated)

VETERINARIAN	
CLINIC	
PRODUCER	

REQUIREMENTS	ITEMS	√
Date on which the prescription is written	DATE	
Veterinarian's <u>signature</u>	SIGNATURE	
Name and address of the person for whom the feed is to be	NAME	
manufactured and by whom it is intended to be used	ADDRESS	
Generic name and level of inclusion in the feed of the	MEDICATION	
medicating ingredient prescribed by the veterinarian	INCLUSION LEVEL	
Type and amount of feed to be manufactured  (The amount of feed manufactured does not exceed the amount that would be	TYPE OF FEED	
normally consumed by the number of animals prescribed to receive the feed during the prescribed period of medication)	AMOUNT OF FEED	
Number, kind, class and age and/or weight of the livestock	NUMBER	
intended to be fed the feed	KIND	
	CLASS	
	AGE and/or WEIGHT	
Special manufacturing instructions including necessary mill clean-up warnings, <b>if any</b>	MANUFACTURING INSTRUCTIONS	
Feeding instructions or directions for use of the feed which should include the period of medication during which the feed is to be fed to the livestock	FEEDING INSTRUCTIONS	
Warning statements and caution statements, where	WARNINGS	
applicable	CAUTIONS	



Figure A1 - CFIA Veterinary Prescription Checklist

#### **Medicated Feed/Premix Prescription Template**

Owner / Farm Inform	ation				
Owner:		Address:			
Tel:	Fax:	E-Mail:			
Farm Manager:		Address:			
T-I.	F	E Mail.			
Tel: Barn Location:	Fax:	E-Mail: Bin #:			
Feed Mill & Address:		Feed Mill Phone	#-		
r ood min a radiooo.		Feed Mill Fax #:			
Species:		Production Type	:		
No. Animals:		Age or Weight:		Class:	
Type of Feed (Complete/Supp	element/Premix):	Amount of Feed	(Complete/Supplement/	Premix), kgs or tonnes:	
Drug Information		1			
Medicating Ingredient(s) (Generic name)	Drug Trade Name (product)	Amount of Dr Tonne	ug Product Used per (kg/1000 kg)	Amount of Active Ingredient per Tonne (mg/kg)	
Feeding directions or Direction	ns for Use:				
Trootmont: Onco	Twico		or	timos	
Treatment: Once Twice ortimes  Starting Date (mm/dd/yyyy) Expiry date (mm/dd/yyyy)					
Lxpiiy date (minudayyyyy)Lxpiiy date (minudayyyyy)					
Manufacturing Instructions:					
Cautions:					
Warning:					
Recommended withdrawal Time: gFARAI			gFARAD Reference #:		
Veterinarian Information					
NAME:		NAME OF	CLINIC:		
SIGNED		DVM	Date:		
Address:					
Tel:	Cell:	Fax:		E-Mail:	
Owner's Statement					
"I have read and understand the directions for use, the warning statement and the caution statements set out on this prescription" (note: this statement is not required if the signing veterinarian issued the prescription directly to the manufacturer of the feed and is satisfied that owner was adequately aware of the information set out on the prescription).					
Owner's Signature:					
Legal disclaimer:					

Figure A2 - CFIA Medicated Feed/Premix Prescription Template

<sup>\*</sup> CFIA Regulations stipulate that shaded areas must be completed

#### Medicated Feed/Premix Prescription Template Appendix **Owner / Farm Information** Owner: The individual or company that owns and is responsible for Address: the animals that will be fed the medicated feed. The owner's address may be different from the location of the animals. Critical that th information be complete in the event of a feed recall. Fax: E-Mail: Farm Manager: The person on the farm responsible for following the Address: instructions of the prescription pertaining to which animals receive the medicated feed, caution, warning and withdrawals Fax: E-Mail: Barn Location, Bin #: Critical in event of feed recall so that exact location of suspect feed manufactured is known - GPS location number preferred. Feed Mill & Address: Feed Mill's Phone & Fax #: Regulations require that the Number, Kind, Class and Age or Weight be listed. Neither Class nor Kind are defined, but CFIA will accept the following-Production Type: e.g. Ewes, Stockers, Replacement Heifers, Gilts Species: Species, number of animals, production type, weight or age. This provides important information for the farm manager as to which animals receive (do not receive) the medicated feed No. Animals: Age or Weight: Class: Usually listed as Sex or Gender Type of Feed (Complete, Supplement, Premix, Description, e.g. Amount of Feed (kgs or tonnes): Can create problems since prescriptions are Grower) Exact name of feed is helpful and use rate of often time-based. Can seek input from Feed Company. supplement/premix must be known, can be obtained from Feed Co. **Drug Information** Names of Medicating Drug Trade Name (product) Amount of Drug Product Used per Amount of Active Ingredient per Ingredient(s) Tonne (kg/1000 kg) Tonne (mg/kg) Example: Chlortetracycline, Examples: Aureomycin® 220 G, Example: 2.0 kg Example: 400 mg/kg. Do not use tiamulin, tylosin Denagard® Medicated Premix, ppm'. Use concentration units Tylosin® 10 Premix listed for that drug. The exact name and total amount of the medicated feed or premix to be manufactured should be clearly stated on the prescription. A feed manufacturer cannot begin to fulfill a prescription for medicated feed unless the amount of medicated feed to be manufactured is known. Drug trade name is not mandatory, but circumstances may dictate that specific Drug Trade names be used. Feeding Directions or Directions for Use: Should include the period of medication during which the medicated feed is to be fed Optional as part of Feeding directions Twice Treatment: Once times Starting date (mm/dd/yyyy) Expiry date (mm/dd/yyyy) Manufacturing Instructions: Suggestion: Follow Feed Mill's Sequencing & Flushing Guidelines for medicated feeds Cautions: Animal health hazards, product storage and handling Transcribe from Compendium of Medicating Ingredient Brochure or Compendium of Veterinary Products, current edition. In the event of Schedule F Drugs (Romet®-30, Tribrissen® 40% powder, or Uniprim® Oral Powder), obtain recommendation from the drug manufacturer, or consult gFARAD (Canadian Food Animal Residue Avoidance Database) Warning: Human health hazards Transcribe from Compendium of Medicating Ingredient Brochure or Compendium of Veterinary Products, current edition. In the event of Schedule F Drugs (Romet®-30, Tribrissen 40% powder, or Uniprim Oral Powder, obtain recommendation from the drug manufacturer. Recommended withdrawal Time: If gFARAD Reference #: Indicates to the Feed Mill that the Veterinarian has consulted the gFARAD recommendation has been given by gFARAD, quote reference number. Withdrawal time is database, and that this case has been assigned a case number. Since gFARAD or CAPP reference numbers and Withdrawal must be recorded at processing for poultry, ANAC recommends that mandatory for poultry, CFIA Meat Inspection gFARAD reference be used for broiler and turkey scripts, strongly advised for other poultry, advised for swine and feedlot cattle, and optional for dairy cattle. Veterinarian Information. Veterinary client patient relationship requires veterinarian to be accessible in the event of adverse drug reaction or unforeseen circumstances when the medicated feed is being fed

NAME: please ensure that you PRINT your name, sign, and date Prescription Form		NAME OF CLINIC: not necessary if Prescription Form includes Clinic Logo and Address		
SIGNED		DVM	Date:	
Address:				
Tel:	Cell:	Fax:	E-Mail:	

Owner's Statement: "I have read and understand the directions for use, the warning statement and the caution statements set out on this prescription" (note: this statement is not required if the signing veterinarian issued the prescription directly to the manufacturer of the feed and is satisfied that owner was adequately aware of the information set out on the prescription).

Owner's Signature:

Legal disclaimer: Optional statement that prescription is null and void if veterinary protocol is not followed (no changes or substitutions)

\* CFIA Regulations (Feed - gray, Meat Inspection -yellow) stipulate that shaded areas must be completed.

Figure A3 - CFIA Medicated Feed/Premix Prescription Template - Appendix

#### **Medicated Feed/Premix Prescription Template - Poultry**

Owner / Farm Information											
Owner:				Address:							
Tel: Fax:				E-Mail:							
Farm Manager:				Address:							
Tel:		Fax:		E-Mail:	:						
Barn Location:							Bin #:				
Feed Mill & Address:						Feed Mill Phone #: Feed Mill Fax #:					
Species/ Production Type/Class:						# Birds:					
Placement date (							Final date processed (mm/dd/yyyy) or Processing age (days):				
Name of Feed, C below ):			(or ı	refer to	Type of Fee	ed -					
DRUG INFORMA	ATION						,				
Type of Feed Age Amount of Medicat			licating Ingredient Generic name)		Drug Tr (pro	rade Name oduct)	Amount of Drug Product Used (kg/ 1000 kg)	Amount of Active Ingredient (mg/kg)			
Feeding Directions or Directions for Use:  Treatment: Once Twice or times								es			
Starting date (mn Manufacturing Ins					Exp	piry d	ate (mm/do	d/yyyy)			
Cautions:											
Warning:											
Recommended W	Vithdrawal Ti	me:				CA	CAPP or gFARAD Reference #:				
Veterinarian	Informatio	on									
NAME:						NA	NAME OF CLINIC:				
SIGNED:				DVM	Da	Date:					
Address:	·										
Tel:				Fax:		E-Mail:					
	e: this staten	nent is not requir	ed if t	the signi	ing veterina	rian i	ssued the	prescription dir	e caution statements ectly to the manufact		
Owner's Signature:											
Legal disclaimer:											

- Gray shaded areas: Mandatory for CFIA Feed Regulations
- Yellow shaded areas: Mandatory for Poultry CFIA Meat Inspection requirements

Figure A4 - CFIA Medicated Feed/Premix Prescription Template - Poultry

### 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 all 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

In the interest of protecting animal health and welfare, veterinarians' right to prescribe ELDU must be maintained.

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

- 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.
- 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.

 Any drug approved for human but not veterinary use, active pharmaceutical ingredients (APIs), and compounded drugs.

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 CMIB and/or drug label.

However, in exceptional circumstances a feed prescription issued for an antimicrobial or other medications not listed in the CMIB, or for a species, dosage, duration or withdrawal time not listed in the specified CMIB or on the label, is considered ELDU. 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 antimicrobials of very high importance in human medicine which are listed as 'Category I: Very High Importance' antimicrobials by Health Canada should not be used in an extralabel 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 ELDU, the veterinarian has the responsibility to ensure safety, efficacy and, if appropriate, food safety.

Veterinarians must obtain informed consent from the owner when prescribing ELDU.

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





ELDU 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.

#### PRESCRIBING SCENARIOS

#### **Large Animal**

#### **Cow Calf Operation**

#### Scenario 1

A veterinarian provides service for a cow-calf producer, including examining some infected animals, consultations in herd health, animal health protocols for animals entering the backgrounding operation, calf disease treatment, cow vaccination, etc. The veterinarian maintains medical records that document these interactions.

Approximately 60 calves out of a pen of 300 are showing reduced feed intake, lethargy, hunched appearance and some coughing. The veterinarian reviews the producer's medical records, which document the occurrence of respiratory disease in similar groups of weaned calves twice over the past three years. Medical records include results of gross necropsies performed on farm, histopathology reports and bacteriology results. A diagnosis of *Manheimia hemolytica* was returned on previous investigation.

The animals in this outbreak have been sourced similarly every year.

Does the veterinarian have the required information necessary to establish the medical need to prescribe pharmaceuticals for this group of calves?

**YES** – Based on extensive documented laboratory information in the medical record, the examination of some animals and an established VCPR, the veterinarian considered this sufficient information to establish medical need and issue a prescription to treat the pen of backgrounded calves.

The veterinarian has an obligation to follow up on the prescribed treatment if an adverse reaction and/or treatment failure situation arises. It is important for the veterinarian to explore/discuss husbandry practices so the outbreaks do not occur year after year.

#### Scenario 2

A client brings their cat into the veterinary practice for a neuter and mentions that he also backgrounds some calves.

The next day the producer stops at the practice to purchase some antimicrobials and Banamine to treat an outbreak of respiratory disease.

Does the veterinarian have an established VCPR to prescribe the pharmaceuticals?

NO - the client mentioning that he backgrounds some calves is not in itself enough to establish a VCPR. In addition to being professionally acquainted with the keeping and care of the animal(s), the veterinarian must have documented relevant and timely interaction between the veterinarian, animal owner or caretaker and animal patients, and the veterinarian must have documented medically appropriate information and knowledge about the animal(s).

#### **Cow Calf Operation**

#### Scenario 3

A cow calf producer stops in at a veterinary practice to pick up drugs for processing bought calves including vaccines (MLV BVD-IBR-PI3-BRSV, Manheimia/Pasteurella, Histophilus Somnus and Clostridial) along with an antimicrobial for treatment on arrival. This is the same protocol that was followed last year.

The veterinarian is out on call and the registered veterinary technologist (RVT) consults the medical record to find these products were dispensed last year but there is no prescription written in the medical record.

Is it appropriate that the RVT dispenses the products to the producer based on the fact that they were dispensed last year?

**NO** – In order for the products to be dispensed, there must be a valid prescription. A prescription may not be issued after the fact. The medical records must document an existing prescription, or the producer would have to present a valid prescription from another veterinarian. A written prescription is valid for one year and is limited to the amount prescribed.



#### **Equine Infection**

A 10-year-old quarter horse gelding is examined for a two-day-old wound over the dorsal aspect of the right front limb mid-radius. It is found to be a moderate grade 3/5 lame, and it has marked swelling, heat and pain on palpation of the right front limb. The wound is full thickness but does not extend to the bone and no joint involvement is suspected. The wound is cleaned and attended to but. in addition, a cellulitis of the right front limb is diagnosed.

Trimethoprim-sulfa (TMS) and phenylbutazone are prescribed for the gelding. That evening, the owner calls and wants to start her mare, which has purulent nasal discharge, on the gelding's trimethoprim-sulfa.

The veterinarian cannot approve the use of TMS in the mare without examining her. It is unknown by the veterinarian whether TMS is an appropriate course of treatment for the mare, and consent to usage would be deemed inappropriate in this case.

If the stable owner or mare owner try to refill the existing prescription for the gelding, the dispensing veterinarian must question why the previous dispensed amount has been used faster than expected.

#### **Companion Animal**

#### Farm Cat with Ear Mites

A client has a small hobby farm with several barn cats. The client brings in a barn cat that is scratching her ears. With some difficulty, the veterinarian manages to examine the cat, get an ear swab and diagnoses ear mites. According to the owner, there are three more cats in the barn showing the same symptoms as the cat just examined.

Is the veterinarian required to examine the other three cats in order to prescribe medication to treat their ear mites?

NO – The veterinarian may consider the information collected from the examination of the single animal, the nature of the condition and information from the owner as sufficient to establish the medical need for the other three cats and appropriately issue a prescription and dispense medication for those animals.

The "herd" approach is commonly taken with deworming and antiparasitic medications to establish need for companion animals that are not examined but where an animal representative of a group is examined and diagnosed. There is a concern with establishing accurate weight estimates when prescribing these medications and it is the veterinarian's professional obligation to obtain this information before prescribing. Veterinarians and practices must determine what information is required to establish need and appropriately prescribe in these cases.

#### **Owner Declines Examination**

A client with whom the veterinary practice you work in had a VCPR and has been treating a senior hyperthyroid cat for the past three years. The owner has been quite diligent with follow-up, annual examinations and blood levels.

The current prescription is set to expire this week, and the client has called to say she is unable to bring in the cat and is wondering if the cat's condition is deteriorating to the point where she should consider euthanasia.

The receptionist tells the owner that it is "against the law of the ABVMA" for the practice to sell her any more medication without an examination.

A long-time client of the practice is now upset and calls the ABVMA to get some clarity on this "law." The ABVMA's response to the client is that:

"The practice is acting in the best interest of the cat to make sure that continuing to prescribe the current medication at the current dose is indicated and provides appropriate care.

It is the veterinarian's professional responsibility to determine medical need for treatment."

The veterinarian may rely on relevant information other than an examination and blood work to issue a prescription (review records and query the owner). The veterinarian could issue a prescription for medication for a shorter period of time to allow the owner some time to consider how to proceed.

If the cat truly is deteriorating, it should be examined by a veterinarian. Although it is the owner's responsibility to provide for their animal, veterinary practices, at the discretion of the veterinarian, need not withhold necessary treatment because an owner is reluctant to comply with recommended follow-up examinations or monitoring. The client's lack of compliance and declination to perform tests must be documented thoroughly in the medical record.

#### **APPLICATION IN PRACTICE**

#### **Veterinarians Prescribing for Agricultural Bee Populations**

#### **Changing Environment**

Health Canada has directed that the use of Medically Important Antimicrobials (MIA) in food producing animals shall be under veterinary oversight. This will be achieved by moving all MIAs to the prescription only drug list, to be fully implemented by the end of 2018.

This change will have a significant impact on the apiculture industry. To access tetracycline, tylosin or any other medically important antimicrobial for use in their operation, a veterinary prescription must be provided.

It is necessary that veterinarians become familiar with apiculture and the specific treatment requirements of bees. This is essential in order to develop a legitimate veterinarian-client-patient relationship (VCPR), establish evidence based medical need and subsequently prescribe and dispense antimicrobial treatment for patients presented by this industry.

#### **Establishing a VCPR**

While the traditional VCPR requires animal examination and site visits, the nature of beekeeping may make this impractical and even unnecessary. Building upon the definitions and policies outlined in the CVMA Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards for Veterinarians, the sub-section Providing Veterinary Oversight of Antimicrobial Treatment of Agricultural Bee Populations aims to provide clarity in respect to the unique needs of this specific species and industry.

Specific requirements to establish a VCPR for Agricultural Bee Populations:

#### Veterinarian

- express a willingness to engage with this species and has assumed the responsibility for making clinical assessments and recommendations regarding the health of the animal(s) and the need for medical treatment
- have access to resources regarding industry and health management
- engage in continuing education regarding the species
- Access and review disease surveillance information relevant to their region, province and across Canada
- be knowledgeable about provincial and federal legislation as it relates to beekeeping and the production of honey

#### **Veterinarian - Beekeeper Relationship**

The veterinarian has assumed the responsibility for making clinical assessments and recommendations regarding the health of the animal(s) and the need for medical treatment. The veterinarian and beekeeper must develop a relationship and the **veterinarian must document:** 

- · producer name
- address and location of production sites
- confirmation of registration of operation with the province where this is required by legislation
- premises identification number (where applicable)
- · number of apiaries
- · number of colonies or hives
- annual production

- reasonableness of access to production units by veterinarian
- evidence of in person consultation either by actual visits to production sites or consultation by real time video communication
- history of health management practices of the operation

#### Veterinarian - Bees Relationship

The following represents the information upon which the veterinarian establishes the relationship with the bee patients and which may provide sufficient knowledge of the animal(s) on which to base the assessment, diagnosis and treatment of the medical condition of the animal(s).

Some or all of the following pieces of information may be used by the veterinarian to **establish the medical need for a prescription:** 

- records of colony health
- · previous disease history
- treatment history for all diseases
- documentation of site visits by provincial apiculturists, including report and recommendations
- clinical evidence of disease based on visual inspection by the veterinarian or qualified provincial apiculturist
- laboratory reports from all submitted samples, confirming the presence of disease or spores
- culture results regarding resistance to antimicrobials
- results of antibiotic residue testing



#### **Follow Up**

As with all VCPRs and prescriptions, the veterinarian must **be available** or **have arranged for follow up evaluation,** especially in the event of adverse reactions or failure of the treatment regimen.

#### Summary

In all cases where the registered veterinarian is asked to provide oversight of the use of antimicrobials and issue a prescription for treating bees, the registered veterinarian is required to:

- Establish and meet the conditions of a valid VCPR regarding the beekeeper and bees
- Make an evidence-based determination of medical need
- 3. Complete the appropriate documentation in the medical record
- 4. Provide oversight of use and follow up

PART B

# DISPENSING PRESCRIPTION DRUGS

33



#### **Dispensing Prescription Drugs**

#### **Guidelines for Veterinarians**

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.

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.



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.

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 client's request. Such a transcribed prescription permits a client to access medication from a source other than the prescribing veterinarian.



### Professional Obligations - Dispensing

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 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 be 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 labelling 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.

#### **Dispensing Out-of-Province**

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 (see APPENDIX B) provided the following conditions are met:

- The dispensing veterinarian is also registered by the professional regulatory organization in the jurisdiction where the animal(s) are located,
- 2. 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,
- 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,
- 4. 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
- 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.

#### **FAO**

I have received a prescription from a client from another veterinarian, and something does not seem "right" about it. Do I have to fill it?

NO – The dispensing veterinarian must confirm the identity and registration of the prescribing veterinarian as well as the fact that the prescribing veterinarian is practicing in conjunction with an appropriately certified veterinary practice entity in Alberta. The dispensing veterinarian must also confirm the validity or reasonableness of the prescription. If the prescription is not valid, not reasonable, or improperly written, the dispensing veterinarian must reject the prescription and not dispense any medication.

I have a staff member who has worked for me for 10 years and has lots of experience. Is it okay for her to dispense medications for me, even though she is not a RVT?

NO – The ABVMA Council Guidelines Regarding Prescribing, Dispensing, Compounding and Selling Pharmaceuticals "appropriate delegation of dispensing" is very clear that dispensing is a professional activity that must be performed by a registered veterinarian and may only be delegated to a registered veterinary technologist under certain conditions.

#### **DISPENSING SCENARIOS**

#### Dispensing for animals out of province

#### **Permitted Inter-jurisdictional Practice**

A veterinarian registered with the ABVMA and the Saskatchewan Veterinary Medical Association (SVMA) is practicing out of a certified and inspected VPE in Alberta with her ambulatory vehicle in Saskatchewan. She writes a prescription for vaccine and antimicrobials for a producer in Saskatchewan. She may ship appropriately dispensed pharmaceuticals from the VPE in Alberta to her client for animals in Saskatchewan. The ABVMA and SVMA may both audit the practice.

Through an agreement between the ABVMA and the SVMA, a recent amendment to the Guidelines now permits dispensing of pharmaceuticals by a registered veterinarian working out of a VPE in Alberta to dispense pursuant to a prescription they have written for animals located in Saskatchewan, provided certain conditions are met. (see APPENDIX B)

#### **Inter-jurisdictional Consultation**

A couple is travelling from their home in British Columbia through Alberta. Upon arrival in Calgary, they discover they left their dog's heart medications at home. They attend at a local veterinary practice to get some medications. The Calgary veterinarian contacts the couple's regular veterinary practice in British Columbia and is informed the patient has been recently examined and there is a current prescription for furosemide and pimobendin. However, the Calgary veterinarian may not dispense pursuant to this prescription, since according to the Guidelines, a veterinarian may only dispense pursuant to a prescription written by a veterinarian practicing in Alberta.

Notwithstanding, the veterinarian may review the medical record, communicate directly with the primary veterinarian, consult with the client and issue a new prescription for a reasonable amount (sufficient for the duration of time away from home) and dispense the medications according to that prescription. It is not necessary that the veterinarian reestablish the diagnosis and repeat procedures to establish the diagnosis.

#### **Non-permitted Inter-jurisdictional Practice**

A long-time client of a veterinarian practicing in Lethbridge moves to British Columbia and has requested his veterinarian send pharmaceuticals for his dog, who has been under the veterinarian's care for the past five years for anxiety disorder.

The veterinarian may not dispense pharmaceuticals for the dog located in British Columbia. The professional activity of dispensing pharmaceuticals is considered within the scope of practice of veterinary medicine. The ABVMA regulates the practice of veterinary medicine in Alberta and cannot permit a veterinarian to practice in another jurisdiction.

Alternatively, the veterinarian could prescribe and dispense a reasonable amount of necessary pharmaceuticals prior to the move, provide a copy of the medical record and encourage the client to establish a VCPR with a veterinarian in the new province once the move is made.





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 on the TPP form.

# Labelling of Dispensed Pharmaceuticals

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 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 FDR 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.

#### **ABC Veterinary Clinic**

123 First Street, Anytown, Alberta 780-555-5555

Jane Smith, DVM Date: Feb 9/18

Patient: Cleo Client: Sam Jones ID #2188
Metronidazole Apo-M 250 mg Exp: 3/31/2022

DIN: 00545066

Quantity: 5 Refills: 0
Give 1/2 tablet by mouth every 12 hours for 5 days.

Veterinary use only. Keep out of reach of children.



#### Fortune Veterinary Clinic

Box 123, Anytown, Alberta 403-555-5555
James Bond, DVM

Client: ABC Farming Co. Exp: 12/1/2018
Patient: Swine DIN: 02317214

Excenel RTU EZ 100 ml 50 mg/ml

Directions for Use: Give IM 1 ml per 17 kg once daily for 5  $\,$ 

days as per veterinary protocol.

Quantity Dispensed: 1 Quantity Prescribed: 20
Quantity Remaining: 19 Withdrawal time: 5 days
Storage Precautions: Protect from freezing

Storage receasions. Protect from freezing

Veterinary use only. Keep out of reach of children.

#### 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 manufacturer's 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 manufacturer's label.



#### **Dispensing Record Audit**

All VPEs must create and maintain medical records of dispensing undertaken 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, declining balance of refills and labelling 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 labelled in accordance with Part B of this Guideline before leaving the dispensing VPE.
- The properly dispensed and labelled 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.



#### SHIPPING SCENARIO

#### **Commercial Poultry Operation**

A veterinary practice provides veterinary services to a commercial broiler (poultry) operation located a four-hour drive away from the practice location. The veterinarian in that practice has an established VCPR with the producer and has issued several prescriptions for products to be administered to the flock, in accordance with established animal health protocols.

One Friday afternoon, the producer identifies, through the health protocols, one barn requires treatment with an antimicrobial administered through the watering system.

In his veterinary practice, the veterinarian has the appropriate antimicrobials in stock. The producer normally picks up required products from the practice, but on this occasion he is not able to pick it up. The veterinarian appropriately reviews the prescription on file (medical record), determines refills are available, applies the appropriate label and provides required information on the use and safe handling of the product, including withdrawal times.

Once the act of dispensing is completed the veterinarian may:

	May or May Not
Arrange for transport by commercial carrier to the production facility. The veterinarian is responsible to maintain the integrity of the shipment.	<b>✓</b>
Send the drug with the feed truck driver to be dropped off.	X
Send a supply of the product to the local feed store in the producer's community so the producer can pick it up there.	X
Provide the dispensed drugs to a person authorized by the producer for transport to the production facility.	<b>√</b>
Have a staff member drive the appropriately packaged dispensed product to the producer.	<b>√</b>
Have the pharmaceutical company representative drop off some product she has on hand as she is in the area.	X
Request that the veterinarian's distribution centre send the product directly to the producer.	X



PART C

# SELLING NON-PRESCRIPTION DRUGS

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## **Selling Non-Prescription Drugs**

#### **Guidelines for Veterinarians**

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

They will typically apply to:

- Drugs that are not on the Prescription
   Drug List and are not antimicrobials:
- Certain pesticide products;
- · Certain parasiticides; and
- 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 VCPR 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. Repackaging of non-prescription products requires that the product is prescribed and dispensed in accordance with Parts A and B.
- Veterinarians must consider all antimicrobials as prescription only.
   All MIAs, regardless of their route of administration, must be appropriately prescribed and dispensed in accordance with Parts A and B. MIAs 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. 21.1 of the Veterinary Profession General Regulation (opposite), which prohibits the sale of any pharmaceutical or biological product to a warehouse, pharmacy, Authorized Medicine Sales Outlet (AMSO) or any other individual who intends to resell 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.

#### **FAO**

A local dog food and horse tack store wants to purchase some equine dewormer and vaccine to have on hand to sell. Is it OK if a veterinary practice sells to this store?

**No** – Veterinarians are reminded of s.21.1 of the Veterinary Profession General Regulation, which prohibits the sale of any pharmaceutical or biological product to a warehouse, pharmacy, AMSO or any other individual who intends to resell the drug.

#### **OVERSIGHT OF NON-PRESCRIPTION DRUGS**

A pruritic dog is examined by a veterinarian. The veterinarian collects skin scrapings to rule out external parasites and promises that she or the RVT will call the client later. The registered veterinary technologist calls the client to tell her that the skin scrapings did not show an external parasite. She also relays the message that the veterinarian has recommended 100 mg Benadryl as needed to be picked up at a drug store.

The client happens to have Benadryl Total Allergy & Sinus at home (this medication contains both diphenhydramine and pseudoephedrine.) Thirty minutes after the medication is given the dog becomes nervous, hyperactive and panting, this continues for two hours. The owner becomes very concerned and an emergency visit is necessary.

Even though Benadryl is an OTC medication, the veterinarian should treat the medication as a prescription medication and provide specific written directions to avoid this scenario.



PART D

# COMPOUNDING DRUGS

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## **Compounding Drugs**

#### **Guidelines for Veterinarians**

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

Compounding is defined in the CVMA 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 the 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 ELDU.



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";
- 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 (DIN) for use in food animals.



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

## **COMPOUNDING SCENARIOS**

	Appropriate
A veterinarian who prescribes tapazole be compounded from an approved veterinary or human formulation into a chewable for administration to cats is appropriately compounding in that it provides a different form of the drug for administration.	<b>✓</b>
A veterinarian that prescribes an active pharmaceutical ingredient toltrazuril be compounded into a bolus /liquid formulation for treatment of calf coccidiosis in calves because it is lower cost than proprietary Baycoxx® is not a justifiable reason for compounding.	X



PRESCRIBING
NARCOTIC,
CONTROLLED
AND TARGETED
SUBSTANCES

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PART E



# Prescribing Narcotic, Controlled and Targeted Substances

#### **Guidelines for Veterinarians**

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 (Veterinary Profession Act) to dispense. With this privilege comes significant risks with regards to the accessibility of narcotic, controlled and targeted substances.

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 ABVMA is committed to the protection of the public and to 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 (CPSA) Triplicate Prescription Program (TPP).





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 the general public, as well as the veterinary practitioner, allied professionals and staff.



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.

Veterinarians in Alberta are not permitted to authorize the purchase of marijuana for the treatment of animals under the Access to Cannabis for Medical Purposes Regulations (ACMPR).

#### **FAQ**

We had a theft of a controlled substance from our veterinary practice. What are my legal obligations?

According to Health Canada, in any case of theft, loss or forgery,—which includes significant amounts not reconciled in controlled drug use logs,—of a narcotic, targeted or controlled drug, the matter must be reported to the local police immediately and to the Office of Controlled Substances no later than 10 days after its discovery.

## **Triplicate Prescription Program (TPP)**

The TPP is a program administered by the 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. 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 advanced 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.



#### **FAQ**

I employ a supervised limited practice registered veterinarian. Can she apply for and receive a TPP pad?

**No** – Veterinarians who are registered with temporary or supervised limited practice licensure are not eligible to participate in 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 veterinarians use a TPP form to prescribe any of the above-listed medications.

#### **FAQ**

My physician tells me that he had to take a course to receive an exemption to prescribe buprenorphine. Do I?

**No** – A Health Canada training program to prescribe buprenorphine is not required for veterinarians.

#### **TPP Forms and Pads**

Upon enrolment in the TPP with the CPSA, a veterinarian is provided with their own TPP prescription pad. The three-part TPP prescription forms are personalized with the veterinarian's individual information and veterinary practice location. The unique prescriber identification number is NOT the prescriber's 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.

#### **FAQ**

Whose responsibility is it to return my TPP pad when I move to a new practice? Is it my responsibility or the responsibility of the practice?

It is the responsibility of the veterinarian to return his or her old TPP pad to the CPSA and apply for a new pad printed with the new practice name and address on it.

#### 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 TPP Form Reference, 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.

#### **FAO**

I prescribe tramadol for all spays and neuters for three days post-op. Do I need to fill out a TPP form for each of them?

**No** – A TPP form is not required for TPP medications that are dispensed from a veterinary clinic for a usage period of less than 96 hours; however, these medications must be recorded in the practice controlled/narcotic/targeted drug use logs.

I am prescribing two TPP medications to a patient. Can I put them on the same TPP form?

**No** – 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.

If I send a prescription for a 3-day quantity of tramadol to the Pharmacy, I don't need to fill it out on a TPP pad do I?

If you are sending a prescription to a pharmacy for a TPP medication, it must be on a TPP form. The length of time is irrelevant in this circumstance. If you are prescribing and dispensing a TPP medication from your practice for a period less than 96 hours, you do not need to complete or submit a TPP form, as the dispensing is accounted for in the practice controlled drug use log.

# TPP FORM REFERENCE

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## **TPP Form Reference**

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

TPP Alberta	Void after 3 days.  we both copies to a pharmacy.
Alberta	PLEASE PRINT CLEARLY
Health care number 2	Date Issued DD   MA 3   W
Patient full name (First, Initial, Last)	
Male Female	Date of Birth 5
Patient address 6	
City/town	Province
⚠ ONLY ONE DRUG/DOSAGE P	ER FORM   NO REFILLS ALLOWER
Drug name & dosage	
Quantity Numeric	iry Alpha
Indication for therapy:	☐ Headache/Migraine
□ Post-operative pain     □ Neurop.     □ Acute musculoskeletal pain     □ Chronic musculoskeletal pain     □ Other (s	Palliative
Direction for use:	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
10	
11)	No Sui
ID #: (	PRESCRIBER'S SIGNATUR
PHARMACY USE ONLY: Rx # 14	Date Dispensed 15
DIN 16 Quant	Pharmacy LIC #
Pharmacist Sign, & Reg. #	

- The dispenser (pharmacist or veterinary practice) must be presented with the top two copies of the TPP form.
- When the patient is an animal, the Health Care Number field is left blank.
- 3 Prescriptions are only valid for 72 hours. The prescription cannot be honoured after midnight of the third day.
- When the prescription is written by the veterinarian for an animal, the form should include the animal name followed by the owner's name in brackets.
- 5 When the prescription is written by a veterinarian for an animal, the animal's date of birth must appear here.
- 6 The patient's address provides further verification of their identity within the TPP database.
- 7 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.
- 8 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.
- The prescriber MUST provide the intended indication for therapy. The Check-boxes MUST NOT be interpreted as a

- list of valid indications for TPP Medications. Prescribers and dispensers MUST individually verify the validity of each indication within the context of the clinical care being provided and the history for each patient.
- 10 The directions of use must be as complete as possible, as this assists in verifying quantities. An interval must be noted here for part-fills.
- 11 Prescribers must only use their own personalized TPP forms.
- 12 Prescribers MUST use their personalized TPP forms with their printed ID number. Pharmacist & pharmacy technicians should ensure the correct prescriber is identified for the prescription record. Misattributions significantly impede PIN data quality and TPP Alberta efficiency.
- 13 TPP Tracking Number is a sequential number assigned to each form within the pad. Prescribers MUST report this number(s) if form(s) is lost or stolen.
- 14 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).
- 15 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."

- 16 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)
- 17 The quantity dispensed is verified against the quantity order. 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).
- 18 Pharmacy license number is used to identify the pharmacy in the database. When the dispenser is a veterinary practice, the veterinary practice identification number should be recorded here.
- 19 The pharmacist dispensing the medication signs and provides their practice permit number. When the dispenser is a veterinary practice, the veterinarian or veterinary technologist dispensing the medication signs and provides their registration number.
- 20 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.

#### 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).

#### **FAO**

If I am filling a prescription for a TPP medication, how many physical copies of the prescription must I receive from the prescribing practice?

The dispenser (pharmacist or veterinary practice) must be physically presented with the top two copies of the TPP form. If faxed, the original copy of the TPP form must be destroyed or marked VOID by the prescribing practice, and must not be given to the patient. The pharmacy or dispensing practice must submit a copy of the fax to the 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.

#### **FAQ**

I want to dispense a diazepam rectal kit for a dog with cluster seizures. Are there any special considerations because diazepam is on the TPP list?

As with any prescribing and dispensing, it is the veterinarian's professional obligation to ensure the client is well instructed including how to use the medication correctly and store it appropriately. In the case of diazepam, the dispensing process would include:

- Completion of a TPP form
- Specific directions on administration
- It is important to keep all medications out of sight and reach of children
- Diazepam is light sensitive.
   Because it has been put in a
   syringe for quick access, keep the
   syringe in the envelope in which it
   is dispensed until use, OR because
   diazepam binds to plastic it has
   been dispensed in a glass tube.
   When your dog has a seizure, draw
   up the diazepam into the syringe to
   administer it.
- Expiry date on the prescription
- Input a reminder client contact for when the medication expires to follow up. If the medication has not been used, it should be returned to the VPE for disposal and a new syringe dispensed.



#### In Addition

Veterinarians may obtain CPSA addressed 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 (one 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:

CPSA www.cpsa.ab.ca 780-423-4764.

#### **APPENDIX A: ABVMA Restricted Medications**

Despite the outlined 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.

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





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

# APPENDIX B: ABMVA and SVMA Memorandum of Understanding

#### **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 neighbouring 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 SVMA and the 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 ABVMA in Alberta and the SVMA 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,
  - 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.



#### **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
  - 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

