2015

DISPENSING MANUAL FOR VETERINARIANS

Saskatchewan Veterinary Medical Association
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Veterinary practices offer a wide variety of biologics, pharmaceuticals, and pesticides to their clients. The veterinarian’s privilege to both prescribe and dispense medications requires the acceptance of several significant responsibilities.

Aside from ethical considerations, veterinary practitioners are required to be familiar with a large volume of federal and provincial legislation. The purpose of this manual is to review relevant legislation with the intent of clarifying dispensing methods, procedures and obligations for veterinarians.

The Saskatchewan Veterinary Medical Association has modified this manual from a document created by Carolyn Carruthers, B.S. P. at the Western College of Veterinary Medicine’s Teaching Hospital. Ms Carruthers has more than 20 years of experience as a pharmacist at WCVM.

This manual documents and verifies proper procedures veterinarians are to follow when dealing with drugs, pesticides and biologics.
CHAPTER 1 – Introduction

Drug laws and regulations are complex and can be confusing. Drug laws exist for the protection of the public. Early in the 20th century, consumers were often victimized by sellers of remedies that were ineffective, dangerous, or both. It became necessary to establish a system for the regulation of drugs. Certain types of drugs have significant risk associated with their use and should be prescribed and dispensed only by licensed health care professionals. These professionals are mandated to ensure efficacy, proper dosing, administration, and the provision of appropriate information on drug use. Today the responsibility for evaluation and regulation of drugs in Canada belongs to Health Canada and in the United States, to the Food and Drug Administration (FDA).

Health professionals have specialized knowledge and expertise and, because they are in positions of trust, have the responsibility of acting in the best interests of the public. The average person has little ability to assess the professional skills of a veterinarian, physician, or pharmacist. For that very reason, these professions are self-regulating. The regulatory bodies for the practice of veterinary medicine in the different provinces are:

- College of British Columbia Veterinarians (CBCV)
- Alberta Veterinary Medical Association (ABVMA)
- Saskatchewan Veterinary Medical Association (SVMA)
- Manitoba Veterinary Medical Association (MVMA)
- Ontario Veterinary Medical Association (OVMA)
- ordre des médecins vétérinaires du Québec (OMVQ)
- New Brunswick Veterinary Medical Association (NBVMA)
- Prince Edward Island Veterinary Medical Association (PEIVMA)
- Nova Scotia Veterinary Medical Association (NSVMA)
- Newfoundland and Labrador Veterinary Licensing Board (NLVLB)

These associations define the scope of practice for veterinarians and establish the standards of practice for veterinary medicine in Canada. While federal laws allow veterinarians, pharmacists and physicians to perform certain tasks, provincial authorities determine qualifications for practise and the licensing requirements for health professionals, in effect defining who can claim membership in these professions. The provincial authorities, through the implementation of regulations and bylaws, also specify how the profession will be practised in that province.

Similarly, provincial legislation plays a part in determining who can sell drugs and under what conditions. Health Canada is the federal body charged with regulating drugs. Before a drug may be sold in Canada, the manufacturer must apply to Health Canada for approval. Veterinary drugs are evaluated and approved by a branch of Health Canada the Veterinary Drugs Directorate (V.D.D.) The federal Food and Drug Act and the Food and Drug Regulations prescribe matters pertaining to approval and sale of drug products in Canada. Within provincial borders, each province has the authority to further restrict the sale, distribution and dispensing of approved drugs.
Legislation

Federal

Federal laws apply everywhere in Canada and cannot be made less stringent by other regulatory bodies.

- Pest Control Products Act
- Health of Animals Act and Regulations
- Controlled Drugs and Substances Act
- Narcotic Control Regulations
- Regulations Exempting Certain Precursors and Controlled Substances from the Application of the Controlled Drugs and Substances Act
- Benzodiazepines and Other Targeted Substances Regulations
- Food and Drugs Act
- Food and Drug Regulations Part
- Feed Act and Regulations

Provincial

Areas of provincial responsibility are subject to regulation by the provinces. Each province has its own set of legislation dealing with control and can be different from province to province. In general, Provincial laws can be MORE stringent than federal laws but cannot diminish them. The following provincial legislation is applicable in the respective provinces:

Alberta’s Applicable Legislation

- Veterinary Profession Act (Alberta Regulation 44/86) and Regulations.
- ABVMA Guidelines on the Veterinary/client/patient relationship
- Livestock Diseases Act (Alberta Regulation 300/64) and Production Animal Medicine Regulations under the Act.

British Columbia’s Applicable Legislation

- Veterinarian’s Act, SBC 2010 c. 15
- Pharmacy Operations Act and Drug Scheduling Act
- Veterinary Drug and Medicated Feed Regulation (BC Reg 47/82)
- BCVMA Guidelines on the Veterinarian Client Patient Relationship
- BCVMA Drug Dispensing Protocol

Manitoba’s Applicable Legislation

- The Manitoba Pharmacy Act
- Bylaws of the Manitoba Pharmaceutical Association
- The Veterinary Medical Act (Legislative Assembly of Manitoba, July 14, 1999)
- Bylaws of the Manitoba Veterinary Medical Association (November 30, 2004)
- MVMA Practice Inspection and Practice Standards Bylaws
New Brunswick’s Applicable Legislation
- Veterinarian’s Act
- NBVMA Bylaw #21( Minimum Standards for the handling and dispensing of drugs)
- Department of Agriculture, Fish and Aquaculture Pharmaceuticals Dispensing Policy.

Newfoundland and Labrador’s Applicable Legislation
- Veterinarian's Act
- Pharmacy Act

Nova Scotia’s Applicable Legislation
- Veterinarian's Act

Northwest Territories’ Applicable Legislation
- Veterinarian's Act

Ontario’s Applicable Legislation
- Veterinarian's Act
- Regulation 1093 under the Veterinarian's Act.
- Bylaws of the College of Veterinarians of Ontario
- Livestock Medicines Act (Revised Statutes of Ontario 1990) and Regulation 730.

Prince Edward Island’s Applicable Legislation
- Veterinary Act of Prince Edward Island
- Pharmacy Act

Québec’s Applicable Legislation
- Québec Professional Code (RSQ Chapter C-26)
- Veterinary Surgeon’s Act (RSQ M-8, Division IV).
- Regulations under the Veterinary Surgeons.
- Pharmacy Act (RSQ C. P-10)
- Animal Health Protection Act
- Regulation on medications that may only be sold on prescription by a veterinary surgeon.
- Animal Health Protection Act.
- Veterinary Surgeon’s Prescription Regulation.

Saskatchewan’s Applicable Legislation
- The Pharmacy Act
- Bylaws of the Saskatchewan Pharmaceutical Association
- The Veterinarians Act
- Bylaws of the Saskatchewan Veterinary Medical Association (SVMA)
- Practice Standards of the SVMA
Hazardous Materials (WHMIS) Labeling Requirements

WHMIS stands for Workplace Hazardous Material Information System. In the late 1980s it was introduced as legislation making employers responsible for having information on hazardous materials in the workplace readily available to personnel working with such products. It also requires that such materials be labeled specifically with appropriate symbols and warnings.

Products covered under other legislation (e.g. Food and Drugs Act, PCPA, and drugs sold pursuant to a prescription) have specific detailed requirements for appropriate labeling. These products are identified by the DIN or PCP Act Registration number and are exempt from WHMIS labeling requirements; however, the employer still bears responsibility for informing employees and having information available regarding safe handling of these products e.g. insecticides, cleaning products, DOMOSO (dimethyl sulfoxide gel/solution), prostaglandins, etc.

Extra-Label Drug Use (ELDU) In Canada

One of the key requirements for the sale of an approved drug in Canada is that it be labeled correctly.

**C.1.3** "No person shall sell a drug that is not labeled as required by these regulations."

– Food and Drug Regulations

The Regulations to the Food and Drugs Act (F and D Regulations) state the specific information that must appear on drug labels. The only exemption to the labelling regulations is when a drug is sold or compounded pursuant to a prescription. This means that drugs are to be sold in the original manufacturer-labelled container unless they are being sold on a prescription order or are being compounded (compounding being the art of preparing a drug dosage form from individual ingredients). **However, if part of the contents of a manufacturer's container are dispensed (repackaged and labelled), OR if the drug is being used for an extra-label use (ELU), a prescription label is required.**

Definition of ELDU in Canada

“Extra-label Drug Use”, often referred as **"off-label use"**, refers to the actual use or intended use of a drug, whether it is a prescription drug or over-the-counter (OTC) drug, in an animal in a manner that is not in accordance with the approved label or package insert of the drug approved by Health Canada (HC). This includes the use of all unapproved drugs (including unapproved bulk pharmaceutical substances and compounded drugs). Extra-label drug use may take many forms, such as, but not limited to the following:

- The use of a drug product in a different dosage than what is approved on the label
- The use of a drug with a greater or lesser frequency of administration that what is approved on the label.
- The use of a drug for a different indication (i.e. different disease or condition) than what is stated on the label.
- The use of a drug for a shorter or longer duration of treatment than what is stated on the label.
- The use of a drug by different routes of administration (oral versus injectable)
- The use of a drug in a different species than what is indicated on the label (e.g., a drug approved in cattle administered to sheep)
- The use of a drug in a different age group (e.g. weanling).
- The use of a drug in a different stage of an animal’s production cycle (e.g. dry cow vs lactating dairy cow)
• The use of a drug in a different dosage form (e.g. a tablet may be crushed and incorporated into a gel, i.e. compounding)
• The use of a drug approved in humans to treat an animal
• The use of a drug(s) in a medicated feed outside the Medicating Ingredient Brochure (MIB) listing.
• Compounding is considered a form of ELDU. Compounding for veterinary use has been defined as the reformulation of an active pharmaceutical compound to address the unique physiological need of an individual animal, as determined under a valid VCPR, which cannot be met by current, commercially available (i.e. approved) product formulations.
• The use of a drug in a different formulation (e.g. two drugs mixed together in the same syringe i.e. compounding)
• The use of unapproved drugs in animals, or of bulk pharmaceuticals substances, also call Active Pharmaceutical Ingredients (API), which has been formulated or can be administered as is.

For more information on ELDU, visit VDD’s website at http://www.hc-sc.gc.ca/dhp-mps/vet/label-etiquet/index-eng.php

While information needed on a manufacturer’s label is listed in F and D Regulations, provincial regulatory bodies specify information required on labels of medication dispensed by veterinarians or pharmacists. While practitioners have the professional privilege of using drugs in an extra-label manner, the responsibility for all aspects of such use, including safety and withdrawal time, rests with the practitioner.

The term “drug” is defined in the F and D Regulations but does NOT include products regulated under the Health of Animals Act (veterinary biologics) or those registered under the Pest Control Products Act (insecticides, pesticides). Thus ELDU for those products is NOT a professional privilege.

Health Canada’s Policy on ELDU in Animals

• ELDU should be avoided unless no other alternative therapy exists
• The primary concern is that drugs which are used in animals are safe to both animals and (the) human handling those drugs
• The administration of drugs to food animals must not result in residues which are dangerous for humans consuming food derived from those animals.
• Potential occupational hazards should also be assessed and addressed in decisions involving extra-label drug use.
• (There are) concerns regarding the risk of adverse reactions to ELDU, and that drugs selected may not be effective in the clinical situation.
• The professional abilities of veterinarians, and their right to prescribe drugs to be used in an ELDU manner in animals is recognized
• It is further recognized that there will be instances where it will be necessary for drugs to be used in an extra-label manner.
• It is also important to have established a veterinarian/client/patient relationship when distributing drugs especially if it is recommended that drugs are to be used extra-label. This assumes that the practitioner assumes the responsibility for clinical judgments, and has sufficient knowledge of the animals to make the diagnosis, recommend treatment and be available for follow-up evaluations

Compounding is a form of Extra-Label Drug Use (ELDU)

Compounding for veterinary use has been defined as the reformulation of an active pharmaceutical compound to address the unique physiological needs of an individual animal, as determined under a valid VCPR, which cannot be met by current, commercially available and approved drugs.
CVMA Guidelines for Legitimate Use of Compounded Drugs in Veterinary Practice

PREFACE

This document has been prepared by the Canadian Veterinary Medical Association (CVMA) in consultation with a multi-member task force consisting of:

- Alberta Veterinary Medical Association (AVMA)
- Canadian Animal Health Institute (CAHI)
- Canadian Food Inspection Agency (CFIA)
- Canadian Veterinary Medical Association (CVMA)
- Health Canada, Health Products and Food Branch Inspectorate
- Health Canada, Veterinary Drugs Directorate
- National Association of Pharmacy Regulatory Authorities (NAPRA)
- Ontario Veterinary Medical Association (OVMA)
- ordre des médecins vétérinaires du Québec (OMVQ)

The purpose of these guidelines is to summarize and clarify all existing legislation and policy regarding the compounding and prescribing of compounded products for use in animals. For the most part, the wording is a concise reflection of the text from various pieces of legislation \(^1\), \(^2\). However, the document is intended for guidance only; it is not to be used as a legal interpretation.

The CVMA believes that there is a significant need for information in this area. Concerns have been expressed about some current compounding practices. On occasions, compounding practices have crossed the line and become manufacturing. In these cases, veterinarians may unknowingly be assuming significant liability. Food safety could be placed at risk. There could be unknown threats to animal health. Inappropriate compounding practices may prove to be a disincentive to the development and approval of new animal health products.

This document is intended to be a guideline for veterinarians and to provide veterinary practitioners with information needed to make appropriate professional decisions when considering whether or not to use a compounded product for the treatment of a patient.

BACKGROUND

The compounding of drugs is an ancient art and science that has been practiced by health professionals, including veterinarians, for centuries. The process involves combining two or more ingredients, at least one of which is a drug, to create a final product in an appropriate form for dosing. It can involve the use of raw chemicals or the alteration of the form of commercially available drug.

Compounded drugs are unapproved drugs that have not undergone the Health Canada approval process. They should not be confused with generic drugs, which have undergone the Health Canada approval process.

Compounding is both necessary and beneficial for the treatment of veterinary patients. However, the potential exists for causing harm to animals and the public when drugs are compounded without adherence to the principles of contemporary pharmaceutical chemistry and current good compounding practices, as outlined by provincial standards of practice for compounding by pharmacists \(^1\). In the absence of adequate safety, potency, and efficacy data for the use of a compounded drug in animals, the potential exists for treatment failures and/or adverse reactions, including death. Furthermore, because the pharmacokinetics and residual depletion times for compounded drugs are not known, assigning an empirical withdrawal time may result in residues of concern being in food derived from treated animals. Inactive ingredients in compounded drugs, such as excipients and vehicles, may also pose additional risk.
GUIDELINES

• For the purpose of these guidelines, the term “compounding” refers exclusively to the making of veterinary pharmaceutical preparations within the practice of veterinary medicine or pharmacy, as permitted under the Canadian Food and Drugs Act and Regulations \(^2\). Accordingly, the term “Compounded drugs” refers only to pharmaceutical preparations that have been formulated in accordance with legitimate pharmacy and veterinary practices.

• Compounding and dispensing are licensed activities under provincial legislation that fall within the professional scope for pharmacists and veterinarians \(^3\). No person other than a licensed pharmacist or veterinarian may compound drugs for use in animals.

• These guidelines do not waive or diminish in any way the obligation by all parties to comply with all applicable federal and provincial laws and regulations, including the Food and Drugs Act and Regulations, insofar as they apply to manufacture drugs and to compounded pharmaceutical preparations. Accordingly, veterinarians must prescribe and dispense compounded pharmaceutical preparations according to federal, provincial and territorial acts and regulations.

• Further guidance as to what is considered to be compounding practices under the Food and Drugs Act and Regulations is provided in Health Canada’s policy document entitled Manufacturing and Compounding Drug Products in Canada \(^3\).

• The following practices can only be considered as legitimate compounding when a Health Canada approved veterinary or an equivalent human drug, labelled with a Drug Identification Number (DIN), is NOT available, but whose active ingredient is commercially available or the product is available but the appropriate method for dosing or dose concentration does not exist and a practical alternative does not exist. **Cost is not a defensible reason for choosing a compounded drug.**

• Prescribing and dispensing a compounded drug must be practiced within the confines of a valid veterinary-client-patient relationship (VCPR), and informed consent from the animal’s owner must be obtained.

• Prescribing a compounded drug is considered to be extra-label drug use (ELDU) and as such, the veterinarian is responsible for the safety and efficacy of the prescribed drug and, when used in food producing animals, for establishing adequate withdrawal times in order to avoid residues. The Canadian global Food Animal Residue Avoidance Databank (gFARAD)\(^4\) is unable to provide withdrawal times for compounded drugs. When prescribing a compounded drug, veterinarians must be aware that they are responsible for the potency and purity of the compounded drug.

• **Veterinarians should:**
  
  o Prescribe a compounded drug based on a specific patient need. Under certain circumstances, veterinarians may need to obtain a compounded drug in anticipation of reasonable prescribing needs or for use within their own clinical practice. In such instances, the veterinarian should ensure that the compounded drug is prescribed or used within its duration of stability, which could be as short as a few days for some compounded drugs.

  o Use the services of a registered pharmacist who has expertise in compounding procedures. Veterinarians should have appropriate expertise in pharmaceutical compounding if they are going to compound drugs for dispensing in their practice.

  o Establish a good working relationship with the compounding pharmacist. The veterinarian should request the compounding pharmacists to provide any information they have available that will aid in the veterinarian’s critical assessment of the compounded drug(s). Such information includes the source of all active pharmaceutical ingredients (APIs), and the efficacy, safety, pharmacokinetic, and
stability studies performed on the compounded product, as well as any potency or purity data that may be available.

- Establish practical clinical assessment parameters for efficacy and toxicity prior to prescribing the compounded drug. Document and record therapeutic successes and failures experienced with compounded medications. Adverse reactions associated with the use of a compounded drug should be reported to Health Canada’s Veterinary Drugs Directorate (5) and the compounding pharmacist.

- **There must be a clear distinction between legitimate compounding and manufacturing activities.**
  This includes:
  - Compounding activities performed by a person other than a licensed veterinarian or pharmacist (such as animal owner, breeder, feed mill operator, agricultural producer) not pursuant to a prescription, or outside the scope of a valid VCPR will be considered manufacturing and subject to all applicable provisions of the *Food and Drugs Act and Regulations*.
  - Only establishments (usually pharmaceutical fabricators/distributors) which meet the requirements of Good Manufacturing Practices (6) and are licensed under the Establishment Licensing Framework (7), may manufacture drugs in Canada.
  - Guidance from the Health Products and Food Branch Inspectorate (3) states that bulk compounding intended for distribution or sale outside the established pharmacist-patient-prescriber relationship, or VCPR, for resale is considered to be manufacturing and thus subject to all applicable requirements from the *Food and Drugs Act and Regulations*.

- **Veterinarians should be aware that:**
  - Compounding of products for the treatment of an individual patient should be used only for therapeutic purposes and only when there are no other commercially available options for that specific patient.
  - Restrictions in the *Food and Drugs Act and Regulations* also apply to compounding practices. Certain substances (for example chloramphenicol, S-nitrofurans, S-nitroimidazoles, clenbuterol, diethylstilbestrol and other stilbene compounds), are banned substances for use in animals that produce food or are intended for consumption as food (8).
  - It is necessary to obtain informed consent from the client before prescribing a compounded product. The client must be aware of the potential risks and available alternative treatments.
  - Any drugs or raw material for compounding must be obtained legally.
  - As a basic quality requirement, oral and topical products should not be used to prepare parenteral formulations.

- **A compounded drug must include the following information on its label:**
  - Clear identification that it is a compounded drug; it must not be misrepresented as having a DIN
  - A list of all active ingredients of the compounded product
  - Generic name(s) of all active pharmaceutical ingredients (APIs)
  - Date of compounding
  - Patient’s name/identification and owner’s name (pursuant to a prescription)
  - Prescribing veterinarian’s name
  - Expiration date based on known stability data. If stability data are not available, the expiration date should be short, usually limited to the duration of the prescription
  - Dosage regimen and withdrawal times (if applicable), as prescribed by the veterinarian
  - Name of the person (pharmacist or veterinarian) or pharmacy that compounded the drug
  - Proper storage recommendations
DECISION CASCADE

When deciding on which medication to prescribe, a veterinarian should follow the course of the Decision Cascade and choose the level of least risk to the patient. Choose the first available level on the cascade below:

- Approved veterinary drug (DIN): label instructions
- Approved veterinary drug (DIN): extra-label drug use (ELDU)
- Approved human drug (DIN): ELDU
- Compounded product: from approved veterinary drug (DIN): ELDU
- Compounded product: from approved human drug (DIN): ELDU
- Compounded product: from active pharmaceutical ingredient (API): ELDU

Foreign approved veterinary drugs obtained through Health Canada’s Emergency Drug Release (EDR)\(^{(9)}\) may be an alternative option available to veterinarians when considering use of a compounded drug.

DEFINITIONS

Active Pharmaceutical Ingredient (API) - Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure and function of the body. Bulk, pharmaceutically active substances that are used in the formulation of medicine in dosage form.

Adverse drug reaction - A noxious and unintended response (signs of toxicity, idiosyncrasy, hypersensitivity, intolerance, and incompatibility) to a drug that occurs at doses normally used or tested for the diagnosis, treatment, or prevention of a disease or the modification of an organic function. Also included are events related to a suspected lack of expected efficacy or noxious reactions in humans after being exposed to veterinary medicinal products.

Approved drug - A drug that has been assessed for its safety and effectiveness by Health Canada and meets the appropriate requirements of the Food and Drugs Act and Regulations. Includes innovative and generic products.

Banned drugs - Drugs banned by Health Canada from use in animals intended for use as human food. (8)
Dispensing Manual for Veterinarians

**Compounding** - 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. It can involve the use of raw chemicals or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel drug delivery. Compounding does not include mixing, reconstituting, or any other manipulation that is performed in accordance with the directions for use on an approved drug’s labelling material.

**Compounded drug** - Refers to pharmaceutical preparations formulated as per the definition for compounding and in accordance with legitimate pharmacy and veterinary practice.

**Dispense** - To provide a drug pursuant to a prescription; does not include the administration of the drug.

**Drug** - Includes any substance or mixture of substances manufactured, sold or represented for use in:
- The diagnosis, treatment mitigation, or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals;
- Restoring, correcting, or modifying organic functions in human beings or animals;
- Disinfection in premises in which food is manufactured, prepared, or kept.

**End user** - The person or corporation who actually administers a medicine to any animal.

**Extra-label drug use (ELDU)** - Often termed “off-label use,” refers to the actual use or intended use of any drug, whether it is a prescription drug or an over-the-counter (OTC) drug, in an animal in a manner that is not in accordance with the label or the package insert of the drug approved by Health Canada. This includes the use of all drugs (including unapproved bulk pharmaceutical substances and compounded drugs) that do not have a Canadian approved label.

**Generic drug** - A second and/or subsequent entry of a drug to the market, defined by reference to the generic drug’s equivalence to a Canadian reference product (a drug that is already approved for sale in Canada). In accordance with the Canadian *Food and Drugs Act and Regulations*, a Canadian reference product has a New Drug Submission approved by the Minister of Health, a Notice of Compliance, and a Drug Identification Number (DIN).

**Maximum Residue Limit (MRL)** - MRLs for specific drug residues are permitted in specified, edible animal products sold as food, as determined by Health Canada.

**Medicine** - Drugs and biological supplies for the prevention, treatment, control, or eradication of disease in animals.

**Prescribe** - Written or verbal directives for the compounding or dispensing and administration of drugs or for other medical services to an animal patient based on a diagnosed or determined need (an animal patient may be a group of animals with a similar diagnosed condition).

**Repackaging** - Subdividing or breaking up a manufacturer’s original package of a drug for the purpose of dividing and assembling the drug in larger or smaller quantities for redistribution or sale by retail.

**Sell** -
- Any transaction, activity, or operation relating to the transfer of possession (or of legal right) in a product or medicine from one person to another, including selling, loaning, bartering, leasing, consigning, or depositing with another for the performance of a service;
- Distribute, whether or not the distribution is made for consideration or;
- Having in possession, offering, or exposing with a view to accomplish any of the above. **Unapproved drug** - A drug that does not have a valid Drug Identification Number (DIN) and whose sale has not been authorized.
Valid Veterinary-Client-Patient Relationship (VCPR) - A valid VCPR exists when these conditions apply:

- The client (owner or owner’s agent of the animal[s]) has given the responsibility of medical care to the veterinarian and has agreed to follow the instructions of the veterinarian, and;
- the veterinarian has assumed the responsibility from the client for making clinical judgment regarding the health of the animal(s), the need for medical treatment, and for ensuring the provision of ongoing medical care for the animal(s), and;
- the veterinarian has sufficient knowledge of the health status of the animal(s) and the care received or to be received. The knowledge has been obtained through a recent examination of the animal(s) and the premises where they are (it is) kept or through a history of medically appropriate and timely examinations and interventions, and;
- the veterinarian is readily available, or has made the necessary arrangements with another veterinarian, for ongoing medical care in case of adverse reactions or therapy failure.

Veterinary facility - Any place or unit where veterinary medicine is practiced.

Withdrawal time - Time after cessation of treatment with a particular drug before the animal or any of its products can be safely or legally used as human food.

REFERENCES

1. Consolidation of the Canadian Food and Drugs Act and Regulations

2. Section C.01A.002. of the Canadian Food and Drugs Act and Regulations


   http://www.gfarad.org

5. Veterinary Drugs Directorate (Health Canada) Pharmacovigilance Program 1-877-VET-REAC


7. Establishment Licenses -Health Canada Guidance

8. List of Drugs Banned by Health Canada

9. Emergency Drug Release Program Veterinary Drugs Directorate (Health Canada)
Distinction between Compounding and Manufacturing

Government of Canada regulates the manufacturing of products, and compounding should not be a form of manufacturing. The distinction between manufacturing and compounding is made as follows:

"Manufacturing activities are subject to regulation under the Food and Drugs Act and regulations, GMO guidelines and inspection by Health Canada, while compounding activities are conducted by a pharmacist or practitioner within the professional practice of pharmacy or medicine, regulated by provincial regulatory authorities in accordance with guidelines and standards that ensure the quality and safety of pharmaceuticals they compound.

Compounded products are prepared for individual patients, within a specific population pursuant to, or in anticipation of, a prescription within an establish pharmacist- patient-prescriber relationship."

Ref: HPFB Inspectorate: Manufacturing and Compounding Drug Products in Canada. 2.3.1 [Manufacturing versus

U.S. Approach to ELDU

The following information is taken from guidelines and laws effective in the United States, where regulations on compounding and ELDU are much more detailed and more strictly enforced than those existing at present in Canada.

ELDU and the Animal Medicinal Drug Use Act (AMDUCA)

In the United States, animal drugs are recognized to be distinct from human drugs and restrictions on the treatment of food animals are stricter than for non-food animals. In 1994, the Animal Medicinal Drug Use Act (AMDUCA) legalized extra-label use (ELDU) in animals as long as it followed the stipulations in the Act. ELDU applies only to approve human or animal drugs and drugs compounded from approved animal or human drugs. AMDUCA does not apply to medicated feeds, herbs, nutraceuticals or products compounded from bulk chemicals or to compounded products intended for non-therapeutic purposes such as growth promotion. AMDUCA specifies that ELDU can only occur within the existence of a valid VCPR and recognizes the FDA concern that public health may be at increased risk due to the potential exposure of humans to compounded drugs used in animals.

Compliance Policy Guidelines (CPGs) direct regulatory agents in the interpretation of and implementation of the laws. CPGs are not legally binding, are open to interpretation by the FDA and can be changed by FDA without public comment or consultation.

ELDU Algorithm for Food Animals

**ELDU for FOOD ANIMALS** (must be within the context of a valid VCPR): In order of preference, the choices for selection of a drug in the treatment of **FOOD ANIMALS** should be:

1. use of a veterinary-approved food animal drug according to the label (withdrawal times for milk or slaughter must be observed);
2. extra-label use of a veterinary-approved food animal drug (extended withdrawal times for milk or slaughter must be established by the veterinarian);
3. extra-label use of a veterinary-approved non-food animal drug or, if unavailable, a human-approved drug (adequate scientific information must be available to determine a withdrawal time; otherwise, the drug
must not be used, or the treated animal must not enter the food supply);

4. use of a compounded product prepared from approved veterinary or, if unavailable, human drugs to relieve animal pain and suffering in accordance with CPG 608.400;

5. the extremely rare need for a compounded product prepared from a bulk chemical in accordance with CPG 608.400 Appendix A.

Compounding Restrictions

Compounding is recognized as important and necessary in the drug treatment of companion and exotic animals and where the drug needed is not available in an appropriate dosage form. Compounding for animals is defined under an AMDUCA CPG as “any manipulation to produce a dosage form drug other than that manipulation that is provided for in the directions for use on the labeling of the approved product, for example, the reconstitution of a sterile powder with sterile water for injection,” and states that the compounding must be performed by a licensed veterinarian or pharmacist. The National Association of Boards of Pharmacy has defined compounding as the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner’s prescription drug order or initiative based on the practitioner/patient/pharmacist relationship. Examples are dilution of a drug beyond what is specified on the manufacturer’s label, combining two or more products in the same preparation and crushing tablets in order to prepare an oral liquid formulation.

While compounding a drug from an approved product will result in an unapproved product, AMDUCA allows extra-label use of drugs compounded from APPROVED veterinary or human drugs as long as the provisions for ELDU stipulated in the Act are adhered to (existence of a valid Veterinarian-Client-Patient Relationship or VCPR, withdrawal time estimates, appropriate labeling) and NO APPROVED dosage form or concentration of the drug (for humans or animals) exists to treat the diagnosed condition. Responsibility for the safety and efficacy of any drug used in animals rests with the prescribing or dispensing veterinarian, who should not assume that provision of a compounded product assures scientific evidence of safety, stability, or efficacy.

The source of a bulk drug substance and any other inactive ingredients used in a compounded formulation must meet the standards of the USP/National Formulary or an equivalent standard. AMDUCA specifically states that compounding from bulk drugs is not allowed under the Act.

Bulk drugs are defined by AMDUCA in CPG 608.400 as “any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.” This basically means compounding a drug from the chemical form (e.g. gentamicin powder) is NOT allowed regardless of whether or not a finished dosage form of the drug is approved for humans or animals. Compounding from bulk drugs IS legal in human medicine.

While technically not legal, compounding may be permissible under certain conditions if the need for such a product cannot be met under conditions specified in AMDUCA. Those conditions require:

- identification of a legitimate medical need (health of animal is threatened and suffering or death would result from failure to treat)
- a need for an appropriate dosage form for the species age, size or medical condition of the patient
- no marketed, approved animal drug which could be used as labeled or “extra-label”, or no human-label drug which could be used to treat the condition, or other rare extenuating circumstances exist (e.g.) an approved drug cannot be obtained in a timely manner to treat the animal or there is a medical need for different excipients.

**excipient:** any more or less inert substance added to a prescription in order to confer a suitable consistency or form to the drug; a vehicle
When a situation exists where approved drugs are necessary to treat animals but are not available in any form (e.g.) poison antidotes, regulatory discretion under the CPG will be applied with the right to take regulatory action if it is perceived to be in the public’s best interest. The CVM is more likely to regulate compounding of a bulk drug where an approved product does NOT exist rather than when there is an approved form especially if the compounded drug is likely to be used in food animals with potential risk of tissue residues.

CPGs require that veterinarians ensure no illegal residues will occur in food-producing animals, that appropriate patient records for treated animals are maintained, that drugs dispensed to the animal’s owner are labeled specifically with:

- name and address of the veterinary practitioner
- active ingredients
- date dispensed
- expiration date (should not exceed the length of prescribed treatment except where there is rationale for a longer date)
- directions for use INCLUDING species or identification of the animals, dosage, frequency, route of administration, duration of treatment
- cautionary statements regarding safety, storage, etc.
- veterinarian’s specified withdrawal/discard time (the veterinarian is responsible for establishing this)
- name and address of the pharmacy dispensing, prescriptions number and dispensing date.

In the U.S., when contemplating compounding drugs for use in food animals, the risk of regulatory action is higher than for use in non-food animals. The veterinarian should consider compounding only in response to a specific patient’s medical need where there is no appropriate approved animal or human drug. Compounding should be reasonable in amount, not performed in anticipation of need or in large volumes, and should not result in third party sale. Compounded products should not duplicate approved products or claim to replace them. Economic considerations are not normally an acceptable reason for prescription of a compounded drug.

Drugs for which ELDU have been prohibited in food animals should not be compounded for intended use in food animals. Compounding for minor food animal uses, where public health and animal safety are not threatened, and where need is great and risk is small, may be considered of low regulatory priority. Examples would be the combination of agents in anesthesia, large volume parenterals, animal-side compounding, etc.

The following are actions, which would be considered to be of high regulatory priority:

- Compounding of drugs for use in situations (a) where the health of the animal is not threatened; and (b) where suffering or death of the animal is not likely to result from failure to treat.
- Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving prescriptions issued within the confines of a valid VCPR.
- Compounding of drugs that are prohibited for extra-label use in food-producing or non-food producing animals, under 21 CFR 530.41(a) and (b) respectively, because the drugs present a risk to the public health.
- Compounding finished drugs from human or animal drugs that are not the subject of an approved application, or from bulk drug substances, other than those specifically addressed for regulatory discretion by the FDA, Center for Veterinary Medicine, e.g., antidotes (see Appendix A). Inquiries about compounding from unapproved drugs or bulk drug substances should be directed to CVM, Division of Compliance, 301-827-1168.
- Compounding from approved human drugs for which FDA has implemented a restricted distribution system.
• Using commercial scale manufacturing equipment for compounding drug products
• Compounding drugs for third parties who resell to individual patients, or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
• Failing to operate in conformance with applicable state law regulating the practice of pharmacy.
• Compounding of drugs for use in animals where an approved new animal drug or approved new human drug used as labeled or in conformity with 21 CFR Part 530 will, in the available dosage form and concentration, appropriately treat the condition diagnosed.
• Compounding from a human drug for use in food-producing animals if an approved animal drug can be used for the compounding.
• Instances where illegal residues occur in meat, milk, eggs, honey, aquaculture, or other food producing animal products, and such residues were caused by the use of a compounded drug.
• Labeling a compounded drug with a withdrawal time established by the pharmacist instead of the prescribing veterinarian.
• Labeling of compounded drugs without sufficient information, such as withdrawal times for drugs for food-producing animals or other categories of information that are described in 21 CFR 530.12.

Animal generic drugs (products considered to be bioequivalent to the brand name approved product) may NOT be equivalent to human generic drugs even if the active ingredient is the same. Differences in formulation may contribute to differences in drug disposition in treated animals, including differences in withdrawal times in food animals.

While the preference for choice of drug in treating NON-FOOD ANIMALS should be primarily veterinary approved products, it is acceptable to use approved human generic drugs. All use of human drugs, generic or brand name, prescription or OTC status, is extra-label. Human products do not bear directions for use in veterinary patients.

It is recommended that prescriptions for drugs used in the treatment of animals be veterinarian driven within the context of a valid VCPR that veterinarians accommodate client requests for written prescriptions, and that veterinarians should disclose to clients any conflict of interest where the veterinarian benefits from prescriptions filled outside the veterinary practice.

Canadian Global Food Animal Residue Avoidance Database

The Canadian Global Food Animal Residue Database (CgFARAD or FARAD) officially opened on October 1, 2002 and exists to protect the human food supply and help producers and veterinarians avoid residue violations by providing expert-mediated decision support for inquiries related to drug or chemical residues in food animals. Extra-label drug withdrawal information is only provided to veterinarians authorized to practice in Canada. Withdrawal recommendations are not provided for formulations without valid Drug Identification Numbers. The purpose of CgFARAD is not to promote extra-label drug use, but to protect the public safety when it is necessary for veterinarians to use drugs in an extra-label manner. To access the database, call 1-866-CgFARAD (243-2723) or look online at www.cgfarad.usask.ca.

Responsibility for residue violations remains with the prescribing veterinarian. Practitioners are encouraged to consult this database when withdrawal times and extra label drug use are an issue.
When submitting a request to CgFARAD, accurate and complete information will facilitate a timely response. Veterinarians should include:

(a) How the extra-label dose differs from a label dose:
   - Is it a multiple of the label dose (2X, etc.)?
   - Is it being administered more frequently than the label indicates?
   - Is it being used in a different species?

(b) Explain how much drug is being administered to the treated animals:
   - If the drug is administered in feed or water, calculate how much drug the animal is actually getting.

(c) Be specific regarding:
   - the volume of drug per injection site
   - location of injection site(s)
   - age and weight of animals
   - health status (dehydration or anorexia may greatly affect drug or chemical elimination).

**Pest Control Products**

Products registered under the Pest Control Products Act (PCPA) will have a registration number on their label and are NOT considered to be drugs. Use of these products in any way other than under label conditions is an offence under the PCPA Regulations and charges can be laid. Veterinarians are NOT exempt from this legislation and, if a complaint is registered (e.g. use of Spotton in dogs, lime-sulfur dips) can be charged with violating the PCPA. Reporting of violations is usually on a complaint basis.

Extra-label use is not an option for veterinarians. Repackaging or dispensing these products in other than the intact, original packaging is NOT a safe practice and because of labeling requirements should NEVER be done.

45. (1) No person shall use a control product in a manner that is inconsistent with the directions or limitations respecting its use shown on the label.

**Sale of Veterinary Biologics**

Veterinary biologics are regulated under the Health of Animals Act and Regulations. The Canadian Food Inspection Agency (CFIA) is responsible for licensing veterinary biologics in Canada. Products regulated include vaccines, immunoglobulin products (colostrum), and diagnostic kits used for the prevention, treatment, or diagnosis of diseases in animals including domestic livestock, poultry, pets, wildlife, and fish. Importation of veterinary biologics is allowed only under a permit issued by the Minister. Under Section 130.1 of the Health of Animals Regulations, labeling requirements are very specific.

**BIOLOGICS** cannot be “dispensed pursuant to a prescription” as if they were a drug. There is no extra label use permitted for biologics. These products must be sold in original labeled manufacturer’s packages.

121. (1) No person shall import a veterinary biologic into Canada unless he does so under and in accordance with a permit issued by the Minister.

123. No person shall prepare, manufacture, preserve, pack, label or test a veterinary biologic unless he does so under and in accordance with an establishment license issued by the Minister.

130.1 (1) Every veterinary biologic imported, sold, advertised or offered for sale in Canada shall be stored at a temperature between 2°C and 7°C unless otherwise stated in the product outline or the labeling.
To comply with this section, it is recommended that facilities storing veterinary biologics should have a minimum/maximum thermometer for recording temperature in centigrade degrees. The minimum and maximum temperature of the storage area should be recorded on a daily basis. In addition, emergency procedures should be developed should a power failure or significant deviation in cooler temperature occur. Where the Minister is satisfied from tests of a veterinary biologic, or otherwise, that a veterinary biologic is unsafe to use, is likely to cause communicable disease in animals or is contaminated or ineffective, he may, by order, prohibit the importation, manufacture, sale or distribution of the veterinary biologic.

131.1  
(1) Where an emergency exists with respect to the availability of and need for a veterinary biologic, the Minister may exempt that veterinary biologic from the application of any of the provisions of these Regulations during the period of the emergency.

(2) An exemption referred to in subsection (1) shall be in writing and shall state the veterinary biologic that is exempted, the provision or provisions of these Regulations from which it is exempted and the reasons for that exemption.

132.  
(1) No person shall import, sell, advertise or offer for sale a veterinary biologic unless it is packed and labeled in accordance with these Regulations.

(2) All information required by section 134 to be shown on the label of a veterinary biologic
(a) shall be clearly and prominently displayed on the label; and
(b) shall be readily visible by a purchaser under the customary conditions of purchase and use.

133.  
(1) Subject to subsection (2), every veterinary biologic sold, advertised or offered for sale in Canada shall carry a label on or attached to every container in which the veterinary biologic is packed.

(2) Subsection (1) does not apply to a single dose of a killed veterinary biologic packed in a ready to use syringe if the syringe is in a sealed pouch that carries a label.

(3) Every veterinary biologic imported into Canada shall carry a label on or attached to every outer container and shipping container.

134.  
(1) Subject to this section, every label of a veterinary biologic imported, sold, advertised or offered for sale in Canada shall show
(a) the assigned name of the veterinary biologic,
(b) the name of the manufacturer of the veterinary biologic or, if there is more than one manufacturer of that veterinary biologic, the name of the first or the name of the final manufacturer,
(c) the place where the manufacturer referred to in paragraph (b) manufactures the veterinary biologic,
(d) the lot or serial number or other means of identifying the veterinary biologic,
(e) the same establishment licence number, whether Canadian or foreign, on all components of the label except that the Minister may, in writing, exempt from that requirement diluents manufactured in Canada,
(f) directions for use of the veterinary biologic or that directions for its use are contained inside the package,
(g) the expiration date of the veterinary biologic,
(h) the components of the veterinary biologic, including
1. viruses, bacteria, toxoids and antibodies, and
2. antibiotics, if added during the production process as preservatives,
(i) the net quantity of the veterinary biologic in the container, expressed in metric units or in doses the temperature range, expressed in metric units, necessary to maintain prescribed potency of the veterinary biologic,
(j) in the case of a veterinary biologic manufactured for use in food producing animals, the cautionary statement indicating the appropriate withdrawal period as stated in the product outline on the basis of which the import permit or product license was issued, and
(k) in the case of modified live virus rabies vaccines, the cautionary statement “In the event of accidental human exposure to the vaccine virus, the possible hazard to health should be considered and public health officials or a physician should be consulted”, and shall be marked with the words “For veterinary use only”.

(2) Where the label of a veterinary biologic is too small to show all the information required by subsection (1), any such information as the Minister may permit may be shown on the directions for use inside the package.

34.1.1  
No person shall sell or offer for sale a veterinary biologic after its expiration date.
RABIES VACCINE

134.2  (1) Except as provided in subsection (2) no person shall sell or offer for sale a rabies vaccine to anyone other than a veterinarian of the Department of Agriculture of Canada or a veterinarian who holds a valid license to practice veterinary medicine issued by the veterinary licensing body of a province.

(2) Subsection (1) does not apply in respect of rabies vaccine that is sold or offered for sale in accordance with the written permission granted by the Minister for its use

(a) in a temporary emergency veterinary clinic; or

(b) in a remote area where veterinary services are not readily available

Levels of Control of Drug Classes

The control of access to drugs is in a hierarchical structure from most controlled to no control. Narcotic drugs are subject to the greatest degree of control with non-scheduled drugs at the lowest level.

Psychotropic substances have the capacity to produce a state of dependence and central nervous system stimulation or depression. They may cause hallucinations or disturbances in motor function, thinking, behaviour, perception or mood. The UN Convention on Psychotropic Substances, 1971 (1971 Convention) groups 111 psychotropic substances into four schedules, each associated with distinct control measures. Placing a substance in a specific schedule is based on an assessment of the extent and potential for abuse, the degree of seriousness of the public health and social problems and the degree of usefulness of the substance in medical therapy. Psychotropic substances are listed in the various schedules according to the differences in their potential for addiction or dependence, their therapeutic value, and their risk of abuse.

Narcotics

• highest potential for addiction and abuse
• most tightly controlled access
• orders signed by authorized person or practitioner required

Controlled Drugs

• less but still significant potential for addiction and abuse
• still tightly controlled but less so than narcotics

Benzodiazepines and Other Targeted Substances

• benzodiazepines included in this group
• commonly called tranquilizers
• used in the treatment of anxiety and sleep disorders
• can produce psychological and physical dependency
Prescription Drugs: Federal Level

Effective December 2013, the Food and Drug Regulations were amended repealing Schedule F. Prescription drugs formerly listed under Schedule F Part I were moved to the Prescription Drug List (PDL). It should be noted that there are separate human and veterinary Prescription Drug Lists and that the lists are not identical. Schedule F Part II or non-prescription veterinary drugs are no longer specifically listed.

However, if a drug displays a DIN (Drug Identification Number) and is not on the veterinary Prescription Drug List or listed as a controlled substance in the Controlled Drugs and Substances Act, it is a non-prescription drug. As such, it may be sold without a prescription provided it is labelled for veterinary use only, its intended use is consistent with label directions and the drug is sold in its original container.

If the non-prescription veterinary drug’s intended use is extra-label (such as a different dosage, a different species or, a different indication) a prescription is required. Also, non-prescription veterinary drugs must be sold in their original container bearing the approved label. If only a portion of the drug is dispensed, a prescription and prescription label is required. All prescription drugs and human labeled non-prescription drugs require a prescription.

Historically, Schedule F was established as the PRESCRIPTION DRUG schedule. In order to obtain any of the listed drugs for animal use, it was necessary to have either access to a veterinarian or a prescription for the drug. At that time, veterinarians and pharmacists were often separated by great geographical distance and it became difficult for producers to access needed drugs. The case was made that certain Schedule F drugs were necessary for the management of livestock and if labeled appropriately by the manufacturer, so that they could be safely used by a layperson, should be made available without the necessity of a prescription. Because of the limited professional resources available, the distances involved, etc., government responded by splitting Schedule F into Parts I and II.

Their intention was, once professional services became more readily available in the provinces, the provinces (through their pharmacy acts and professional regulatory bodies) would act to restrict the drugs to prescription status, because provincial laws are able to be more restrictive than federal laws. Unfortunately, that did not happen: at the provincial level this has led to inconsistencies in the requirements from province to province. The unfortunate consequence is today we find drugs available in many lay outlets without the benefit of the professional advice of a veterinarian or pharmacist.

There have also been concerns about the appropriate use of many drugs for which a prescription is not required. To address these issues on a national approach, pharmacy regulatory bodies formed an association. An advisory committee was also formed to advise the provincial regulatory authorities on the placement of drugs in a national model for harmonized drug schedules. Adoption of these schedules aligned provincial drug schedules so that conditions for the sale of drugs would be consistent across Canada. To date all provinces except Quebec are generally following the national model.

Prescription Drugs: National Drug Schedule Model, Schedule I

- this schedule includes a list of drugs which require a prescription following diagnosis by a practitioner even though no prescription is required under federal law
- these drugs do NOT display the “Pr” designation because at the federal level a prescription is not required
- also includes all drugs which require a prescription under federal regulation (i.e.) human and veterinary prescription drugs, human and veterinary labeled OTC drugs, Controlled Drugs, and Narcotics
Non-Prescription Drugs: National Drug Schedule Model, Schedule II

- less strictly regulated but do require professional intervention from the pharmacist and possibly referral to a practitioner
- available only from the pharmacist and must be kept in an area with no public access or opportunity for patient self-selection

Non-Prescription Drugs: National Drug Schedule Model, Schedule III

- available in the clearly identified “professional services area”
- of a pharmacy which is operated under the direct supervision of a pharmacist
- available for self-selection but a pharmacist is available, accessible and approachable to assist in appropriate selection

Non-Scheduled Drugs

- drugs that are not listed on any of the above schedules
- anyone may sell them from any sales outlet
CHAPTER 2 – Sale of Drugs

In the Regulations to the Food and Drugs Act, the first statement dealing with the sale of drugs is very clear.

C.1.3 No person shall sell a drug that is not labeled as required by these Regulations.

In Canada, a person cannot sell a drug UNLESS it is labeled in accordance with the requirements of the Food and Drug Regulations. To fully understand the meaning of this regulation, one must know the definitions of the terms “drug” and “sell” in the Food and Drugs Act:

“drug” includes any substance or mixture of substances manufactured, sold or represented for use in
a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals
b) restoring, correcting or modifying organic functions in human beings or animals
c) disinfection of premises in which food is manufactured, prepared or kept.

Other products such as biologics and pesticides may also meet the definition of “drug” but are regulated under other legislation and are not considered to be “drugs”.

“sell” includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration

This definition means that any provision of a drug is deemed to be a sale regardless of whether or not something has been received in return. “Consideration” in terms of contracts (sales) can be money, goods, or services. Examples are a normal transaction where X dollars is charged for drug Y, a practitioner providing drugs in return for other supplies or goods, and where a practitioner provides veterinary services in exchange for a client performing a service. Even if a veterinarian does not charge for a drug provided, it is considered to be a sale under the Food and Drugs Act and is subject to its Regulations.

Labeling of Drugs

If one cannot sell a drug unless it has been labeled in accordance with Food and Drug Regulations, we must next examine what the labeling regulations require. A summary follows:

C.1.4 1) The INNER and OUTER LABELS of a drug shall show

“inner label” means the label on or affixed to an immediate container of a food or drug
“outer label” means the label on or affixed to the outside of a package of a food or drug

Name of Drug

(a) on the PRINCIPAL DISPLAY PANEL:

“principal display panel” has the same meaning as in the Consumer Packaging and Labeling Regulations

(i) the PROPER NAME, if any, of the drug which, if there is a brand name for the drug, shall immediately precede or follow the BRAND NAME in type not less than one-half the size of that of the brand name,
“proper name” is defined more precisely in the Regulations but roughly means what is commonly known as the “generic” name and is the name appearing in the Regulations or assigned in official publications.

“brand name” means the name assigned to the drug by its manufacturer, under which the drug is sold or advertised, and that is used to distinguish the drug.

(ii) If there is no proper name, the COMMON NAME of the drug.

“common name” means the name by which the drug is commonly known and that used in scientific or technical journals – in many cases, it is the same as the “generic” name.

(iii) deals with drug standards – See Regulations
(iv) deals with publications for drug standards, and – See Regulations.

Sterility

(v) In both official languages, the notation “STERILE” if the drug is required to be sterile by these Regulations.

Ophthalmic and parenteral preparations are required to be sterile.

Symbols

(b) on the upper left quarter of the PRINCIPAL DISPLAY PANEL:

(i) the symbol “Pr” in the case of a drug required by this Part or Part D to be sold on PRESCRIPTION, but in no other case shall the symbol Pr appear on the label of a drug.

“Pr” indicates that in accordance with federal regulations the drug can only be sold pursuant to a prescription.

“prescription” means an order given by a PRACTITIONER directing that a stated amount of any drug or mixture of drugs specified therein be dispensed for the person named in the order.

“practitioner” means a person authorized by the law of a province of Canada to treat patients with any drug listed or described in Schedule F to the Regulations.

(ii) the symbol “C” in a clear manner and a conspicuous colour and size, in the case of a CONTROLLED DRUG, OTHER THAN a controlled drug contained in an AGRICULTURAL IMPLANT and set out in Part III of the schedule to Part G,

“controlled drug” means a drug set out in the schedule to Part G of the Food and Drug Regulations and includes a preparation.

“agricultural implant” means a product that is presented in a form suitable to allow sustained release of an active ingredient over a certain period of time and that is intended for insertion under the skin of a food-producing animal for the purpose of increasing weight gain and improving feed efficiency;

(iii) the symbol “N” in a colour contrasting with the rest of the label or in type not less than half the size of any letters used thereon, in the case of a NARCOTIC as defined in the Narcotic Control Regulations, and

“narcotic” means any substance set out in the schedule or anything that contains any substance set out in the schedule to the Narcotic Control Regulations, Controlled Drugs and...
Substances Act.

(iv) in the case of a TARGET SUBSTANCE as defined in subsection 1(1) of the Benzodiazepines and Other Targeted Substances Regulations, the symbol “T/C”.

“targeted substance” means a controlled substance or a product or compound containing a controlled substance that is included in Schedule 1 of the Benzodiazepines and Other Targeted Substances Regulations, Controlled Drugs and Substances Act

Address - Lot Number

(e) on any panel:

(i) the NAME AND ADDRESS OF THE MANUFACTURER of the drug

(ii) the LOT NUMBER of the drug

“lot number” means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution

Directions

(iii) ADEQUATE DIRECTIONS FOR USE of the drug,

This is an extremely important requirement, which has implications when drugs are dispensed AND when used in an extra-label manner. The manufacturer’s label contains directions for all approved indications for the drug including the indications for use, species, dosage recommended, and route of administration.

(iv) a QUANTITATIVE LIST OF THE MEDICINAL INGREDIENTS of the drug by their proper names or, if they have no proper names, by their common names, and

Expiry Date

(v) the EXPIRATION DATE of the drug

“expiration date” means the earlier of: the date, expressed at minimum as a year and month, up to and including which a drug maintains its labeled potency, purity and physical characteristics, and the date, expressed at minimum as a year and month, after which the manufacturer recommends that the drug not be used

Products manufactured in the United States show a date as month/day/year. A date of 01/10/05 is January 10, 2005. In Canada, the date is expressed as day/month/year, following the British system. The same date is October 1, 2005 – a significant difference. The manufacture’s address on the drug label should be considered when interpreting expiry dates. If the expiry date comprises only a month and year, the date includes the entire month (e.g.) JN 04 is June 30, 2004.

The abbreviations for the names of months have been standardized:

<table>
<thead>
<tr>
<th>JA</th>
<th>January</th>
<th>FE</th>
<th>February</th>
<th>MR</th>
<th>March</th>
<th>AP</th>
<th>April</th>
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<td>JN</td>
<td>June</td>
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<td>July</td>
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<td>SE</td>
<td>September</td>
<td>OC</td>
<td>October</td>
<td>NO</td>
<td>November</td>
<td>DE</td>
<td>December</td>
</tr>
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</table>
Net Contents

(2) In addition to the requirements of subsection (1), the outer label of a drug shall show

(a) the net amount of the drug in the container in terms of weight, measure or number;
(b) in the case of a drug intended for parenteral use, a quantitative list of any
preservatives present therein by their proper names, or if they have no proper
names, by their common names; and “parenteral use” means administration of a
drug by means of a hypodermic syringe, needle or other instrument through or into
the skin or mucous membrane
(c) in the case of a drug for human use that contains mercury . . . see Regulations

Small Containers

(3) Where the container of a drug is too small to accommodate an inner label that
conforms to the requirements of these regulations, the inner label requirements of
these regulations do not apply to the drug in that container if

(a) there is an outer label that complies with the labeling requirements of these
Regulations; and
(b) the inner label shows:

i the PROPER NAME of the drug, the COMMON NAME of the drug if there is no proper
name or, in the case of a drug with more than one medicinal ingredient, the brand name
of the drug,
ii the POTENCY of the drug except where, in the case of a drug with more than one
medicinal ingredient, the name used pursuant to subparagraph (i) for that drug is unique
for a particular potency of the drug,
iii the NET CONTENTS of the drug if it is not in a discrete dosage form,
iv the ROUTE OF ADMINISTRATION of the drug if other than oral,
v the LOT NUMBER of the drug,
vi the name of the MANUFACTURER of the drug,
vii the EXPIRATION DATE of the drug, and
viii the identification of special characteristics of the dosage form if they are not evident from
the name of the drug under subparagraphs (i) or (ii).

For containers that are too small for all of the required information, an inner label must have a
minimum of the information in (i) to (viii) AND there MUST be an OUTER LABEL that COMPLIES with the
full label requirements. Examples are small eye ointment tubes, ampoules, small volume injections,
individual syringes, etc.

(4) REPEALED – See Regulations

Exemptions

(5) THIS SECTION DOES NOT APPLY TO

(a) a drug sold to a drug manufacturer; or

A drug sold to a manufacturer is for the purpose of manufacturing a product. The regulations apply to a
drug sold in dosage form (i.e.) a finished product offered for sale. The label of the finished product
produced by the manufacturer IS subject to these regulations.

(b) a DRUG DISPENSED PURSUANT TO A PRESCRIPTION, if its label carries suitable directions for
use and complies with the requirements of section C.01.005 etc.
Drugs dispensed on the order of a practitioner (“on prescription”) are EXEMPT from these labeling regulations BUT must have “suitable directions for use”. Federal laws do not specify other information required on a prescription label because they deal with approval for sale in general, including approval of the manufacturer’s label. Because this label states everything for which the manufacturer has received approval, it usually contains a great deal of information. It is provincial regulations that specify what information must appear on prescription labels because conditions of sale and regulation of professions are a provincial responsibility. The professional regulatory bodies in each province, acting on behalf of the public, determine what information is required on a prescription label.

A prescription is defined as an order for a stated amount of drug to be dispensed for the person named in the order. For such an order to be given, a diagnosis by a practitioner is required. This diagnosis changes the picture from a “broad spectrum” label (the manufacturer’s label), which includes ALL of the approved indications, species, dosages, etc., to the specific medical problem presented to the practitioner (i.e.) the individual case requiring treatment. Because we are now dealing with a specific case for which the practitioner has diagnosed a condition and is now prescribing a drug treatment, the information required for safe use of the drug on prescription is MUCH LESS than that required on the manufacturer’s label. The information that must appear on a prescription label is determined by provincial legislation. The reader should refer to the respective Provincial sections of this manual.

Importing Drugs

C.01.004.1 (1) No person shall import a drug in dosage form into Canada for the purpose of sale unless they have in Canada a person who is responsible for the sale of the drug.

Importation of drugs for sale in Canada is NOT allowed UNLESS a person in Canada is identified as responsible for such sale. In addition, the name and principal business address of this responsible person must appear on inner and outer labels of the drug.

C.01.045. No person, other than one of the following, shall import a prescription drug:

(a) a practitioner;
(b) a drug manufacturer;
(c) a wholesale druggist;
(d) a pharmacist; or
(e) a resident of a foreign country while a visitor in Canada

This section allows visitors from foreign countries to bring prescription medications necessary for management of their own medical conditions into Canada. It does NOT allow them to give, sell, or otherwise provide such medications to anyone else in Canada.

(2) ANY PERSON MAY IMPORT A SCHEDULE F DRUG LISTED IN PART II of Schedule F IF THE DRUG IS IMPORTED IN SUCH FORM OR SO LABELED that it could be sold by that person pursuant to section C.01.046

Those listed in (1) are the only people allowed to import Schedule F drugs, with the exception of Schedule F Part II drugs labeled in compliance with the regulations and to be sold “For Veterinary Use”. Imported drugs are not exempt from the labeling requirements of the Food and Drug Regulations. Because of the requirement for a DIN to appear on the label, and because a DIN is issued by Health Canada only after approval, even if the drug does not require a prescription for sale, it still MUST BE APPROVED before it can be sold. The only exception to this regulation would be a compounded medicine, which may only be sold pursuant to a prescription under a valid VCPR.
Requirement of Drug Identification Number (DIN)

C.01.005.  (1) The PRINCIPAL DISPLAY PANEL of both the INNER AND OUTER LABEL of a drug sold in dosage form SHALL SHOW in a clear and legible manner the DRUG IDENTIFICATION NUMBER assigned by the Director for that drug pursuant to subsection C.01.014.2 (1), preceded by the words “Drug Identification Number” or the letters “DIN”.

(2) Subsection (1) does not apply to a drug

   (a) compounded by a pharmacist pursuant to a prescription or by a practitioner; or
   (b) sold pursuant to a prescription, where the label of that drug indicates

      i  the proper name, the common name or the brand name of
          the drug,
      ii the potency of the drug, and
      iii the name of the manufacturer of the drug.

(3) For the purposes of this section and section C.01.014, “a drug in dosage form” means a drug in a form in which it is ready for use by the consumer without requiring any further manufacturing.
CHAPTER 3 – Controlled Drugs and Substances

Controlled Drugs and Substances Act (CDSA)

Definitions

“controlled substance” means a substance included in Schedule I, II, III, IV or V;

“practitioner” means a person who is registered and entitled under the laws of a province to practice in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons prescribed as a practitioner;

“provide” means to give, transfer or otherwise make available in any manner, whether directly or indirectly and whether or not for consideration;

“sell” includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration;

“traffic” means, in respect of a substance included in any of Schedules I to IV,
(a) to sell, administer, give, transfer, transport, send or deliver the substance,
(b) to sell an authorization to obtain the substance, or
(c) to offer to do anything mentioned in paragraph (a) or (b), otherwise than under the authority of the regulations.

The Controlled Drugs and Substances Act (CDSA) came into force on May 14, 1997, replacing the Narcotic Control Act and parts of the Food and Drug Act. The CDSA was passed in order:

- to fulfill Canada’s obligations under the international Conventions;
- to establish domestic controls over the distribution and possession of some psychotropic substances that are not listed in the schedules to one of the international Conventions;
- to rectify deficiencies in previous drug legislation;
- to consolidate the Narcotic Control Act and Parts III and IV of the Food and Drugs Act into one piece of legislation; and
- to control the availability and possession of psychotropic substances in Canada.

The CDSA prohibits possession, double doctoring, trafficking, possession for the purpose of Trafficking, importation, exportation and possession for the purpose of exporting and production of listed substances. These activities are illegal unless authorized in the Regulations.
CDSA Schedules

The drugs and substances controlled under the CDSA are grouped into eight Schedules, I-VIII.

**Schedules I to IV** are associated with particular actions, which constitute offences under the Act and are described in Part I of the CDSA. **Schedules I, II and III** include the same offences: possession, obtaining, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation and production. The offences for **Schedule IV** are similar except for the simple possession offence. The offences for **Schedules V and VI** are: importation, exportation and possession for purpose of exportation.

**Schedules VII and VIII** specify amounts of substances in Schedule II (Cannabis and Cannabis resin) associated with milder punishments.

Punishments (prison terms and fines) for offences under this Act range in severity from highest for Schedule I drugs and lowest for Schedule VIII. In the following schedules, items are italicized to indicate those commonly used in veterinary practice.

**Schedule I-VIII**


Regulations Exempting Certain Precursors and Controlled Substances from Application of the CDSA

The substances listed are exempt from the application of the CDSA, which means that even though they ARE controlled substances, they are not, at present, being treated the same way. The schedule to this regulation includes phenylpropanolamine, ephedrine, pseudoephedrine

**Schedule 1**

1. Bezitramide
2. Piritramide
3. Ecloqualon
4. 1-(1-Phenylcyclohexyl)pyrrolidine
5. Fenetylline
6. repealed
7. Glutethimide
8. to 17- repealed
9. Phenylpropanolamine
10. Propylhexidrine
11. Jpyrovalerone
12. Benzyl methyl ketone
13. Ephedrine
14. Ergometrine
15. Ergotamine
16. Lysergic acid
17. Pseudoephedrine

**Phenylpropanolamine** (PPA), ephedrine and pseudoephedrine are used for treatment of urinary incontinence in dogs. PPA and ephedrine require a prescription but pseudoephedrine is available without prescription for human use as a decongestant.


**Narcotic Control Regulations**

The Narcotic Control Regulations specify what drugs are considered to be “narcotics” and what actions are allowed in the handling of these drugs. Some narcotics have therapeutic use but, due to the serious risk of abuse, stringent restrictions monitor their availability. Examples of drugs listed in the Schedule to the Narcotic Control Regulations are cocaine, opium, codeine, morphine and Cannabis (marihuana). The drugs in this schedule are virtually the same as those listed in Schedules I and II of the CDSA.

The Narcotic Control Regulations listed here are abbreviated.

**Schedule to the Narcotic Control Regulations**

1. Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:

   | (1) | Opium          | (15) | Hydrocodone (dihydrocodeinone) |
   | (2) | Codeine (methylmorphine) | (16) | Hydromorphanol |
   | (3) | Morphine         | (17) | Hydromorphanone (dihydromorphanone) |
   | (4) | Thebaine (paramorphone) and the salts, derivatives and salts of derivatives of the substances set out in subitems (1) to (4), | (18) | Methylhydromorphanone |
   |     |                  | (19) | Methylmethadonone |
   |     |                  | (20) | Metopon |

   **INCLUDING**

   | (5) | Acetorphine (acetylmorphine) | (21) | Morphinone |
   | (6) | Acetyldihydromorphine | (22) | Metylpipapaverone |
   | (7) | Benzylmorphine | (23) | Nalorphine |
   | (8) | Codecine | (24) | Nicocodine |
   | (9) | Codoxime | (25) | Nicomorphine |
   | (10) | Desomorphine (heroin) | (26) | Norcodeine |
   | (11) | Diacetylmorphine | (27) | Norapomorphine |
   | (12) | Dihydromorphine | (28) | Oxymorphanone (dihydroxycodeinone) |
   | (13) | Ethylmorphine | (29) | Oxymorphone (dihydroxycodeinone) |
   | (14) | Etorphine | (30) | Pholcodine |
   | (31) | Thebacin |

   **BUT NOT INCLUDING**

   | (32) | Apomorphine | (35) | Narctine |
   | (33) | Cyprerophine | (36) | Papaverine [1-[3,4-dimethoxyphenyl]methyl] |
   | (34) | Nalophene |
   | (34.1) | Noroxone |
   | (34.2) | Norotroxone |
   | (37) | Popyseed |

2. Coca (Erythroxylon), its preparations, derivatives, alkaloids and salts, including:

   | (1) | Coca leaves | (3) | Ecgomine (3-hydroxy-2-tropane carboxylic acid) |
   | (2) | Cocaine (benzoylmethylcgonine) |

3. Phenylpiperidines, their intermediates, salts, derivatives and analogues and salts of intermediates, derivatives and analogues, including:

   | (1) | Allylpipradine | (12) | Hydroxypropidine |
   | (2) | Alphapropadine | (13) | Ketobemidone |
   | (3) | Alphaprodine | (14) | Metylphenylinisonipeconitirle |
   | (4) | Anileridine | (15) | Mophepidine |
   | (5) | Betapropadine | (16) | Norpethidine |
   | (6) | Betaprodine | (17) | Pethidine |
   | (7) | Benzeprodine | (18) | Phenoperidine |
   | (8) | Diphenoxylate | (19) | Pimindine |
   | (9) | Difenoxin | (20) | Properidine |
   | (10) | Etoxeridine | (21) | Trimeperidine |
   | (11) | Furethidine | (22) | Pethidine Intermediate C |
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<tr>
<td>13</td>
<td>Carbamethidine</td>
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<td>14</td>
<td>Oxpheneridine</td>
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### 4. Phenazepines, their salts, derivatives and salts of derivatives including:

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<tr>
<td>1</td>
<td>Proheptazine</td>
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<tr>
<td>2</td>
<td>Ethoheptazine</td>
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<tr>
<td>3</td>
<td>Metothoheptazine</td>
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### 5. Amidones, their intermediates, salts, derivatives and salts of intermediates and derivatives including:

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<tr>
<td>1</td>
<td>Dimethylaminodiphenylbutano-nitrile</td>
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<td>Dipipanone</td>
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<td>3</td>
<td>Isomethadone</td>
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<td>4</td>
<td>Methadone</td>
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### 6. Methadols, their salts, derivatives and salts of derivatives including:

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<tr>
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<td>Alphamethadol</td>
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<tr>
<td>4</td>
<td>Betacetylmethadol</td>
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### 7. Phenalkoxams, their salts, derivatives and salts of derivatives including:

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<tr>
<td>1</td>
<td>Dimenoxadol</td>
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<tr>
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### 8. Thiambutenes, their salts, derivatives and salts of derivatives including:

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<tr>
<td>1</td>
<td>Diethylthiambutene</td>
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<tr>
<td>2</td>
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### 9. Moramides, their intermediates, salts, derivatives and salts of intermediates and derivatives including:

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<tr>
<td>1</td>
<td>Dextromoramide</td>
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<tr>
<td>2</td>
<td>Diphenylmorpholinoisovaleric acid</td>
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### 10. Morphinans, their salts, derivatives and salts of derivatives including:

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<tr>
<td>1</td>
<td>Buprenorphine</td>
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<td>Drotebanol</td>
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<td>Levomethorphan</td>
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<td>Levorphanol</td>
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<td>Levophenacylmorphan</td>
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<td>10</td>
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<td>Dextrophan</td>
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<td>Levallorphan</td>
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<td>Levargorphan</td>
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### 11. Benzazocines, their salts, derivatives and salts of derivatives including:

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<tr>
<td>1</td>
<td>Phenazocine</td>
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<td>2</td>
<td>Metazocine</td>
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<tr>
<td>14</td>
<td>Butorphanol</td>
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<td>15</td>
<td>Nalbuphine</td>
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### 12. Ampromides, their salts, derivatives and salts of derivatives including:

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<tr>
<td>1</td>
<td>Diampromide</td>
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### 13. Benzimidazoles, their salts, derivatives and salts of derivatives including:

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<tbody>
<tr>
<td>1</td>
<td>Clonitazene</td>
</tr>
<tr>
<td>2</td>
<td>Bezitramide</td>
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</tbody>
</table>
Chapter 3 – Controlled Drugs and Substances

14. Phencyclidine, its salts, derivatives and analogues and salts of derivatives and analogues

15. Fentanyls, their salts, derivatives, and analogues and salts of derivatives and analogues, including:

(1) Acetylmethadol [148]
(2) Alfentanil
(3) Carfentanil
(4) p-Fluorofentanyl
(5) Fentanyl (11.1) Remifentanil
(6) β-Hydroxyfentanyl
(7) β-Hydroxy-3-methylfentanyl
(8) a-Methyfentanyl
(9) a-Methylthiofentanyl
(10) 3-Methylfentanyl
(11) 3-Methylthiofentanyl
(12) Sufentanil
(13) Thiofentanyl

16. Tilidine (ethyl2(dimethylamino)1phenyl3cyclohexene1carboxylate), its salts, derivatives and salts of derivatives

17. Cannabis, its preparations, derivatives and similar synthetic preparations, including:

(1) Cannabis resin
(2) Cannabis (marihuana)
(3) Cannabidiol
(4) Cannabinol
(5) Nabilone
(6) Pyrahexyl
(7) Tetrahydrocannabinol
(8) Nonviable Cannabis seed, with the exception of its derivatives
(9) Mature Cannabis stalks that do not include leaves, flowers, seeds, or branches; and fiber derived from such stalks

BUT NOT INCLUDING

Narcotic Control Regulations: Part G and Part J

The Narcotic Control Regulations and Part G and Part J Regulations to the Food and “Drug Act govern the activities of producers, distributors, importers, exporters and health care professionals relating to substances listed in the Schedules to these Regulations. They require dealers to be licensed in order to produce, distribute, import and export narcotics, controlled and restricted drugs. Licensed dealers must meet strict security requirements and obtain permits to import and export these drugs. These Regulations restrict the distribution activities of pharmacists, practitioners and hospitals and outline the records that must be kept for these drugs.

Part G of the Food and Drug Regulations (Part G Regulations) regulates the possession, sale and distribution of stimulants, sedatives and androgenic anabolic steroids, referred to as “Controlled Drugs”. They may be prescribed to humans and animals following specified conditions.

Part J of the Food and Drug Regulations (Part J Regulations) provides appropriate control measures for “Restricted Drugs”, most of which demonstrate hallucinogenic properties, have no recognized therapeutic use and are dangerous. They are only available for scientific use.

Definitions

In these Regulations, “hospital” means a facility

(a) that is licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness, or
(b) that is owned or operated by the Government of Canada or the government of a province and that provides health services
Most veterinary clinics or hospitals are not “licensed” per se. It is the practitioner who is licensed to provide care. To qualify as a “hospital” within the intent of the CDSA the “province” must “designate” a facility as such. In the case of veterinary facilities, the provincial regulatory body would have to specify what constitutes a veterinary “hospital”.

Most veterinary associations are not specific as to what a clinic is versus a hospital so, in the handling of controlled substances, veterinarians, being practitioners, follow the “practitioner” regulations.

“narcotic” means any substance set out in the schedule or anything that contains any substance set out in the schedule;

“pharmacist” means a person who is registered and entitled under the laws of a province
(i) to practice pharmacy, and
(ii) to operate a pharmacy or dispensary and who is operating a pharmacy or dispensary and is practicing pharmacy thereunder in that province

“prescription” means, in respect of a narcotic, an authorization given by a practitioner that a stated amount of the narcotic be dispensed for the person named in the prescription

“verbal order” means an order given orally

Possession

3.(1) A PERSON IS AUTHORIZED TO HAVE A NARCOTIC IN HIS OR HER POSSESSION WHERE THE PERSON HAS OBTAINED THE NARCOTIC UNDER THESE REGULATIONS, in the course of activities performed in connection with the enforcement or administration of an Act or regulation, or from a person who is exempt under section 56 of the Act from the application of subsection 5(1) of the Act with respect to that narcotic, AND THE PERSON:

(a) REQUIRES the narcotic FOR HIS BUSINESS OR PROFESSION AND IS
   (i) a licensed DEALER,
   (ii) a PHARMACIST, or
   (iii) a PRACTITIONER who is registered and entitled to practice in the province in which he has such possession;

(b) is a PRACTITIONER who is registered and entitled to practice in a province other than the province in which he has such possession and SUCH POSSESSION IS FOR EMERGENCY MEDICAL PURPOSES ONLY;

(c) is a hospital employee or a practitioner in a hospital;

(d) HAS OBTAINED THE NARCOTIC, other than diacetylmorphine (heroin), for his own use
   (i) FROM A PRACTITIONER,
   (ii) PURSUANT TO A PRESCRIPTION that is not issued or obtained in contravention of these Regulations, or
   (iii) FROM A PHARMACIST pursuant to section 36.

Only authorized persons who have obtained the narcotic as allowed in the Regulations can possess narcotics. If obtained outside of what is allowed, possession of a narcotic is an offence. Practitioners and pharmacists are allowed to possess narcotics for use in the practice of their professions. Some other situations where a person is authorized to possess a narcotic are specified in the Regulations. Otherwise a person must have obtained the drug pursuant to a prescription or from a practitioner.
“Double Doctoring”

(3) A PERSON in whose favour a prescription or a narcotic has been issued SHALL NOT SEEK OR RECEIVE ANOTHER PRESCRIPTION or a narcotic FROM A DIFFERENT PRACTITIONER WITHOUT DISCLOSING to that practitioner PARTICULARS OF EVERY PRESCRIPTION OR NARCOTIC that he has OBTAINED WITHIN THE PREVIOUS 30 DAYS.

This regulation is intended to stop the practice of “double-doctoring”, where a person presents to more than one physician and is issued a prescription for a narcotic from each one. Drugs obtained in this manner are often abused or diverted and sold illegally. A person cannot seek to obtain or receive a prescription for a narcotic unless they tell the practitioner the details of every prescription or narcotic they have received within the previous 30 days. If they do not divulge such information, charges can be laid.

Practitioners – Narcotic Control Regulations

Limitation of Provision

53. (1) NO PRACTITIONER SHALL ADMINISTER, PRESCRIBE, GIVE, SELL OR FURNISH A NARCOTIC TO ANY PERSON OR ANIMAL EXCEPT AS PROVIDED IN THIS SECTION.

(2) Subject to subsections (3) and (4), A PRACTITIONER MAY ADMINISTER, PRESCRIBE, GIVE, SELL OR FURNISH A NARCOTIC to a person or animal if

(a) the person or animal is a patient under his professional treatment; and

(b) the narcotic is required for the condition for which the person or animal is receiving treatment.

Practitioners are very limited in their provision of a narcotic. They can ONLY provide a narcotic IF the patient is under their professional treatment AND if the narcotic is required for the condition being treated. Examples of illegal provision of a narcotic are:

- a practitioner provides narcotics or a prescription for a narcotic in return for money or other services
- a practitioner provides a prescription for a person to obtain a narcotic where that person’s medical condition does not require a narcotic
- a practitioner provides a prescription for a narcotic for someone who is NOT his or her patient
- a veterinarian provides a prescription for a narcotic for an animal that he/she has never examined and therefore is not under their professional treatment
- a veterinarian provides a prescription for a narcotic for an animal that doesn’t exist or does not require treatment
- a practitioner provides a narcotic (sells or “loans”) to another practitioner
- a practitioner provides a narcotic to anyone who is not under his/her professional treatment.

Veterinarians can feel uncomfortable pressure to provide narcotics or other controlled substances in some situations. It is not illegal to provide such drugs where conditions warrant and it is a misconception to believe the veterinarian is required to administer the drug. A client requesting an anabolic steroid (a controlled drug) to “bulk up” an animal in preparation for a show can be refused since the animal does not have a medical condition for which the drug is required. Veterinarians questioning whether provision of narcotics or controlled substances is appropriate and satisfies the conditions in the Regulations need to answer “Yes” to the following questions:
Dispensing Manual for Veterinarians

- “Is this MY patient?”
- “Do I have a valid VCPR?” and
- “Is this drug REQUIRED for the condition I am treating?”

(3) No practitioner shall administer, prescribe, give, sell or furnish METHADONE to any person or animal unless the practitioner has been exempted under section 56 of the Act with respect to methadone.

(4) No practitioner shall administer, prescribe, give, sell or furnish diacetylmorphine (HEROIN) to
(a) any animal; or
(b) any person unless that person is an inpatient or outpatient of a hospital providing care or treatment to persons.

Record Keeping Requirements

54. (1) A PRACTITIONER WHO FURNISHES A NARCOTIC to a person for self-administration or for administration to an animal, whether or not he makes a charge therefore, IF HE FURNISHES THE NARCOTIC IN AN AMOUNT
   (a) that EXCEEDS THREE TIMES THE MAXIMUM DAILY DOSAGE RECOMMENDED by the manufacturer of that narcotic for that narcotic, or
   (b) if the manufacturer has not recommended a maximum daily dosage, that EXCEEDS THREE TIMES THE GENERALLY RECOGNIZED MAXIMUM DAILY THERAPEUTIC DOSAGE for that narcotic.

   SHALL KEEP A RECORD, SHOWING
   (c) the NAME AND QUANTITY of the narcotic furnished,
   (d) the NAME AND ADDRESS OF THE PERSON to whom it was furnished, and
   (e) the DATE on which it was furnished.

This regulation appears to state that unless a practitioner supplies MORE than three days’ supply of a narcotic, he/she is not required to keep records of where such quantities of drug are distributed. One can imagine the absurdity of a practitioner not needing to account for his/her use of narcotics by claiming they were all dispensed in quantities that were less than three days’ supply. This is addressed in Section 55.

(2) A PRACTITIONER who is required by this section to keep a record SHALL KEEP THE RECORD IN A PLACE, FORM AND MANNER THAT WILL PERMIT AN INSPECTOR TO READILY EXAMINE AND OBTAIN INFORMATION FROM IT.

The records required to be kept under this section must be in a form that allows an audit of the receipts and use of narcotics by the practitioner. The system used should indicate the following information for receipts of narcotics:

- Date Drug Received
- Name of the Drug Received, Strength, Dosage Form (e.g.) Morphine 15 mg/mL Injection
- Quantity Received and Size of Container (e.g.) 12 x 30 mL vials
- Supplier Name and Address
- Invoice Number

Most practices will not have extensive use of a wide variety of narcotics so simple manual systems can work very well with minimal labour input. There are various computer programs available for narcotic record keeping purposes.

Other Obligations

55. A PRACTITIONER SHALL
   (a) FURNISH to the Minister ON REQUEST such INFORMATION RESPECTING
      (i) the RECEIPT AND USE BY THE PRACTITIONER OF NARCOTICS (INCLUDING THE ADMINISTERING AND FURNISHING thereof to a person), and
      (ii) the PRESCRIPTIONS for narcotics ISSUED by the practitioner, as the Minister may require;
At any time the Minister (of Health) can request documentation of a practitioner’s receipt of narcotics AND their use by the practitioner. This means the Minister or his agent can request information and the practitioner must comply. Many of the inspection and enforcement duties of the federal government have been delegated to the provincial regulatory and licensing bodies. It is felt these organizations are better suited to monitoring compliance of their members. Thus the respective provincial veterinary medical associations can act in these matters as agents of the federal government.

If a practitioner has NOT been keeping records of where he/she has used or provided narcotics (due to the three day supply regulation), it will be impossible to comply with the request for such information in Section 55. If one cannot provide the information requested, he or she may have to resort to a review of their medical and surgical records in order to generate the needed information. To avoid this situation,

IT IS STRONGLY RECOMMENDED THAT VETERINARIANS KEEP RECORDS OF THE PRESCRIPTIONS THAT THEY ISSUE and THEIR DISPENSING OF NARCOTICS regardless of the quantity.

(b) PRODUCE TO AN INSPECTOR on request any RECORDS that these Regulations require the practitioner to keep;
(c) PERMIT AN INSPECTOR to make COPIES of such records or to take extracts there from;
(d) PERMIT AN INSPECTOR to CHECK ALL STOCKS OF NARCOTICS on the practitioner’s premises;
(e) RETAIN IN HIS POSSESSION FOR AT LEAST TWO YEARS ANY RECORD that these Regulations require him to keep;

Destruction

There are no regulations authorizing destruction of controlled substances. The Office of Controlled Substances allows unused partial doses in non-re-sealable containers to be discarded as long as the administration records account for the amount administered AND discarded. Any other amounts of unusable controlled substances can only be destroyed after written authorization from OCS and in the presence of a witness (either another practitioner or a pharmacist).

Protection from Loss or Theft

(f) TAKE ADEQUATE STEPS TO PROTECT NARCOTICS in his possession FROM LOSS OR THEFT; and

Other than some guidelines for hospitals to assess the level of security needed, no special measures for security are given. If a practitioner has a theft or loss, he/she is required to do whatever is necessary to further protect the drugs from loss or theft. This can result in the need to upgrade security if the problem continues.

(g) REPORT TO THE MINISTER ANY LOSS OR THEFT of a narcotic WITHIN 10 DAYS OF THE PRACTITIONER’S DISCOVERY of the loss or theft.

Theft is sometimes more visibly evident if a break-in has occurred but loss can be harder to detect. While it is difficult to believe colleagues or employees might divert or abuse drugs, access to narcotics should be severely restricted. A monitoring system of checking and balancing supplies of narcotics against their use should be implemented. Stock should be checked regularly to ensure the amount remaining in inventory corresponds to what SHOULD be left. If a loss is discovered, the practitioner must report it within 10 days of discovery. Typically a report listing the drugs missing, the amounts, and the date of loss or discovery of loss is filed with the Office of Controlled Substances, Health Canada. Forms can be obtained from this office. As follow-up, the practitioner may be asked to outline what measures are being taken to ensure such a loss does not occur again.
Burden of Proof in Prosecutions

56. WHERE A PRACTITIONER ALLEGES OR, in any prosecution for an offence under the Act or these Regulations, PLEADS THAT HIS POSSESSION OF A NARCOTIC WAS FOR USE IN HIS PRACTICE or that he PRESCRIBED, ADMINISTERED, GAVE, SOLD OR FURNISHED a narcotic to any person or animal AS A PATIENT UNDER HIS PROFESSIONAL TREATMENT and that such NARCOTIC WAS REQUIRED FOR THE CONDITION for which the patient received treatment, the BURDEN OF PROOF THEREOF SHALL BE ON SUCH PRACTITIONER.

If a practitioner is charged with an offence under the CDSA and claims his/her possession, use or provision of a narcotic or a prescription for a narcotic was in his/her professional capacity, the burden of proof is on the practitioner. This means the practitioner has to prove innocence rather than the prosecution proving guilt. This is significantly different from any other area of the legal system and if nothing else, should encourage practitioners to be “above board” in all transactions involving narcotics.

Controlled Drugs

Regulations governing controlled drugs are published in Part G of the Food and Drugs Regulation. The regulations for controlled drugs, with few exceptions are exactly the same as those for narcotics. The term “designated drug” denotes drugs, which are restricted as to under what circumstances they can be prescribed. A controlled drug is defined as a drug listed in the Schedule to Part G, which comprises three parts.

Part I lists drugs such as amphetamine, methylphenidate and pentobarbital and is more tightly controlled than Parts II and III. It is an offence to possess controlled drugs such as amphetamines unless they have been obtained as allowed in the regulations. Part II contains barbiturates and butorphanol, and Part III, anabolic steroids.

Anabolic steroids were moved from prescription to controlled drug status after the report of the “Commission of Inquiry Into the Use of Drugs and Banned Practices Intended to Increase Athletic Performance”. More commonly known as the Dublin Inquiry, it was established to investigate the use of performance-enhancing drugs in sports after Ben Johnson, who tested positive for stanozolol at the 1988 Seoul Olympic Games, was stripped of his gold medal in the 100 m event. Anabolic steroids contained in agricultural implants are not affected by the Controlled Drug Regulations.

Control of drugs in Parts I, II, and III involve differences in the requirement for written (signed) orders, permitting refills, and accounting for usage. While refills of narcotic prescriptions are NOT permitted, refills for controlled drugs may be allowed BUT the prescriber must specify the number of times AND the interval of time that must pass between refills. The CDSA and the Controlled Drug Regulations do not apply to a drug listed in Part 3 that is contained in an agricultural implant.

“agricultural implant” means a product that is presented in a form suitable to allow sustained release of an active ingredient over a certain period of time and that is intended for insertion under the skin of a food-producing animal for the purpose of increasing weight gain and improving feed efficiency;

G.01.004 The Controlled Drugs and Substances Act and this Part do not apply in respect of a controlled drug that is contained in an agricultural implant and set out in Part III of the schedule to this Part, but nothing in this section exempts such a drug from the requirements of Part C.
Schedule to Part G, Food and Drug Regulations Part I

1. Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, excluding those substances set out in item 1 of the schedule to Part I but including:
   (1) amphetamine*
   (2) methamphetamine*
   (3) benzphetamine*

2. Methylphenidate and any salt thereof
3. Methaqualone and any salt thereof
4. Phendimetrazine*
5. Phenmetrazine*
6. **Pentobarbital**
7. Secobarbital
8. 4-hydroxybutanoic acid (GHB and any salt thereof)

* **Designated Drugs** (for prescribing purposes may be used in animals by veterinarians ONLY for treatment of depression of cardiac and respiratory centres)

Part II

1. **Barbiturates**, their salts and derivatives, excluding the substances set out in items 6 and 7 of Part I but including:
   (1) Allobarbital
   (2) Alphenal
   (3) Amobarbital
   (4) Aprobarbital
   (5) Barbital
   (6) Barbituric Acid
   (7) Butabarbital
   (8) Butalbital
   (9) Butallylronal
   (10) Butethal
   (11) Cyclobarbital
   (12) Cyclopal
   (13) Heptabarbital
   (14) Hexethal
   (15) Hexobarbital
   (16) Meprobambarbital
   (17) Methabarbital
   (18) Methylpheno-barbital
   (19) Propallylronal
   (20) Phenobarbital
   (21) Probarbital
   (22) Phenylmethyl-barbituric Acid
   (23) Sigmodal
   (24) Talbutal
   (25) Vinbarbital
   (26) Vinylbutal

2. Thiobarbiturates, their salts and derivatives, including:
   (1) Thialbarbital
   (2) Thiambutal
   (3) Thiobarbituric Acid
   (4) Thiopental

3. Chlorphentermine
4. Diethylproprion
5. Phentermine
6. **Butorphanol**
7. Nalbuphine

Part III

**G.01.004**

The **Controlled Drugs and Substances Act** and this Part do not apply in respect of a controlled drug that is contained in an AGRICULTURAL IMPLANT and set out in Part III of the schedule to this Part, but nothing in this section exempts such a drug from the requirements of Part C.

“**agricultural implant**” means a product that is presented in a form suitable to allow sustained release of an active ingredient over a certain period of time and that is intended for insertion under the skin of a food-producing animal for the purpose of increasing weight gain and improving feed efficiency;
1. Anabolic steroids and their derivatives, including:

   (1) Androisoxazole  (23) Metenolone
   (2) Androstanolone  (24) Methandriol
   (3) Androstenediol  (25) *Methyltestosterone Geri-Tabs*
   (4) Bolandio      (26) Metribolone
   (5) Bolasterone   (27) *Mibolerone Cheque Drops – disc*
   (6) Bolazine      (28) Nandrolone
   (7) *Boldenone Equipoise* (29) Norboleton
   (8) Bolenol       (30) Norclostebol
   (9) Calusterone   (31) Norethandrolone
   (10) Clostebol    (32) Oxabolone
   (11) Drostanolone (33) Oxandrolone
   (12) Enestebol    (34) Oxybolone
   (13) Eptiostanol (35) Oxyethinone
   (14) Ethylestrenol (36) Prasterone
   (15) 4-Hydroxy-19-nortestosterone (37) Quinbolone
   (16) Fluoxymesterone (38) *Stanozolol Winstrol – V*
   (17) Formebolone  (39) Stenbolone
   (18) Furazabol    (40) Testosterone (many names)
   (19) Mebolazine   (41) Tibolone
   (20) Mesabolone   (42) Tiemesteron
   (21) Mesterolone (43) *Testosterone etc.*
   (22) Metandienone

2. Zeranol - Raigro

**Controlled Drugs Regulations: Practitioners**

G.04.001.  (1) In this section,

"ADMINISTER" includes prescribe, give, sell, furnish, distribute or deliver; "DESIGNATED DRUG" means any of the following controlled drugs:

(a) amphetamine and its salts,
(b) benphetamine and its salts,
(c) methamphetamine and its salts,
(d) phentramine and its salts, or
(f) phenidimetrazine and its salts.

These drugs are “designated” for prescribing purposes. The amphetamines and similar substances have a history of dangerous abuse as stimulants especially to aid in weight loss. They can now be prescribed ONLY FOR the treatment of the medical conditions listed in (4).

(2) SUBJECT TO SUBSECTIONS (3) AND (4) and to an exemption granted under section 56 of the Controlled Drugs and Substances Act with respect to the administration of the controlled drug specified in the exemption, NO PRACTITIONER SHALL ADMINISTER A CONTROLLED DRUG TO ANY PERSON OR ANIMAL.

(3) A practitioner MAY ADMINISTER A CONTROLLED DRUG, other than a DESIGNATED DRUG, to a person or to an ANIMAL, IF

(a) that person or animal is a PATIENT UNDER HIS PROFESSIONAL TREATMENT; AND
(b) the controlled DRUG IS REQUIRED FOR THE CONDITION for which the patient is receiving treatment.

Practitioners are allowed to prescribe or provide controlled drugs, except for designated drugs, if the patient is under their professional treatment AND drug is required for the medical condition being treated. If the animal is NOT your patient, you can’t provide/prescribe controlled drugs.

(4) A practitioner may administer a DESIGNATED DRUG to an animal or a person who is a patient under his professional treatment where the designated drug is for the treatment of any of the following conditions:
(a) in humans
(i) narcolepsy,
(ii) hyperkinetic disorders in children,
(iii) mental retardation (minimal brain dysfunction),
(iv) epilepsy,
(v) parkinsonism, or
(vi) hypotensive states associated with anesthesia; or

(b) in ANIMALS, depression of cardiac and respiratory centres.

It is highly unlikely a veterinarian would give a client a prescription for amphetamines to be filled at a local pharmacy if the veterinarian was treating depression of cardiac and respiratory centers (usually an intensive care situation), which are the only conditions for which amphetamines can be used in animals! However, if a case presents where there is documentation supporting use of a designated drug in a condition other than those specified, it is important for the veterinarian to request authorization from the Veterinary Drugs Directorate (VDD) and the Office of Controlled Substances (OCS). The conditions listed are the only known legitimate medical conditions for which designated drugs are useful. However, research often reveals new uses for drugs and sharing of such information with these government agencies may result in changes to the regulations. Authorization is informal, often verbal, with the OCS consulting veterinarians at VDD to assess the validity of the request.

G.04.002. (1) A PRACTITIONER WHO Furnishes A CONTROLLED Drug to a person for self-administration or for administration to an animal shall, whether or not he makes a charge therefore, IF HE Furnishes the controlled drug in an amount
(e) THAT EXCEEDS THREE TIMES THE MAXIMUM DAILY DOSAGE recommended by the manufacturer of that controlled drug for that controlled drug . . .
(f) . . . KEEP A RECORD SHOWING
(g) the NAME and QUANTITY of the controlled Drug furnished;
(h) the NAME and ADDRESS of the person to whom it was furnished; and
(i) the DATE on which it was furnished.

(2) A PRACTITIONER who is required by this section to keep a record shall keep the RECORD IN A PLACE, FORM and MANNER that will PERMIT an INSPECTOR readily to EXAMINE and OBTAIN INFORMATION from it.

The requirements for record keeping, documentation “on request of the Minister”, other practitioner obligations including reporting loss or theft, and the “burden of proof” in prosecutions are the same for controlled drugs as for narcotics.

G.04.002A. A PRACTITIONER SHALL
(a) Furnish to the minister on request such INFORMATION respecting
(i) the RECEIPT and USE by the practitioner of controlled drugs (INCLUDING THE ADMINISTERING and furnishing thereof to a person), and
(ii) the PRESCRIPTIONS for controlled drugs ISSUED by the practitioner, as the Minister may require;
(b) produce to an INSPECTOR on request any RECORDS that these Regulations require the practitioner to keep;
(c) PERMIT an INSPECTOR to make COPIES of such records or to take extracts therefrom;
(d) PERMIT an INSPECTOR to CHECK ALL STOCKS of controlled drugs on the practitioner’s premises;
(e) RETAIN in his possession FOR AT LEAST TWO YEARS any record that these Regulations require him to keep;
(f) TAKE adequate steps to PROTECT controlled drugs in his possession from LOSS OR THEFT; and
(g) REPORT to the MINISTER any LOSS or THEFT of a controlled drug WITHIN 10 DAYS of the practitioner’s DISCOVERY of the loss or theft.

G.04.003. WHERE a practitioner ALLEGES OR, in any prosecution for an offence under the Controlled Drugs and Substances Act, the Food and Drugs Act or this Part, pleads that his POSSESSION of a controlled drug was for USE IN HIS PRACTICE or that he prescribed, administered, gave, sold or furnished a controlled drug TO ANY person or ANIMAL as a PATIENT UNDER his PROFESSIONAL TREATMENT and that such controlled drug was REQUIRED FOR THE CONDITION FOR WHICH THE PATIENT RECEIVED TREATMENT, the burden of proof thereof SHALL be on such practitioner.
Benzodiazepines and Other Targeted Substances

“targeted substance” means a controlled substance that is included in Schedule 1

In September 2000, a new classification of controlled substances, Targeted Substances, came into force. Benzodiazepines were officially moved from prescription drug status under Schedule F of the Food and Drugs Regulations to “targeted substances” under the Benzodiazepines and Other Targeted Substances Regulations. These drugs are more tightly controlled than Schedule F (prescription) drugs but less so than controlled drugs or narcotics. Definitions for “hospital”, “practitioner”, “pharmacist”, “prescription” etc. remain the same as found in previous sections. The regulations are very similar to narcotics and controlled drugs but with some important differences.

Destruction

Destruction is allowed under specified circumstances:
• before destruction, the practitioner or pharmacist must record the name, strength, quantity of the substance to be destroyed, and the date of destruction
• the substance must be destroyed in compliance with federal, provincial and municipal environmental legislation
• immediately after destruction, the person destroying and the person witnessing must sign and print their names on a joint statement, indicating they witnessed the destruction and the targeted substance destroyed has been altered or denatured to such an extent that its consumption has been rendered impossible or improbable a targeted substance that constitutes the remainder of an open ampule, the partial contents of which have been administered to a patient, may be destroyed by a hospital employee who is a licensed health professional without a witness.

Practitioners

Similar to the regulations for narcotic and controlled drugs, veterinarians are allowed to prescribe, administer, provide, etc. a targeted substance only if the animal is a patient being treated in their professional capacity AND the targeted substance is required to treat the animal’s medical condition.

Records

Practitioners must keep records of:
• the name, strength, and quantity of any targeted substance received
• the date it was received
• name and address of the supplier of the targeted substance
• the disposition of the targeted substance and date of disposition if the quantity exceeds five times the usual daily dose for the substance

There is no requirement for documentation “on request” of the practitioner’s use or provision of targeted substances.

Security and Reporting Loss or Theft

Practitioners are required to report to the Minister loss or theft of a targeted substance no later than 10 days after discovery.
CHAPTER 4 – Prescription Drugs

Effective December 2013, the Food and Drug Regulations were amended, repealing Schedule F. Prescription drugs formerly listed under Schedule F Part I were moved to the Prescription Drug List (PDL). It should be noted that there is a human and veterinary Prescription Drug List and that the lists are not identical. Schedule F Part II or non-prescription veterinary drugs are no longer specifically listed.

However, if a drug displays a DIN (Drug Identification Number) and is not on the veterinary Prescription Drug List or listed as a controlled substance in the Controlled Drug and Substances Act it is a non-prescription drug. As such, it may be sold without a prescription provided it is labelled for veterinary use only, its intended use is consistent with label directions and the drug is sold in its original container.

If the non-prescription veterinary drug’s intended use is extra-label such as a different dosage, a different species or a different indication, a prescription is required. Also, non-prescription veterinary drugs must be sold in their original container bearing the approved label. If only a portion of the drug is dispensed, a prescription and prescription label is required. All prescription drugs and human labeled non-prescription drugs require a prescription.

The following definitions apply:

“prescription drug” means a drug that is set out in the Prescription Drug List, as amended from time to time, or a drug that is part of a class of drugs that is set out in it;

“Prescription Drug List” means the list established by the Minister under section 29.1 of the Act;

Both human labelled and veterinary labelled Schedule F Part II (OTC) drugs are no longer specifically listed.

However, if a drug has a DIN number and is not on the respective Prescription Drug List or in the Schedules I to V of the Controlled Drug and Substance Act, it is a NON-PRESRIPTION drug.

C.01.041. (1) No person shall sell a prescription drug unless

- (a) they are entitled under the laws of a province to dispense a prescription drug and they sell it in that province under a verbal or written prescription that they received; or
- (b) they sell it under section C.01.043.

(2) In the case of a verbal prescription, the person referred to in paragraph (1)(a) or a pharmacy technician shall create a written record of the prescription that includes the following information:

- (a) the date on which the prescription was received and, if applicable, the number of the prescription;
- (b) the name and address of the person to whom the prescription was issued;
- (c) the proper name, common name or brand name of the drug and its quantity;
- (d) the person’s name and the name of the practitioner who issued the prescription; and
- (e) the directions for use provided with the prescription, whether or not the practitioner authorized it to be refilled and, if refills are authorized, the number of authorized refills.

If a drug is listed in Prescription Drug List (PDL) a prescription is required for its sale whether or not the drug is labeled for human or for veterinary use. Both human and veterinary labeled prescription products will display the symbol “Pr”

Examples:  Human labeled -  ciprofloxacin (Cipro®) and metronidazole (Flagyl®)
Veterinary labeled -  xylazine (Rompun®) and amoxicillin (Amoxil®)

These drugs can be sold ONLY “on prescription” even though their labels state “For Veterinary Use Only”
The list of non-prescription drugs is fairly short. It contains some tranquillizers, certain antibiotics, diuretics, hormones needed for the management of reproduction, and some vitamin and mineral supplements. Drugs listed here may be sold without a prescription IF they are in the original container with the manufacturer’s label (to comply with the requirements of the labeling Regulations) AND that label states “For Veterinary Use Only”. If repackaging and dispensing only part of the product, it must be sold pursuant to a prescription with a prescription label.

If a non-prescription drug is human labeled, a prescription is required for sale of the product if the product is to be used in an animal. If the non-prescription drug is veterinary labeled, and meets the labeling requirements of the F and D Regulations and the drug is not being used for an unapproved use, (extra label) the drug may be sold without a prescription.

Example: There is no label claim for use of many injectable tetracyclines for use in sheep. If this drug is to be sold for use in this species, a prescription would be required.

<table>
<thead>
<tr>
<th>REGARDLESS OF WHAT SPECIES THE DRUG IS TO BE USED FOR:</th>
<th>PDL</th>
<th>Not on PDL</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the Drug is listed in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HUMAN labeled</td>
<td>Rx required</td>
<td>Rx required</td>
</tr>
<tr>
<td>VETERINARY labeled</td>
<td>Rx required</td>
<td>Rx NOT Required</td>
</tr>
</tbody>
</table>
Factors Determining Placement of Drug in the Prescription Drug List

The decision to restrict the sale of a drug to prescription status involves consideration of several standardized criteria. Presence of the following characteristics will place the drug in the Prescription Drug List:

(a) require individualized instructions and/or direct practitioner supervision or monitoring
(b) narrow margin of safety between therapeutic and toxic dosages
(c) potential for OR known to cause undesirable or severe side effects at normal therapeutic dosage levels
(d) experimental data shows toxicity in animals but not in clinical use long enough to show pattern or frequency of long-term toxic effects in humans
(e) indicated for serious disease states often misdiagnosed by the public
(f) use may mask other ailments
(g) have or may contribute to development of resistant bacteria in humans
(h) potential for dependence or abuse has led or is likely to lead to harmful nonmedical use if distribution is not supervised
(i) potentially high level of risk relative to expected benefits
(j) therapeutic effect based on recently elucidated pharmacologic concepts, consequences of which have not been adequately established.

If the drug also meets this next set of criteria it will be placed in Prescription Drug List (PDL) and will restrict the sale of such drugs to prescription status or use by a licensed practitioner. Factors placing drugs in PDL include:

(a) veterinary drugs known to be liable to be diverted to humans
(b) veterinary drugs for which it is not possible to write directions for use that could be easily followed by a layman
(c) veterinary drugs which may be hazardous to the administrator
(d) new antibiotics for veterinary use which are useful in human medicine
(e) certain veterinary drug dosages or formulations may be listed in Part I and other dosages or formulations may be listed in Part II.

Exceptions may be made for drugs which:

(a) are required to be readily available for emergency use where not practical to get Rx (e.g.) adrenalin in insect bite kits
(b) are rarely use without a practitioner’s supervision and where need for free availability outweighs the need for Prescription Drug List (e.g.) insulin and nitroglycerin
(c) have potential to interact dangerously with other drugs or food but where risk can be minimized by effective labeling.

C.01.043. (1) A person may sell a prescription drug to
   (a) a drug manufacturer;
   (b) a practitioner;
   (c) a wholesale druggist;
   (d) a pharmacist; or
   (e) the Government of Canada or the government of a province, for the use of a department or agency of that government, on receipt of a written order signed by the minister responsible for the department or by the person in charge of the agency, or by their duly authorized representative.

(2) If a person sells a prescription drug under paragraph (1)(e), they shall retain the written order for the drug for a period of at least two years after the day on which the drug is sold.
Prescription drugs are to be sold only on prescription but certain exceptions are permitted. It is possible to sell a prescription drug without a prescription to a drug manufacturer, a practitioner, a wholesale druggist, or a registered pharmacist. This is intended to allow the sale of drugs respectively for the purpose of manufacturing a drug product, for use by a practitioner in practicing his/her profession, for the provision of prescription drugs for resale to authorized sellers, and for distribution pursuant to prescription orders. Other conditions under which a drug may be sold without a prescription are described in the Regulations and may include an order signed by the Minister of a Department of the Government of Canada or a province.

Scope of Practice and Prescription Drugs

This regulation is not intended to allow a practitioner or pharmacist to buy drugs for personal use without a prescription. Every person has the right to self-medicate with nonprescription drugs. However, prescription drugs require a diagnosis. Prescribing for a person, including your own self is NOT within the scope of practice of veterinarians or pharmacists. Physicians have rules dealing with prescribing for themselves and immediate family members. Veterinarians are allowed to prescribe for their own animals but not for their own family. Similarly, filling personal or family prescriptions is not within the scope of practice for veterinarians.

Examples: An after-hours phone request through the answering service resulted in a conversation with Dr. X who stated he needed a wormer for his dog. When asked what drug he wanted, he asked “Well, what do they use?” This was my first clue that Dr X was NOT a veterinarian. On revealing he was a dentist, I replied that any of the worms were going to require a prescription. Dr X responded if that were the case he could give me a prescription! This launched a discussion of prescribing privileges and scopes of practice – dentists can prescribe within their scope of practice for their patients but are not licensed to prescribe for animals. We filled Dr X’s prescription for wormer after consultation with and prescribing by a veterinarian the next day.

A similar situation occurred in my human practice before coming to WCVM. In this case a dentist prescribed an appetite suppressant for his daughter. Again this was a medical condition outside the scope of practice of a dentist and was not permitted.

A veterinarian requesting Tribriissen (trimethoprim – sulfadiazine) tablets to treat a dog was told it would have to be documented on prescription. When questioned as to the weight of the dog and the dosage needed, the veterinarian admitted rather sheepishly the drug was actually for personal use. The veterinarian had been suffering from a recurring urinary tract infection for some time that resolved on treatment with Tribriissen but came back. When told that we could dispense the drug only on a physician’s prescription, the veterinarian asked that we call her physician. When contacted, the physician admitted he was completely frustrated by this case because he couldn’t get a urine culture due to the antibiotic treatment! Another major concern here was the treatment of a person with a VETERINARY labeled drug and the legal issues involved.

At some point in their careers, veterinarians will have a physician finally bring to the clinic their dog, which they have unsuccessfully treated with every antibiotic under the sun, and now expect the veterinarian to clean up the mess. It is very easy to be scornful and wonder what they could have been thinking. After all, physicians are not trained in species differences or knowledgeable about drug doses for animals. Both physicians and veterinarians are highly educated professionals who sometimes do not respect the boundaries of each other’s practices. Veterinarians need to be careful of the problems they may create for their own physicians with self-diagnosis and self-treatment.
Documentation of Sale of Prescription Drugs

C.01.041. (1) No person shall sell a prescription drug unless:
(a) they are entitled under the laws of a province to dispense a prescription drug and they sell it in that province under a verbal or written prescription that they received; or
(b) they sell it under section C.01.043.

(2) In the case of a verbal prescription, the person referred to in paragraph (1)(a) or a pharmacy technician shall create a written record of the prescription that includes the following information:
(a) the date on which the prescription was received and, if applicable, the number of the prescription;
(b) the name and address of the person to whom the prescription was issued;
(c) the proper name, common name or brand name of the drug and its quantity;
(d) the person's name and the name of the practitioner who issued the prescription; and
(e) the directions for use provided with the prescription, whether or not the practitioner authorized it to be refilled and, if refills are authorized, the number of authorized refills.

When the prescription/order for prescription drugs is in writing, the document must be kept for at least two years from the date it is filled. If the prescription is verbal, the person who receives the order must record the order (on paper) and keep that document on file for the same period of time. This written record of the prescription must contain all of the information specified in C.01.041 (4).

Example: In a pharmacy, orders from practitioners are recorded on prescription pads, each prescription is assigned a filing number, and all prescriptions are filed by number. In addition, computer profiles containing each patient's personal drug information are developed. To the pharmacist, these profiles are the equivalent of the practitioner's medical records.

In a small animal veterinary clinic, a technician is requested by Dr. X to dispense 20 amoxicillin 100 mg tablets, 1 bid, 10 days, for the cat “Fluffy” Jones. The technician does not record the order on a prescription pad but does enter it in the patient's medical record which should contain most of the information required as documentation under C.01.041 (4).

Some provincial associations have decided an invoice copy complies with the documentation requirements of C.01.041 (4). While most invoices probably do not contain all of the required information, authorities at Health Canada have delegated much of their monitoring and compliance duties to the provincial professional associations and are unlikely to take any action against the practice.

C.01.041.1 Subject to paragraph C.01.041.3(2)(b), a pharmacist or pharmacy technician may transfer to another pharmacist or pharmacy technician a prescription for a prescription drug.

A pharmacist is allowed to transfer a prescription for a drug to another pharmacist but there are specific documentation requirements when this is done. Note there is no regulation allowing a veterinarian to transfer a prescription to another veterinarian. This regulation is intended to allow people access to their prescription drug refill when they wish or need to obtain them in a different pharmacy or location (e.g.) when traveling, when wanting to change pharmacies, etc.

Example: A technician at a veterinary clinic in Alberta phoned to see if there were any refills on file for a WCVM client who had run out of her dog’s cephalaxin tablets while traveling. In this case, if refills had been authorized, the pharmacist could have transferred the prescription for cephalaxin to another pharmacist in a local community pharmacy and the client could have obtained the drug there. Prescriptions cannot be transferred to veterinarians even though, as the technician stated “we fill prescriptions all the time”.

4 - 5
Prescription Refills

C.01.042. A person referred to in paragraph C.01.041(1)(a) shall not refill a prescription for a prescription drug unless authorized by the practitioner and, in the case of such an authorization, they shall not refill a prescription more than the number of times specified by the practitioner.

Refills of prescriptions for drugs are NOT permitted UNLESS the practitioner has authorized refills and stated the number of times the prescription can be refilled. There are specific requirements for documentation of prescription refills. Most provincial pharmacy regulations do not allow a prescription to be refilled once one year from the original date of filling has passed. This is considered to be consistent with good medical management and the view that the patient should be seen at least once a year to maintain a relationship with the practitioner.

Veterinary Drugs

C.01.600. No person shall sell for veterinary use a drug listed in the Table of Limits of Drug Dosage for Adults, other than a drug in a form not suitable for human use, unless both the inner and outer labels carry the statement “For Veterinary Use Only” or “Veterinary Use Only”.

There are specific regulations dealing with certain drugs for veterinary use and drugs used in medicated feeds. In addition there is a concern for drug residues in food products. Drugs used in lactating animals where milk will or will not be used as food are of concern and must have an appropriate warning statement or withdrawal period. Also of concern is EDDI (ethylenediamine dihydroiodide) when used for foot rot in cattle, estrogenic substances in poultry, chloramphenicol, the nitrofurans, and clenbuterol.

“withdrawal period” means the length of time between the last administration of a drug to an animal and the time when tissues or products collected from the treated animal for consumption as food contain a level of residue of the drug that would not likely cause injury to human health.

C.01.606 No person shall sell an antibiotic preparation for the treatment of animals, other than an antibiotic preparation that is a new drug sold pursuant to section C.01.013, unless,

(a) where the preparation is not to be used for LACTATING ANIMALS providing milk to be consumed as food, the inner and outer labels of the preparation carry a statement to that effect; or

(b) where the preparation may be used for LACTATING ANIMALS PROVIDING MILK TO BE CONSUMED AS FOOD,

(i) there has been submitted, on request, to the Director, acceptable evidence to show the period of time, not exceeding 96 hours, that must elapse after the last treatment with the preparation in order that the milk from treated lactating animals will contain no residue of antibiotics that would cause injury to human health, and

(ii) the principal display panel of the outer label of the preparation, the inner label and the packaging insert, if any, describing the antibiotic preparation carry the warning “WARNING: MILK TAKEN FROM TREATED ANIMALS DURING TREATMENT AND WITHIN . . . HOURS AFTER THE LAST TREATMENT must not be used as food; where the number of hours to be inserted is determined according to evidence submitted pursuant to subparagraph . . .

If a drug is NOT approved for lactating animals the label must state it is not to be used in lactating animals. If the drug may be used in lactating animals where the milk will be used as food, it must carry a statement of the withdrawal time approved by Health Canada in response to documentation of testing submitted by the manufacturer. Withdrawal times for milk cannot exceed 96 hours or the drug will NOT be approved in lactating animals.
C.01.606.1  No person shall sell a product intended for the prevention or treatment of foot rot of cattle if that product contains Ethylenediamine Dihydroidide (EDDI).

EDDI cannot be used in cattle for foot rot because iodine residues in milk were a problem.

C.01.610.  No person shall sell any substance having oestrogenic activity for administration to poultry that may be consumed as food.

Estrogens have been associated with carcinogenicity.

No person shall sell a drug for administration to animals that produce food or that are intended for consumption as food if that drug contains

(a) chloramphenicol or its salts or derivatives;
(b) a 5-nitrofurane compound; or
(c) clenbuterol or its salts or derivatives.

Chloramphenicol is of concern because of the development of aplastic anemia in certain individuals exposed to very low levels of drug and the risk posed by chloramphenicol residues in food. The nitrofurans have been implicated as carcinogens. Clenbuterol has been illegally used as a partitioning agent in show cattle and is heavily abused among body builders. Adverse reactions have been caused in people eating meat such as liver, which contains high levels of drug residues.

C.1.610  No person shall sell an antibiotic preparation containing chloramphenicol, its salts or derivatives, for administration to animals that do not produce food and that are not intended for consumption as food unless

(a) both the inner label and outer label of the preparation carry the words “WARNING; FEDERAL LAW PROHIBITS THE ADMINISTRATION OF THIS PREPARATION TO ANIMALS THAT PRODUCE FOOD OR ANIMALS THAT ARE INTENDED FOR CONSUMPTION AS FOOD.”
(b) Where the preparation is for parenteral use, the preparation contains, in the form of chloramphenicol sodium succinate, not more than one gram of chloramphenicol per vial;
(c) Where the preparation is for ophthalmic use, the preparation contains not more than one per cent chloramphenicol; and
(d) Where the preparation is for oral use, the preparation
   (i) is in tablet or capsule form and contains not more than one gram of chloramphenicol per tablet or capsule, or
   (ii) is in the form of a chloramphenicol palmitate suspension and contains not more than three grams of chloramphenicol per container.

These regulations limit the amount of chloramphenicol contained in a dosage form. Initially, sales volumes did not decrease when chloramphenicol was first banned. Despite the ban on use in food animals (reflected in new labeling) there was some suspicion that the drug was still being used as before. Limiting the total amount of chloramphenicol allowed in a single container of injection or oral suspension made these products more costly and difficult to use. At present no veterinary approved injection is manufactured but tablets and oral suspension are available.

C.01.611. (1)  The Director may, in writing, from time to time require the manufacturer of a drug recommended for administration to animals that may be consumed as food

(a) to file with him in respect of that drug a submission, in form and content satisfactory to the Director, describing in detail tests carried out to determine that no residues of the drug, except residues within the limits prescribed by these Regulations, remain in meat, meat by-products, eggs or milk; and
(b) to print on the principal display panel of the outer label, the inner label and the packaging insert, if any that describes the drug, A WARNING THAT MEAT, MEAT BY-PRODUCTS, EGGS OR MILK FROM ANIMALS to which the drug has been administered CANNOT BE SOLD FOR CONSUMPTION as food unless there has ELAPSED since the administration of the drug A PERIOD OF TIME specified by the Director, based on a review of the available data with respect to drug residue.

This section deals with the requirement to document to Health Canada that there are no residues above prescribed limits in food products. Note, even once the drug is approved, the Director may request more information regarding drug residues in meat, meat by-products, eggs and milk.

Drugs Banned in Food Animals

Certain drugs have well defined public health risk, and have been banned for use in food animals in Canada. The Food and Drug Regulations ban both the sale of these drugs and the sale of animals intended for food that may have been treated with these substances.

C.01.610.1 No person shall sell a drug for administration to animals that produce food or that are intended for consumption as food if that drug contains
(a) chloramphenicol or its salts or derivatives;
(b) a 5-nitrofuranc compound;
(c) clenbuterol or its salts or derivatives;
(d) a 5-nitroimidazole compound; or
(e) diethylstilbestrol or other stilbene compounds. SOR/85-539, s. 1; SOR/85-685, s. 2; SOR/91-546, s. 1; SOR/94-568, s. 2; SOR/97-510, s. 2; SOR/2003-292, s. 3.

C.01.610. No person shall sell any substance having oestrogenic activity for administration to poultry that may be consumed as food.

The Food and Drug Regulation not only restrict the sale of these drugs in Canada but also restrict the sale of animals treated with these products for food.

B.1.48. (1) No person shall sell
(a) any animal intended for consumption as food if any product containing any drug listed in subsection (2) has been administered to the animal;
(b) any meat, meat by-products, eggs or milk intended for consumption as food and derived from an animal if any product containing any drug listed in subsection (2) has been administered to that animal; or
(c) any meat, meat by-products, eggs or milk that contains any residue of any drug listed in subsection (2).

(2) The drugs referred to in subsection (1) are
(a) chloramphenicol and its salts and derivatives;
(b) a 5-nitrofuranc compound;
(c) clenbuterol and its salts and derivatives;
(d) a 5-nitroimidazole compound; and
(e) diethylstilbestrol and other stilbene compounds. SOR/85-685, s. 1; SOR/87-626, s. 1; SOR/94-568, s. 1; SOR/97-510, s. 1; SOR/2003-292, s. 1.
Saskatchewan Provincial Legislation
In addition to Federal legislation regulating prescribing and dispensing the following provincial legislations apply to the sale of drugs in Saskatchewan:

1. The Pharmacy Act, 1996
2. The Veterinarian’s Act, 1987

The Pharmacy Act, 1996

The Pharmacy Act sets the standards for who can become a member of the profession of pharmacy, and prohibits unqualified persons from using the titles of “pharmacist”, “druggist” and any other term that might imply the person is a member of the profession. The Act prohibits the sale of most drugs by anyone other than a pharmacist.

Veterinarians are excluded by Section 23 Subsection 2 of the Pharmacy Act as follows:

23 (1) No person other than a licensed pharmacist or intern practising under the supervision of a licensed pharmacist, may prepare, compound, dispense or sell drugs in Saskatchewan.

(2) Subsection (1) does not apply to:
(a) the practice of any profession or occupation by any person practising pursuant to the authority of any other Act;

The Veterinarians Act, 1987

Similar to The Pharmacy Act; The Veterinarians Act sets standards as to who can become a member and engage in the practice of veterinary medicine. Veterinary medicine in Saskatchewan is defined in the Act as follows:

(l) “veterinary medicine” means that branch of knowledge relating to the prevention, diagnosis and treatment of the diseases of and injuries to animals, and includes:

(i) diagnosing, advising or prescribing a drug, medical appliance or application or treatment of whatever nature for the prevention or treatment of a bodily injury or disease of animals;
(ii) administering a drug, medicine, appliance or other application or treatment of whatever nature for the prevention or treatment of bodily injury or disease of animals except where the drug, medicine, appliance or application or treatment is administered by some other person at the direction and under the direct supervision of a member;
(iii) performing a surgical operation on an animal;
(iv) the management of estrus synchronization, superovulation and the collection, evaluation and processing of embryos;
(v) performing any manual procedures for the diagnosis of pregnancy, sterility or infertility on animals;
(vi) certifying the cause of death of an animal.

The Act empowers veterinarians to act as a self-governing body by establishing the structure and responsibilities of the Saskatchewan Veterinary Medical Association and a format for members to pass bylaws.
Bylaws of the Saskatchewan Veterinary Medical Association  December 10/2006

As regard the sale of drugs by Veterinarians in Saskatchewan, the following SVMA bylaws apply:

31.11  No member shall sell, give, administer or distribute medications which:

(a) have expired or have been returned to him;

(b) have not been properly stored, handled or labelled;

(c) are listed under the Prescription Drug List of the Food and Drug Regulations made under the Food and Drug Act, or under the Controlled Drugs and Substances Act (S.C. 1996, c. 19) and regulations made under this Act unless a veterinarian client/patient relationship exists as follows:

(1) the veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and the need for medical treatment, and the client, owner or other caretaker has agreed to follow the instructions of the veterinarian; and

(2) the veterinarian has seen the animal(s) within the preceding 12 months and is personally acquainted with the keeping and care of the animal or animals by virtue of an examination of the animal(s), and/or by medically appropriate annual visits to the premises where the animal(s) is kept and therefore has sufficient knowledge to initiate a general or preliminary diagnosis of the medical condition of the animal; and

(3) the veterinarian is readily available for follow-up in case of adverse reactions or failure of the regime of therapy; and

(4) a veterinarian-client/patient relationship may not be established by telephone or electronic means; and

(5) a member cannot establish a veterinarian-client/patient relationship for the primary purpose of facilitating sales of pharmaceuticals and biologicals when, due to geographic separation, the member would be unable to attend the premises or animal(s) in a reasonable period of time; and

(6) where a valid veterinarian-client relationship exists, all pharmaceuticals and biologicals must be sold, distributed or shipped directly to the client from the member’s office or clinic or dispensed from a licensed pharmacy.

31.12  Members shall not sell or supply a pharmaceutical or biological product to any other person, group or company who intends to resell the product. This does not apply to the sale or supply of pharmaceutical and biological products to other licensed veterinarians.
Practice Standards

SVMA Bylaws 34 and 35 require that all practices in Saskatchewan comply with current “Practice Standards of the Association”. The following applies as of September 2005:

**SVMA Practice Inspection Standards (Summary)**

**Section 7 Pharmacy**

Requirements apply to all practices

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**a.** The pharmacy area is clean and orderly

**b.** Storage, safekeeping and preparation of drugs are in accordance with Federal and Provincial laws

**c.** All drugs and biologicals are stored according to manufacturers' recommendations

**d.** Adequate refrigeration is available

**e.** Narcotic/Controlled drugs are stored in a locked secure location. It is suggested that a substantial safe which is anchored in place be used

**f.** Each container of Narcotics/Controlled drugs must be marked so as to be uniquely identifiable. It is recommended this be done as soon as possible after receipt of the drug(s)

**g.** The Narcotic/Controlled drug register (log) is kept separate from the locked Narcotic/Controlled drugs

**h.** The Narcotic/Controlled drug register must contain:

1. Date drug received,
2. Quantity of containers received and size of the containers
3. Supplier name and address,
4. Invoice number and assigned identification number
5. Date dispensed
6. Owner’s name – or Owner/Patient ID
7. Drug name, strength, amount dispensed
8. Quantity remaining
9. Number of unopened bottles

The Master register, which contains all the information pertaining to the acquisition of the drug, must contain:

1. Date drug received
2. Drug name, strength, dosage form
3. Quantity of containers received and size of the container
4. Supplier name and address
5. Invoice number
6. Assigned identification number

The Dispensing register, which contains all the information pertaining to administering, dispensing or wastage of the drug, must contain:

1. Date dispensed
2. Assigned identification number
3. Owner and patient ID
4. Drug name, strength, amount dispensed
5. Quantity remaining
6. Number of unopened bottles
7. Veterinarians’ signature
The master and dispensing registers can be physically separate (in 2 different binders) or they can be combined (each drug has its own section in the binder which starts with a master page, followed by all the dispensing pages (see sample pages in Pharmacy: Appendix)). The narcotic register must not be combined with other logs (for example, the anesthesia log). It is a federal requirement that the information for narcotic and controlled drugs to be “filed in a separate file in sequence as to date and number”.

**Drug name, strength and amount**
Each page of the dispensing log must indicate the drug name, strength and size of container. As well as recording the amount of drug dispensed, the log must include the amounts administered or wasted. If small amounts of narcotic and controlled drugs are disposed of, for example, some gets spilled or the whole amount drawn up in a syringe is not administered, it must be accounted for in the register and witnessed. This applies to all narcotic and controlled drugs except single use ampoules. Columns for the amount of wasted drug with a witness signature should be included in the dispensing register (see sample in Pharmacy: Appendix). The safest way to dispose of these small amounts of drug is to squirt it into a small amount of kitty litter, which can then be disposed of in the biohazard container. Permission from Health Canada is required for disposal of larger amounts of drug (for example: expired narcotics). See Pharmacy: Appendix for details.

**Quantity remaining**
The quantity remaining should be kept as a running tally for each bottle and end when the bottle is empty. This information is used to reconcile log and inventory values. Reconciliation should be done regularly. The frequency will depend on the amount of narcotic and controlled drugs the practice uses. High use practices do this daily; less busy ones do it weekly; monthly is the minimum recommended by the Practice Standards Committee; federal regulations state must be done every six (6) months.

**Veterinarian’s Signature**
For any narcotic and controlled drug to be administered or dispensed, there must be a written prescription with veterinarians’ signature OR a signed drug log. The signed drug log is the most practical for most clinics and it means that all the documentation that is required by the Minister and the Practice Standards is in one place. Please note that it must be the VETERINARIAN’S signature, not that of an RVT, since the register is essentially a prescription.

**Computer logs**
Computer drug logs have the problem of not providing a veterinary signature for each drug dispensed or administered. If using a computer generated log the veterinarian must guarantee the validity of the log by ensuring that the information contained within is password protected and providing an accompanying signed dispensing log entry for every narcotic and controlled drug dispensed or administered.

- Prescription pads are available and kept from the public view/access
- Prescription drugs are dispensed only after the establishment of a valid veterinarian-client-patient relationship (as defined in the SVMA Code of Ethics)
- Prescriptions are dispensed under the supervision of the veterinarian and as defined in SVMA Bylaw 31.11 c 6.
- Expired drugs are kept separate and discarded or returned to the manufacturer promptly

### 7A Pharmacy
Small Animal Clinic/Hospital and Small Animal Housecall
Yes No N/A.

- A means of providing positive pressure ventilation is available at all times.
- Emergency drugs are readily available as follows:
  - Epinephrine
  - Atropine
  - Furosemide
  - Anemetic – can be an opioid (for example, apomorphine or hydromorphone), or xylaxine
  - An anticonvulsant – can be diazepam, phenobarbital, pentobarbital or propofol
  - A narcotic analgesic and antagonist.
c. Emergency drug kit or readily available equivalent which contains: sterile needles, syringes, IV catheters, drip sets, parenteral fluids

d. Childproof dispensing containers are available

e. Dispensed drugs (excluding OTC veterinary drugs prescribed and dispensed as packaged and labeled by the manufacturer) must be labeled as to:
   1. Name of client
   2. Identification of animal(s)
   3. Name of drug
   4. Date dispensed
   5. Quantity dispensed
   6. Name of Veterinarian prescribing and/or dispensing the drug
   7. Directions for use
   8. Veterinary Use Only (printed advisory)

**7B Pharmacy**
Large Animal Clinic/Hospital, Ambulatory and Consultation
Yes No N/A

a. Prescriptions contain a warning with the required withdrawal period for medications used in food producing animals.

b. Compendium of Medicating Ingredients Brochure

c. Dispensed drugs (excluding drugs prescribed as indicated on the manufacturer’s label and dispensed in the original, complete manufacturer’s container) are labeled as to:
   1. Name of client
   2. Identification of animal(s)
   3. Name of drug
   4. Date dispensed
   5. Quantity dispensed
   6. Name of veterinarian prescribing and/or dispensing the drug
   7. Directions for use including withdrawal times for meat and/or milk
   8. Veterinary Use Only
   9. Withdrawal time. For drugs that have no withdrawal time it is recommended it be indicated on the label as well.

D. Emergency drugs are readily available. The following list contains the minimum drugs that must be available:
   - Epinephrine
   - Atropine
   - Calcium and magnesium parenteral solutions
   - An antihistamine
   - An alpha-2 antagonist
   - A local anesthetic
   - An analgesic – can be narcotic or non-narcotic. (An antagonist must be available if narcotics are used.)

e. Sterile needles, syringes, IV catheters and parenteral fluids are available
CHAPTER 6 – Dispensing Procedures

Writing Prescriptions

A prescription is defined in the Food and Drug Regulations as “an order by a practitioner directing that a stated amount of any drug or mixture of drugs specified therein be dispensed for the person named in the order”. Veterinarians are allowed to prescribe and dispense drugs.

Most veterinary-labeled drugs are not available to pharmacists due to marketing policies of veterinary drug manufacturers. These drugs are only available from veterinarians. If a client requests a prescription to be filled at a local pharmacy, the choice of drug treatment might have to be changed to a drug available on the human market.

**Example:** A VTH client whose dog required treatment with Baytril (enrofloxacin), after being told the price of the drug, requested a written prescription that he could fill at his local pharmacy. The veterinarian explained the prescription would have to be changed to ciprofloxacin since enrofloxacin is only approved for veterinary use and not available to pharmacies. The client, who had become very agitated, insisted on having a prescription for the original drug and left after receiving it. Several days later he returned to have the prescription filled at the VTH. In the interim he had been unsuccessful in finding a pharmacy that could fill the enrofloxacin prescription and, in frustration, had phoned the drug company to complain and ask why his pharmacist could not buy the drug!

Clients cannot be forced to purchase drugs from their veterinarian. They have the right to request a written prescription. Such a prescription must be written within the context of a valid VCPR and be medically warranted.

Information Required on a Prescription

To comply with Food and Drug Regulation C.01.041.1, a prescription must contain the following information:

(a) **client** name – though the prescription is being written for an animal, legally the animal is owned by a person who must be identified in the order

(b) animal **species** and **name** or **identification** – species is important because in verifying the prescription, dosage, and directions are appropriate, the pharmacist needs to know what kind of animal is being treated

(c) **drug name** and concentration – NEVER abbreviate the drug name!

(d) **quantity** to be dispensed – this is the total amount of drug product to be dispensed (the number of tablets, volume of liquid, etc.)

(e) **directions** for use – including dosage or amount, route of administration, frequency, and duration of treatment. DO NOT USE the abbreviation SID – this is not taught in human medicine or pharmacy and is likely to be interpreted incorrectly. Be specific – if you want something to appear on the label, make sure you include it in your directions. Withdrawal times are required for drugs dispensed for food animals. Determination of the withdrawal time is the responsibility of the veterinarian and must be stated on the prescription. The pharmacist cannot assume WT is the same as the product label states because it may not be possible to determine if the drug is being used “on-label” or “extra-label. When usage is “extra-label” the veterinarian MUST provide the WT.
(f) **refill instructions** (if appropriate) – the NUMBER of times and for controlled drugs, such as Phenobarbital, the interval between refills must be specified. There is no such thing as a “standing prescription”. All prescriptions are for a specific amount of drug and cannot be refilled unless the instruction to do so is included. Prescriptions also “expire” and, in reflection of the fact that the client/patient must be under the care of the prescriber, will not be honored after one year from the original date of filling.

(g) **veterinarian’s signature** – it is helpful if the veterinarian’s name is clearly printed under the signature

(h) **date**.

**Procedures**

Dispensing a drug includes the provision of a product “as is” in the manufacturer’s packaging as well as the process of repackaging and labeling a product for use by the client.

Dispensing involves several functions, many of which are technical in nature. While examination, diagnosis, prescribing treatment, and identification of the product to be dispensed are performed by the veterinarian, technical aspects of the dispensing process are often completed by a technician. Responsibility for the product dispensed in a veterinary clinic remains with the veterinarian in spite of who performs the function. Rarely are prescriptions written for medications to be provided in the clinic. Instead, documentation of the drug order in the medical record is considered equivalent. If the order for the drug is given verbally, the technician to whom it is given must document the order in the medical record. If also dispensing the product, the technician should document, at the time of filling, the name of the actual product dispensed, the lot number and the expiry date, and his/her initials. Documentation of lot number ensures if a product recall occurs, or unusual results are noted in the drug therapy, they can be dealt with effectively. Noting the expiry date ensures it has been checked.

**Selection of Product**

The product chosen to treat an animal often depends on the species. Tablets and capsules are not usually an administration problem in dogs but cats require smaller sizes and “specialized technique”. Ideally, oral solid dosage forms should be followed by administration of 2 to 3 mL of water. Some human-labeled products are the only source of a drug. If no approved veterinary formulation suitable for use is available, the veterinarian has the professional privilege of using these drugs “extra-label”. Such use requires “prescription” labeling appropriate for use in the individual case.

**Compounding**

Compounding of large amounts of drugs in anticipation of need or where an approved drug is available but “too expensive” MAY be interpreted as circumventing the approval process of the Food and Drugs Act. The Food and Drug Regulations exempt drugs compounded by a practitioner or pharmacist on prescription. The exemption is intended to allow compounding a drug to treat a specific patient when approved products are not available or suitable and should only be considered under these conditions. Oral liquids may be more easily administered to cats but are not always available. Compounding pharmacists, knowledgeable in formulation and stability of drugs, may compound some medications into alternate dosage forms in appropriate strengths or concentrations to suit individual cases.
Dispensing

Once the product has been chosen it is important to follow the rule: **READ THE LABEL THREE TIMES.** Drug manufacturers take pride in producing an attractive, professional looking product line. Drugs are packaged in containers with a uniform distinctive colour scheme and often appear very similar. In busy practices where distractions and interruptions are constant it is too easy to grab the wrong bottle. Often we see what we expect to see, not what is really there. Reading the label three times means, **when taking the product from the shelf,** when **removing contents** from bottle/vial for dispensing, and when **replacing the product** on the shelf. In the interests of ensuring correct drug therapy, this practice should be established and consistently followed.

**Examples:** Periodically students come to the VMC pharmacy to ask for trimethoprim-sulfa 80 mg tablets. When told that strength doesn’t exist, they insist it is on the shelf in their treatment room. When the label is examined more closely, the strength, expressed as 400-80 mg is discovered to mean EACH TABLET CONTAINS 400 mg sulfamethoxazole and 80 mg trimethoprim NOT 400 tablets of 80 mg!

Rompun comes in two sizes and strengths: 20 mg/mL -20 mL vials and 100 mg/mL - 50 mL vials. While the outer boxes are well differentiated, the inner labels on the vials require searching for the strength in the fine print on the side panels!

Storage Requirements

It is also important when reading labels to note storage requirements:

- Does the drug need protection from moisture?
- Is it light sensitive?
- Is there a storage temperature requirement?
- If the product is a powder for reconstitution, does it require refrigeration after mixing?
- Is it a suspension or emulsion?

Improper storage may affect the physical stability of drug products or initiate/accelerate chemical reactions. Moisture, temperature, and light are of concern.

**Moisture** affects powder mixtures and tablets, which require airtight containers rather than plastic or paper bags. Many clients store their medications in the bathroom medicine cabinet where humidity is a constant, or by the sink (which is usually by a window) in the kitchen, where both light and moisture will be present. Light contributes to the degradation of many drugs and amber glass is the preferred material for drug containers.

**Temperature** is important in the storage of many drugs. **Freezing** damages suspensions and emulsions, making them unusable. A suspension is a mixture of an insoluble solid and a suspending agent in a liquid vehicle. The suspending agent slows the settling of the solid and aids in its re-suspension. Freezing cause the solids to form clumps that cannot be evenly resuspended. Emulsions are mixtures containing micelles of water in an oil vehicle or oil in a water vehicle. An emulsifying agent with hydrophobic and hydrophilic components surrounds the micelles. Freezing causes the formation of ice micro-crystals, which pierce the micelles, allowing the contents to leak out and “break” the emulsion, resulting in a product that is inconsistent and cannot be used. The manufacturer should be consulted on whether products that have been frozen are safe to use and written documentation should be requested.
If no storage requirements are specified, it is assumed the product must be protected from extremes - moisture, freezing and temperatures over 40 C.

Temperature is defined in the U.S.P.
- COLD < 8 C
- REFRIGERATE 2 – 8 C
- COOL 8 – 15 C or may refrigerate!
- ROOM TEMP 15 – 30 C
- WARM 30 – 40 C
- EXCESSIVE HEAT > 40 C

**Condition of Product**

Does the product appear unusual in any way? Instability is not necessarily visible but may appear as the development of a precipitate, a color change, cloudiness in what should be a clear liquid, or gas evolution.

Are tablets intact? Moisture can cause swelling and crumbling of tablets. Odors may be produced with the degradation of some drugs (e.g., acetic acid odor with ASA.

**Expiry Date of Product**

A dispensed product must be within its expiry date for the entire period of time for which it is expected the animal will be treated. If the product will expire before treatment ends, dispense only enough to last until the expiry date and order new stock for the balance. The expiry date applies to the drug in the original unopened container – once dispensed in other containers, the manufacturer’s expiry date may no longer be accurate and dispensed products may be assigned a shorter expiry date depending on the specifications of the container used. In some states where the expiry date is required to appear on prescription labels, a maximum date of 6 months is used. In the VTH a maximum of three months’ supply of a drug will be dispensed. Monitoring compliance of drug therapy is an important function. A three month supply balances client inconvenience with the opportunity to appropriately review drug therapy. It also encourages turnover of drug supplies and hopefully does not result in large quantities of leftover drugs should the animal’s condition change. Unneeded drugs cannot be returned to the veterinarian for re-use.

**Selection of Dispensing Container**

*Child Resistant Containers (CRCs)*

Oral solid dosage forms such as tablets and capsules must be dispensed in containers that will protect them from moisture, light, etc. Amber dispensing vials with child-resistant caps are readily available. Pharmacists are required to dispense in CRCs unless, in their professional judgment, it is not appropriate or if the patient requests no CRC.

It is important to remember why CRCs are important. In 1992 in the USA, of the 1.1 million children under 5 years old poisoned (44 % were under 3 and 59% under 5), 40 % were poisoned with pharmaceuticals. Various studies reported 13% of poisonings in this group happened away from home, 23 – 36% took place at a grandparent’s home, and 35% of medications taken at home belonged to someone else. At the time of ingestion / poisoning, 61% of all medications had NO CR barrier. Failure to use CRCs was involved in 2% of malpractice claims.
This issue is important in veterinary medication dispensing because people may not connect animal drug use to human drugs. Often they do not realize a very high percentage of drugs used in veterinary medicine are the same as those used in people. Conversely, some people may believe animal drugs don’t work in people and therefore are not dangerous. Education on the dangers of medication use in both animals and people is an extremely important part of the veterinarian and pharmacist’s role. Failure to counsel may increase liability.

People often have valid reasons for requesting CRCs not be used. The elderly may suffer from arthritis and have difficulty opening such containers with a resulting decrease in medication compliance. They also may no longer have young children living at home. What might be asked in these situations is do any children visit at any time? Or do they visit children? Grandma or Grandpa’s colorful medications in a purse or suitcase may easily be confused for the candy treats brought for their grandchildren.

Example: A 1991 California court case where a 19-month-old girl ingested her grandfather’s chloroquine is a startling eye-opener. The child’s grandfather was a helicopter pilot in the U.S. Army and returned from Honduras where malaria is endemic. The medication was dispensed in a child-resistant container and labeled “Keep Out of Reach of Children”. While at home, he stored his medication with the cap loosened on the kitchen counter. The child “got into” the medication on two previous occasions but the grandfather did not change his storage practice. While housesitting and doing chores in the kitchen, her mother placed the child on the kitchen counter where she again ingested the drug. Her mother removed part of a tablet from her mouth but others had been swallowed and within minutes, the child showed signs of toxicity. The child suffered permanent brain damage and her parents claimed negligence against the prescribing physician, the dispensing pharmacist, and the U.S. Army, as the grandfather’s employer. At trial, the court found both physician and pharmacist breached their duty to warn and thus caused the child’s injuries. The U.S. Army was found vicariously liable. Expert testimony indicated people do not respond to general warnings like “Keep Out of Reach of Children” and that it is quite common to store medications on kitchen counters with the tops loosened. The U.S. Army’s defense was doomed by government regulation requiring the grandfather take the drug. It is difficult to understand what more could have been done to avoid liability and the jury did not include that information.

A lesson to be learned is, at least in California, even when we perform exactly what is required of us, it may not be enough to protect from liability. Another lesson is if we do ONLY what is required we may expose ourselves to liability.

While most veterinary standards of practice require CRCs be available, they don’t usually require they be used. When the standard for pharmacy practice is that CRCs MUST BE USED (with exceptions), another profession performing the dispensing function might be subjected to the same standard in a lawsuit.

Testing of CRCs is interesting. In a group of 200 healthy, normal children (with no overt physical or mental handicaps, age 42 to 51 months old, with the number of boys and girls approximately equal) given 5 minutes, 85% must fail to open the CRC. For those unable to open the CRC, 80% must still fail to open the CRC after being given a single visual demonstration, told teeth can be used, and given another 5 minutes. In a group of 100 adults (no overt physical or mental handicaps, 18 to 45 years old, 70% MUST be FEMALE) receiving only printed instructions, given 5 minutes, 90% must successfully open the container. Senior friendly testing has been proposed and would involve 60 to 75 year old seniors being capable of opening the container within one minute.
**Small Containers**

Eye drops and ointments are too small to accommodate a prescription label. Veterinary-labeled containers may be placed in a child-resistant dispensing vial with the prescription label affixed to the vial. Auxiliary labels should be placed on the vial. Human labeled containers should be labeled with the auxiliary labels:

- FOR VETERINARY USE ONLY
- KEEP OUT of REACH of CHILDREN
- FOR THE EYE or FOR THE EAR
- and if indicated: SHAKE WELL BEFORE USING
  REFRIGERATE

For human labeled drugs, directions for use and indications for human use (which are inappropriate for the veterinary patient) may be covered with the auxiliary labels. The drug name (identification of the product), lot number and expiry date should remain clearly visible. The box and package insert may be discarded.

**Food Containers**

Food containers, including pop bottles should never be reused as drug containers. Samples of various bodily fluids and products in recycled cottage cheese containers, bottles, etc. have been mistaken at first glance for someone’s lunch or drink. Food products, including staff lunches, should not be allowed in clinic refrigerators used for the storage of tissue or other samples or drugs.

**Paper Envelopes**

Paper envelopes are **NOT APPROPRIATE** containers FOR DISPENSING. Some drug manufacturers provide envelopes for dispensing small quantities of their products. Most will have some type of “fill-in-the-blank” labeling. These labels are insufficient as dispensing labels due to a lack of information required for prescription labels under most provinces veterinary standards of practice. Paper envelopes also do not protect the contents from moisture or degradation in air and are **NOT CHILD RESISTANT**. The only **exception** to this might be envelopes used to dispense Clavamox tablets. These tablets are in a plasticized foil wrapping that is impossible to open without the use of scissors. The wrapping in this case is the CRC.

**Injection Vials**

Empty sterile injection vials are available from various sources. Ideally these should be used for dispensing small quantities of injections rather than syringes. This occurs when the manufacturer’s container is too large for the case being treated and the veterinarian is uncomfortable with selling that size to the client, either because of expense or uncertainty the leftover drug will be used appropriately. The tops of both vials should be swabbed with alcohol and allowed to dry. The quantity of drug required should be drawn from the stock vial into a sterile syringe and injected through the stopper into the sterile vial to be dispensed. The vial must then be labelled with a prescription label.

**Syringes**

Dispensing in syringes should be a last resort. If only a single or very few doses are required, individual doses in syringes may be considered for dispensing but dispensing in a sterile vial is preferred. It is important to consider the stability of the drug in plastic and light sensitivity. Long term use (anything more than a few days) or **dispensing multiple doses in a SINGLE syringe** is **NOT RECOMMENDED** or acceptable. **Syringes are for SINGLE INJECTION only**. Each syringe must be labeled with at minimum: clinic name, address, and phone number (usually pre- printed on prescription labels), client name, animal species, animal name or identification, name of drug (including strength or concentration and manufacturer – if generic name used), quantity dispensed, date of dispensing, and name of veterinarian. The syringes may
then be placed in a zip-lock bag that is labeled with a complete prescription label bearing all of the previous information plus directions for use. Syringes labeled by the manufacturer (e.g.,) tubes of mastitis treatments, do not require further labeling of the syringe. However, if only a few are being dispensed, they should be placed in a plastic bag with the prescription label placed on the bag.

UNLABELED SYRINGES ARE ABSOLUTELY FORBIDDEN. We have all heard horror stories of someone setting down an unlabeled syringe of euthanasia solution while going to retrieve the animal and another person, thinking it is the syringe drawn up to treat his patient, injects and euthanizes the wrong dog! In the VMC, Euthanyl and Euthanyl Forte are dyed blue with methylene blue solution so they are readily identifiable. UNLESS the syringe is not going to leave your hand from the time (minutes) you draw the drug until the time it is injected in the animal, IT MUST BE LABELLED.

**Plastic Bags**

Plastic bags may be appropriate for short-term storage of very large tablets or capsules, powder papers, powders (usually double bagged), and prepared doses of medication contained in syringes, etc.

**Prescription Ovals (Bottles)**

Any liquid should always be dispensed in a bottle with a tight lid. Dispensing vials are inappropriate and allow leaking. Bottles may be used for dispensing of oral or topical liquids. They are not suitable under any circumstances for dispensing injections. Choose the size closest to the amount being dispensed. For suspensions, choose a slightly larger size to allow room for shaking. For liquids that must be poured, avoid wide-mouth bottles.

**Ointment Jars**

In veterinary medicine, most ointments or creams are dispensed in the original container. If bulk creams/ointments are dispensed, ointment jars should be used. Dispensing vials are not appropriate and allow contents to leak.
Labeling

Prescription Labels

Prescription labels are a reflection of your clinic and should be professional in appearance. Preferably they should be computer generated or at least typewritten. There should be no errors or visible corrections. Labels are necessary not only for legal reasons but also to remind the client of what they have been told. Studies have established within 30 minutes of leaving the doctor’s office patients do not recall a significant percentage of what was discussed. In addition, the person receiving the verbal instructions in the clinic or hospital may not be the person who will administer the drug or the animal may be left in someone else’s care. Written labeling reminds and reinforces the veterinarian’s directions.

Information required on a PRESCRIPTION LABEL includes:

(a) Client name, address and phone number (usually pre-printed)
(b) Client name
(c) Animal species and name or identification
(d) Drug name and concentration
  - may use generic name, concentration and company name; or brand name and concentration
    DIN is not necessarily required or useful since internet access to the drug database of Health Canada is required to decipher information
  - For commonly used prescription or OTC drugs packaged for consumer use and readily identifiable by brand name (horse paste worms, mastitis preparations, etc.) AND when the product contains more than one drug, labeling by brand name is preferable – using the generic names and concentrations of each drug is cumbersome and available space on the label is limited.
  - For clarity and easier identification by the veterinarian of single entity drugs, labeling by GENERIC NAME and CONCENTRATION is preferred. Many veterinary and human drugs have generic equivalents – labeling by brand name may require consultation with a pharmacist or searching references and can cause delays in identifying the drug.

(e) Quantity of product dispensed: this is the number of tablets or the total volume of product dispensed rather than the total amount of active drug dispensed. (e.g.) for amoxicillin 100 mg, quantity would be 14 tablets not 1400 mg. This is important as a quick compliance check and in poisoning cases, allows quick estimation of the amount ingested.

(f) Directions for use MUST BE SPECIFIC and stated such that they are clearly understood by the client.
  “Use as directed” is not acceptable. SPECIFY:
  1. amount to be administered (one tablet, 2 drops, ¼ inch, ½ cm, etc.)
  2. specify route of administration (by mouth, in the eye, etc.)
  3. specify frequency (once daily, every 12 hours, etc.)
  4. specify duration of treatment (for 10 days, until recheck, etc.)

Directions appearing on a prescription label SHOULD NEVER BE ABBREVIATED. This can lead to misinterpretation by clients.

Example: A client requested a refill on a prescription for Tresaderm 15 mL after only four days. He had misread the label directions “Apply 2-4 drops in each ear twice daily” as 24 drops in each ear twice daily and had used the entire bottle. A clearer label instruction would have been “Apply 2 to 4 drops . . .”

(g) Veterinarian’s name

(h) Date dispensed.

(i) “FOR VETERINARY USE ONLY”
Auxiliary Labels

Auxiliary labels contain additional information necessary for the client to know in order to use and store the medication correctly and safely. Sources of information for appropriate choice of auxiliary labels include the product label, package insert, Compendium of Veterinary Products (CVP), Compendium of Pharmaceuticals and Specialties (CPS - for human drugs), guidelines provided by the auxiliary label manufacturers, and common sense. These labels are used to emphasize important points and hopefully to prevent misinterpretation and misuse by clients.

Examples: FOR ORAL USE ONLY: Unaware the dose was to be given by mouth, a horse owner attached a needle to a tube of paste wormer and INJECTED the product, resulting in major sloughing of the skin.

SHAKE WELL BEFORE USING: A client treating his dog with Surolan remarked the condition did not seem to be improving after two days of treatment. When asked whether he was shaking the product before applying, he asked “Where does it say that?”

IMPORTANT – FINISH ALL THIS MEDICATION UNLESS DIRECTED OTHERWISE BY PRESCRIBER: Another client ordering a prescription refill of an antibiotic that had last been filled two years previously was told authorization would not be likely since the veterinarian would want to re-examine the dog. She commented she had just finished the prescription recently – the antibiotic had been prescribed for a bad skin condition. When questioned further, since the original prescription had been for only six weeks treatment, the client revealed she treated her dog for a few days until the condition improved, then stopped. She had continued this way for nearly two years!

ALL Prescriptions get: KEEP OUT OF REACH of CHILDREN.

All of these situations might have been avoided with better communication – the use of auxiliary labels might have prevented the situations. The next table gives examples of auxiliary labels to be used and special considerations in dispensing a variety of drugs used in veterinary medicine.

TABLE – Auxiliary Label Guide

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
<th>Auxiliary Labels</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albendazole</td>
<td>Valbazan</td>
<td>•SHAKE WELL BEFORE USING •FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)</td>
<td>-Suspensions are damaged by freezing</td>
</tr>
</tbody>
</table>
## Auxiliary Label Guide

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| Altrenogest  | Regu-Mate  | •AVOID CONTACT OF THIS DRUG WITH HUMAN SKIN  
•PROTECT FROM LIGHT | - Altrenogest is absorbed through the skin and can potentially disrupt hormonal cycles in human females, causing menstrual irregularities.  
- Nitrile gloves should be worn while handling the drug. |
| Amoxicillin  | Amoxil 50, 100  
200 mg tablets  
Human Generic  
25, 50 mg/mL  
oral liquid, 250 mg capsule | •FINISH ALL THIS MEDICATION  
(unless directed otherwise by prescriber)  
•suspension: REFRIGERATE, SHAKE WELL BEFORE USING  
•EXPIRY DATE | - May be taken with or without food |
| Amoxicillin clavulanic acid | Clavamox 62.5, 125, 250, 375 mg tablets  
62.5 mg/mL | •TAKE WITH FOOD  
•FINISH ALL THIS MEDICATION  
(unless directed otherwise by prescriber)  
•suspension: REFRIGERATE, SHAKE WELL BEFORE USING  
•EXPIRY DATE | - Absorption of clavulanic acid is improved when taken with food.  
- TABLETS are unstable once removed from plasticized foil packaging (begin to deteriorate within one hour).  
- Counsel clients not to remove more tablets than needed for immediate dose and to remove from foil ONLY immediately before use.  
- if half tablets are indicated, the remaining half must be discarded.  
- oral SUSPENSION is stable refrigerated only ONE WEEK (whereas amoxicillin suspensions are usually stable 2 weeks). |
| Ampicillin   | 250, 500 mg capsules  
25, 50 mg/mL oral suspension  
250, 500, 1 g injections | •FINISH ALL THIS MEDICATION  
(unless directed otherwise by prescriber)  
•TAKE ON AN EMPTY STOMACH  
•suspension: REFRIGERATE, SHAKE WELL BEFORE USING | - ampicillin Na injections are stable ONE HOUR once mixed! CHECK THE LABEL |
| Atropine     | Isopto Atropine 1% eye drop eye ointment | •FOR THE EYE | - The fatal dose of atropine in children has been as little as 10 mg. A single 5 mL bottle of 1% eye drops or 3.5 g tube of eye ointment contains 50 mg and 35 mg of atropine respectively. Both are more than enough to kill a child or pet that ingests the contents. |
| Cefazolin    | 1 g injection | •REFRIGERATE  
•PROTECT FROM LIGHT  
•EXPIRY DATE | - Once reconstituted, must be refrigerated.  
- Stability may be different for different manufacturers (72 vs 96 hrs in fridge).  
- Note stability and storage conditions and expiry date after reconstitution. |
| Ceftiofur    | Excenel 1 and 4 g injection  
Excenel RTU suspension All are 50 mg/mL | •REFRIGERATE  
•suspension: SHAKE WELL BEFORE USING  
•EXPIRY DATE | |
### Auxiliary Label Guide

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<tr>
<td>Cephalexin</td>
<td>250, 500 mg</td>
<td>FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)</td>
<td>Better absorbed on an empty stomach but tablet because it tends to cause nausea and vomiting 25, in dogs, often given with food</td>
</tr>
<tr>
<td></td>
<td>50 mg/mL suspension</td>
<td>suspension: REFRIGERATE, SHAKE WELL BEFORE USING</td>
<td>EXPiry date</td>
</tr>
<tr>
<td>Cephapirin Na</td>
<td>Cefa-Lak</td>
<td>- NEVER use dry cow products in lactating animals</td>
<td>Prescription status is determined by scheduling of DRUG not dosage form, which is obviously NOT for human use</td>
</tr>
<tr>
<td>Cephapirin Bensathine</td>
<td>Cefa-dri</td>
<td>- Cephapirin is a Schedule F Part I (prescription) drug</td>
<td></td>
</tr>
<tr>
<td>Chlor-amphenicol</td>
<td>Pentamycin eye drop, ointment 1000 mg Tablets Palm 25, 50 mg/mL oral liquid Chloromycetin Succinate 1 g injection</td>
<td>FOR THE EYE WEAR FINGER COT TO APPLY OINTMENT - WASH AFTER EACH USE WASH HANDS AFTER ADMINISTERING</td>
<td>use BANNED in food animals Ointment should be dispensed with a finger cot for application of the drug and instructions to the client to avoid contact of the drug with human skin - association has been made in Chlor rare cases between low dose exposure and development of aplastic anemia in humans - Pentamycin eye drops - REFRIGERATE until dispensed – long term storage should be in fridge, but once dispensed it may be stored at room temp and should be discarded 3 weeks after opening.</td>
</tr>
<tr>
<td>Chlor-amphenicol Hydrocortisone</td>
<td>Pentamycin HC eye ointment</td>
<td>- Same as chloramphenicol</td>
<td></td>
</tr>
<tr>
<td>Clenbuterol</td>
<td>Ventipulmin</td>
<td>• FOR THE EYE • WEAR FINGER COT TO APPLY OINTMENT - WASH AFTER EACH USE</td>
<td>Use BANNED in food animals Directions on syrup label given in terms of “pumpstrokes” which equals 4 mL</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>Antirobe 25 75, 150 mg capsules, 25 mg/mL oral liquid Dalacin C 15 mg/mL oral liquid (human)</td>
<td>FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber</td>
<td></td>
</tr>
<tr>
<td>Cyclosporine</td>
<td>Optimmune eye ointment</td>
<td>• FOR THE EYE • WEAR FINGER COT TO APPLY OINTMENT - WASH AFTER EACH USE</td>
<td>should be dispensed with a finger cot for 0.2% application of the drug and instructions to the client to avoid contact of the drug with human skin</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Valium, generic brands; mL ampule</td>
<td>• PROTECT FROM LIGHT</td>
<td>Targeted Substance Do not store injection in plastic</td>
</tr>
<tr>
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</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>Dimethyl-sulfoxide (DMSO)</td>
<td>Domoso 90% liquid, gel</td>
<td>• AVOID CONTACT OF THIS DRUG WITH HUMAN SKIN • FOR EXTERNAL USE ONLY</td>
<td>- Prostaglandins are absorbed through skin - Pregnant women should not handle or should use extreme caution in handling - Asthmatics should be warned of the possibility of bronchoconstriction if exposed to prostaglandin</td>
</tr>
<tr>
<td>Dinoprost Tromethamine (Prostaglanda F2a – PGF2a)</td>
<td>Lutalyse 5 mg/mL injection</td>
<td>• AVOID CONTACT OF THIS DRUG WITH HUMAN SKIN</td>
<td>- If administering tablets to CATS, doses should be followed with 5 mL of water to prevent irritation of the throat</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>100 mg tablet compounded suspension</td>
<td>• TAKE WITH FOOD • FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)</td>
<td>- Prepared emulsions are stable for 4 months if stored in amber glass containers at 20 – 24C.</td>
</tr>
<tr>
<td>Eniliconazole</td>
<td>Imaverol 100 mg/mL topical, emulsifiable concentrate</td>
<td>• FOR EXTERNAL USE ONLY • SHAKE WELL BEFORE USING</td>
<td></td>
</tr>
<tr>
<td>Enrofloxacin</td>
<td>Baytril 15, 50, 150 mg tablets, 50 mg/mL injection</td>
<td>• FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)</td>
<td>- Enrofloxacin is very bitter; the injectable solution is sometimes used orally in exotic or small pets – dose may be mixed with juice to improve taste - Do not administer iron, aluminium, dairy or calcium products within 1 hour before or 2 hours after</td>
</tr>
<tr>
<td>Erythromycin Estolate</td>
<td>50 mg/mL oral liquid</td>
<td>• REFRIGERATE • SHAKE WELL • FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)</td>
<td>- Erythromycins may be given with food to decrease stomach upset with and cramping</td>
</tr>
<tr>
<td>Fentanyl patches</td>
<td>Duragesic</td>
<td>• AVOID CONTACT OF THIS DRUG WITH HUMAN SKIN</td>
<td>- Caution clients about safe disposal of used patches and risk of harm if patches are ingested or handled by a child or pet – significant amounts of drug remain in patches</td>
</tr>
<tr>
<td>Fenbendazole mg/mL oral suspension</td>
<td>Panacur 100</td>
<td>• SHAKE WELL BEFORE USING • FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)</td>
<td>- Requires treatment for 3 consecutive days</td>
</tr>
<tr>
<td>Itraconazole</td>
<td>Sporanox 100 mg capsule, oral solution</td>
<td>• TAKE WITH FOOD • FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)</td>
<td>- Sporanox capsules must be taken with food - absorption of itraconazole requires an acid environment - Sporanox Oral Solution should be taken WITHOUT food</td>
</tr>
</tbody>
</table>
## Auxiliary Label Guide

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
<th>Auxiliary Labels</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin mg/mL Injection</td>
<td>Ivomec 10 Ivomectin Pour-On</td>
<td>• PROTECT FROM LIGHT</td>
<td>- note light sensitivity stated in extremely small print on carton, - non-prescription when used in livestock (indicated on label), - use in dogs requires a prescription - accidental overdose in dogs by clients using LA OTC product - normal dog dose for HW prevention is 6 mcg/kg - conc. of OTC product is 10,000 mcg/mL (enough for a 3600 lb dog); collies are more sensitive but tolerate heartworm prevention doses (6 mcg/kg) and up to 100 cg/kg offlabel dosage for ecto and endoparasites = 300 mcg/kg - IM injection in horses caused a high incidence of deep abscesses when equine injection was first introduced in mid 1980s - now only oral products are approved for horses</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td>Anafen 5, 20 mg tablet, 20,</td>
<td>• TAKE WITH FOOD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>100 mg/mL injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meloxicam</td>
<td>Metacam 1.5 mg/mL oral</td>
<td>• TAKE WITH FOOD</td>
<td>- Dose may be measured directly from bottle in syringe provided, calibrated from in kg body weight OR using one drop from the BOTTLE per kg body weight. Dropper tip is calibrated to deliver 0.1 mg per drop – easier for dogs under 10 kg</td>
</tr>
<tr>
<td></td>
<td>suspension, injection</td>
<td>• suspension: SHAKE WELL BEFORE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>USING</td>
<td></td>
</tr>
<tr>
<td>Metronidazole</td>
<td>250 mg tablet compounded</td>
<td>• FINISH ALL THIS MEDICATION</td>
<td>- Warn clients not to let pets drink anything containing alcohol – even small amounts of alcohol in veterinary mouthwashes may cause vomiting</td>
</tr>
<tr>
<td></td>
<td>suspensions</td>
<td>(unless directed otherwise by</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>prescriber)</td>
<td></td>
</tr>
<tr>
<td>Miconazole, Polymyxin B,</td>
<td>Surolan ear drops</td>
<td>• FOR THE EAR</td>
<td>- Instruct clients: not to touch tip of dropper to ear to avoid contaminating contents - and - apply drops, then massage base of ear and wipe out excess with tissue or cotton ball</td>
</tr>
<tr>
<td>Prednisolone</td>
<td></td>
<td>• SHAKE WELL BEFORE USING</td>
<td></td>
</tr>
<tr>
<td>Neomycin, Nyctain, Thiostrepton</td>
<td>Panolog cream, ointment</td>
<td>• FOR THE EAR FOR EXTERNAL USE</td>
<td>- Instruct clients: not to touch tip of dropper to eye to avoid contaminating contents - and - apply drops, then massage base of ear and wipe out excess with tissue or cotton ball</td>
</tr>
<tr>
<td>Triamcinolone</td>
<td></td>
<td>ONLY (if for use on skin)</td>
<td></td>
</tr>
<tr>
<td>Neomycin, Polymyxin B, Bacitracin</td>
<td>Vetroploycin eye ointment</td>
<td>• FOR THE EYE</td>
<td>- Instruct clients: Not to touch tip of dropper or tube to eye in order to avoid contaminating contents - One drop or ½ inch of ointment applied with the fingertip to the conjunctival sac is usually enough for a cat or dog eye</td>
</tr>
</tbody>
</table>

Dispensing Procedures
<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
<th>Auxiliary Labels</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Neomycin, Polymyxin B, Dacitracin Hydrocortisone | Vetropolycin HC eye ointment | • FOR THE EYE                     | - Instruct clients: Not to touch tip of dropper or tube to eye in order to avoid contaminating contents  
- One drop or ¼ inch of ointment applied with the fingertip to the conjunctival sac is usually enough for a cat or dog eye |
| Neomycin, Polymyxin B Gramicidin             | Optimyxin Plus eye drop | • FOR THE EYE                     | - Instruct clients: Not to touch tip of dropper or tube to eye in order to avoid contaminating contents  
- One drop or ¼ inch of ointment applied with the fingertip to the conjunctival sac is usually enough for a cat or dog eye |
| Neomycin, Polymyxin B, Dexa-methasone       | Maxitrol eye drops, Eye ointment | • FOR THE EYE                     | - Instruct clients: Not to touch tip of dropper or tube to eye in order to avoid contaminating contents  
- One drop or ¼ inch of ointment applied with the fingertip to the conjunctival sac is usually enough for a cat or dog eye |
| Oxy-tetracycline                            | Tetraject LA, LP Biomycin |                                  | - Solutions often turn dark due to oxidation. This apparently does not affect efficacy of the drug.                                                                                                     |
| Penicillin G Porcaine                       | Depocillin, Procillin |                                  | - NEVER give procaine subcutaneously  
- Newer products reflect new dosage recommendations of 21,000 units/kg  
- (7 mL of 300,000 u/mL product per 100 kg)  
- WT at this dosage and 24,000 u/kg is 10 days for meat, 96 hours for milk  
- WT at 66,000 u/kg is 21 days (WT established by Veterinary Drugs Directorate)  
- Some products may require refrigeration – CHECK LABEL  
- Suspensions MUST be shaken well before using – some require several minutes of hard agitation to completely suspend the drug |
| Phenobarbital                               | 15, 30, 60 mg tablets 120 mg/ml injection 5 mg/mL oral elixir |                                  | - Elixir is useful for dosage flexibility  
- Elixirs are alcoholic solutions and are not tolerated by cats                                                                                                                                     |
## Auxiliary Label Guide

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
<th>Auxiliary Labels</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Phenylbutazone     | Butequine paste generic 200 mg/mL injection 200 mg, 1 g tablets Buzone powder | •TAKE WITH FOOD (if administering to dogs) | - ensure directions for use are in terms of the calibration of product  
- Butequine Paste is calibrated in GRAMS but quantity shows as mL - 60 mL paste = 20 grams phenylbutazone or 1 gram drug per 3 mL paste  
- Buzone powder comes in two strengths which can be confusing to clients - make sure they understand the correct dose and how to measure it  
- Buzone Concentrate dosage is given by teaspoon (1 g phenyl butazone) or tablespoon (3 g). Labeling with directions of give x grams makes the client do the math with potential for unpredictable results |
| Piroxicam          | 10 mg capsule compounded capsules | •TAKE WITH FOOD             |                                                                                                                                                                                                          |
| Praziquantel, Pyrantel | Drontal tablets for CATS 18.2 mg, 17.6 mg | | - Caution client to give complete dose, which may be several tablets administered at the same time (two tablets as a single dose) |
| Praziquantel Pyrantel Febantel | Drontal Plus – SMALL DOGS 22.7 mg, 22.7 mg, 113.4 mg/tablet Drontal Plus – MED and LGE DOGS 68 mg, 68 mg, 340.2 mg/tablet | | - Caution client to give complete dose, which may be several tablets administered at the same time (two tablets as a single dose) |
| Prednisolone       | Pred Forte 1% drops brands Pediapred 1 mg/mL oral solution | •FOR THE EYE  
•SHAKE WELL BEFORE USING | - Settling of suspensions is not visible eye through opaque dropper bottles Generic  
- Caution client to SHAKE VERY WELL before administering eye drops |
| Prednisone         | 1, 5, 50 mg tablets               | •TAKE WITH FOOD             | - Caution client to follow exact dosage directions of the veterinarian  
- Medication should not be stopped suddenly in animals that have been on long-term treatment |
| Proparacaine       | Alcaine eye drops                 | •REFRIGERATE                | - Solutions MUST be refrigerated and should NOT be used if discouloured. |
### Auxiliary Label Guide

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
<th>Auxiliary Labels</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Pyrantel (base)                     | Pyran 35 tablet,                | • FINISH ALL THIS MEDICATION (unless directed otherwise by  | • Doses should be repeated in 2-3 weeks  
|                                     | Pyrantel suspension             | prescriber)                                                | • Caution client s to make sure they give second dose                                         |
|                                     |                                 | • Suspension: SHAKE WELL BEFORE USING                      |                                                                                               |
| Stilboesterol                       | 1 mg tablet                     | • TAKE ON AN EMPTY STOMACH                                  |                                                                                               |
|                                     |                                 | • suspension: SHAKE WELL BEFORE USING                      |                                                                                               |
| Sucralfate                          | 1 g tablet                      |                                                            |                                                                                               |
|                                     | (generic brands)                |                                                            |                                                                                               |
|                                     | Sulcrate 200 mg/mL Oral         |                                                            |                                                                                               |
|                                     | suspension                      |                                                            |                                                                                               |
|                                     |                                 |                                                            |                                                                                               |
| Tetracycline                        | 100 % Powder                    |                                                            | • FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)                         |
|                                     | 1% eye ointment,                |                                                            | • TAKE ON AN EMPTY STOMACH                                                                      |
|                                     | 250 mg capsule                  |                                                            | • Sensitivity to sunlight may be increased (may cause rupture of pustules and blisters)        |
|                                     |                                 |                                                            | • Inactivated by iron, milk products and antacids (calcium)                                   |
| Tilmicosin                          | Micotil 300 mg/mL injection     |                                                            | • WARN clients of danger of accidental human injection (fatality has been documented) also     |
|                                     |                                 |                                                            | include highlighted copy of package insert if dispensing smaller quantities. Should NOT be    |
|                                     |                                 |                                                            | dispensed in syringes.                                                                         |
| Trimethoprim, Sulfadiazine           | 120, 480, 960 mg tablet          |                                                            | • FINISH ALL THIS MEDICATION (unless directed otherwise by prescriber)                         |
|                                     | 48 mg/mL oral suspension        |                                                            | • ENSURE FRESH WATER AVAILABLE                                                                 |
|                                     |                                 |                                                            | • Uncoated tablets and suspension - DO NOT USE IN CATS – causes severe drooling/foaming        |
| Trimethoprim, Sulfadoxine           | Trivetrin 200 mg + 40 mg/mL     |                                                            |                                                                                               |
|                                     | injection                       |                                                            |                                                                                               |
|                                     |                                 |                                                            | • PROTECT FROM LIGHT                                                                             |
|                                     |                                 |                                                            | • STORE AT ROOM TEMPERATURE                                                                      |
|                                     |                                 |                                                            | • a VTH compounded solution for oral use in warfarin or sweet clover poisoning                   |
|                                     |                                 |                                                            | • available on prescription (verbal or signed order of a licensed veterinarian)                |
|                                     |                                 |                                                            | • light sensitive – store at room temp. up to one year (oil vehicle semi-solid in refrigerator  |
|                                     |                                 |                                                            | temperatures)                                                                                  |
| Vitamin K1                          | 10 mg/mL injection              |                                                            |                                                                                               |
|                                     | 40 mg/mL compounded oral liquid |                                                            |                                                                                               |
### Auxiliary Label Guide

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
<th>Auxiliary Labels</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xylazine</td>
<td>Rompun 20, 100 mg/mL injection</td>
<td></td>
<td>- If dispensing to clients warn of danger on accidental human injection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Individuals exposed to small amounts (oral exposure from drug “leaked” into the plastic cover of a dart needle and a small dose administered subcutaneously when a horse reared) have experienced “woozy, heavy” feelings and spent 24 hours under observation before recovering.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Another individual attempting suicide with a dose thought to be 10 mL (of 100 mg/mL) stopped breathing by the time he reached hospital and remained on a respirator for 60 hours before recovering.</td>
</tr>
</tbody>
</table>

### General Considerations

Drugs must be dispensed in containers that protect from moisture and preferably light. Cotton may be used to prevent tablets from breakage but in humid climates can contribute to drug instability. Note light sensitivity. Drugs provided as powders for reconstitution and injection are most likely in that form because they are unstable in solution. Note stability and storage conditions after reconstitution (two different brands of cefazolin both providing 1 gram of drug - one is stable 72 hours in the fridge, the other 96 hours). Also note date mixed or expiry date after reconstitution.

The presence of food in the stomach may diminish or enhance activity of some drugs especially antibiotics.

Capsules and tablets administered to cats can sometimes get stuck in the throat. A small volume of water (3 to 5 mL) given afterward will help prevent irritation and ensure the drug reaches the stomach.

All suspensions and emulsions must be shaken well before using. Often it is not possible to see settling of solids through opaque containers. Suspensions and emulsions must NOT be frozen. Freezing of suspensions causes clumping of solids, which makes re-suspension of drug impossible and alters concentration. Frozen emulsions are “broken” by micro-crystals of ice piercing micelles, which results in separation of oil/water phases and inability to achieve a uniform product. Suspensions should not be dispensed in syringes due to settling in syringe and difficulty in re-suspending.

With intramammary products NEVER use dry cow products in lactating animals. Note the scheduling of the DRUG not dosage form (obviously NOT for human use) determines prescription status.

Most eye/ear drops or ointments are packaged in containers too small to allow adequate prescription labeling with many human medications prescribed extra-label veterinary medicine. In these cases the directions provided for human use are inappropriate. At WCVM, “For Veterinary Use Only”, “For the Eye”, and “Keep Out of Reach of Children” auxiliary labels are placed on the container in a manner that covers human directions but leaves the product name clearly visible. The product insert and box are discarded. Labels are covered with clear label tape and the bottle placed in a dispensing vial that bears the prescription label and duplicates of the auxiliary labels. While it may be acceptable to use an eye drop in the ear, the
reverse is not safe. **OTIC (ear) drops cannot be used in the eye** unless they are also specifically labeled for use in the eye. Eye drops are adjusted for pH and isotonicity in the eye. Ear drops are not. Use of Gentocin ear drops in the eye has resulted in corneal ulceration.

Clients should be cautioned not to touch the tip of dropper bottles or ointment tubes to the eye or with their fingers as this can contaminate the drug. Applying ointments with a fingertip in the conjunctival sac is preferred rather than squeezing it directly from the tube into the eye. If the animal moves unexpectedly, the metal tip can cause damage to the eye. If clients are administering more than one eye medication, they should wait five minutes between each to allow the medication to distribute and not be washed out by the next medication. **Eye ointments or gels** (such as eye lubricants or tear replacements) should be applied last.
CHAPTER 7 – The Drug Development Process

Development

The identification of compounds to treat complex diseases and the testing to ensure their safety and efficacy is an expensive and time-consuming process. It has been estimated only one out of every 7,500 compounds gets through the approval process and is marketed. Development of a pharmaceutical compound may be abandoned at any stage of the process if the results of research are not encouraging. For each drug that reaches the market, the costs of research and development are about $1.3 billion. The time frame from development to approval and marketing can average 15 years.

The mandate of Health Canada's Veterinary Drugs Directorate (VDD) is to protect human and animal health and the safety of Canada's food supply. VDD evaluates and monitors the safety, quality and effectiveness, sets standards and promotes the prudent use of veterinary drugs administered to food-producing and companion animals. A veterinary drug is approved for sale in Canada if the manufacturer has supplied evidence that the drug is safe for the animals treated, and is effective treating the condition for which it is to be marketed.

When a potential new drug compound is discovered and shows promise for meeting an animal health need, a series of preliminary trials to look at mode of action and safety (usually in vitro) are conducted. Testing on simple organisms like bacteria, yeasts, and molds, or computer modeling help in determining how living systems respond to the drug. Research continues in lab animals and the target species in the pre-clinical testing stage. If the results of this work are encouraging the process continues with the manufacturer filing an Investigational New Drug Submission with Health Canada. Clinical trials are then conducted to confirm safety and efficacy. Areas of interest for animal drugs are:

- tissue residue studies
- reproductive studies
- stability studies (to determine shelf life)
- resistance Studies (for pesticide or antibacterial products)
- field trials (most are blinded) to show how the drug works in target animals under typical conditions.

Approval

The manufacturer then files a New Drug Submission (NDS) with the Veterinary Drugs Directorate of Health Canada and requests the drug be sold in Canada. This submission will contain detailed information of all experimental procedures and results, manufacturing information such as data on raw materials used and suppliers, formulations, product specifications, quality assurance procedures, and proposed package labeling.

Scientists at VDD review the NDS and data. The decision on how the drug should be tested in order to ensure its safety and efficacy will be influenced by questions such as:

- Is it a new drug?
- Are there problems with the drug?
- Is the drug similar to drugs currently being sold?
- How confident are they about the drug?

To ensure all lots of the drug produced are consistent, Health Canada typically tests three to five different lots or batches. Individual or combined ingredients as well as the final product may also be tested.
Once Health Canada decides the drug and manufacturing processes are safe and effective, a Notice of Compliance (NOC) is issued. This informs the manufacturer they have complied with the requirements of the Food and Drugs Act and allows the sale of the drug in Canada. The Patented Medicines Price Review Board reviews the price of new drugs in Canada and after approval Health Canada assigns a Drug Identification Number (DIN). The DIN appears on the outside package of the drug once it is approved for sale.

NOTE: While Health Canada is responsible for approving the drug product for sale in Canada, the actual CONDITIONS for SALE are under provincial jurisdiction. Effectively, this means Health Canada determines WHAT drugs can be sold but the provinces control WHO can sell those drugs as well as HOW and WHERE they can be sold.

Patents and Pricing

Encouraging and recognizing innovation in the pharmaceutical industry requires strong intellectual property protection laws. The presence of these contributes to an attractive investment climate, which is a key component in a company’s decision to conduct research and development in Canada.

Protection under patent registration for drugs is 20 years from the date of filing the application. For that period of time, no one else can copy the product or use the process. Twenty years is longer than patent protection in other countries and was granted with the expectation that research and development in Canada would be more attractive and would increase. Patent protection exists only in the issuing country so patents must be filed in each country where a company wants protection.

Patents on new drugs are filed as soon as the drug is discovered or developed and testing begins. The development and approval process averages 10 to 15 years. This leaves the manufacturer only 5 to 10 years to recover developmental costs and raise funds for the ongoing search for new drugs. Once a patent expires, any company can produce and sell the drug and usually does so at a much lower price. Competition in the pharmaceutical industry is intense. Both private insurance providers and government drug benefit plans encourage (and in some cases require) the use of cheaper “generic” copies of drugs rather than the more expensive original brands.

Patented Medicine Prices Review Board (PMPRB)

The PMPRB, an independent quasi-judicial federal government agency was established in 1987 to protect consumers and health care systems in Canada. It regulates the price of patented drugs that wholesalers, hospitals, or pharmacies pay in Canada but does not control the price consumers pay for drugs. The pharmaceutical company that produces the drug establishes a price, which is reviewed by PMPRB to determine if it is excessive. PMPRB sets guidelines and tracks the price trends of patented drugs and the research and development investments done by pharmaceutical companies. It does not regulate the prices of non-patented drugs (i.e.) generic drugs.
CHAPTER 8 – Pharmaceutical Waste Disposal

Pharmaceuticals

Proper disposal of pharmaceutical drugs and veterinary biologics is an emerging environmental issue. All medications applied externally, injected or ingested (and their bioactive transformation products) have the potential to be excreted or washed into the sewage system and from there discharged into the aquatic or terrestrial environments. Veterinarians should make every effort to ensure these products are properly disposed of.

Pharmaceuticals and biologics can, in many cases, be returned to the manufacturer or distributor. There are several commercial operations that collect and properly dispose of biomedical wastes, including one in Manitoba that regularly calls on pharmacies. In addition, one of the major veterinary drug distribution cooperatives in western Canada also offers a biomedical waste collection service.

In situations where a drug container has been opened and only a small portion of the product remains, it is possible to denature, immobilize or render the product inert or inconsumable. Adding chlorine bleach to pharmaceuticals that are in a solid or powdered form will denature them, as will mixing liquid pharmaceuticals with plaster or cement powder. Some products, treated in this manner, can be disposed of in a landfill. High temperature incineration is a less labor-intensive alternative to immobilization or denaturing.

Controlled Substances and Drugs

In order to return narcotic and controlled substances, veterinarians must obtain an Authorization to Return form from the manufacturer. For destruction of narcotic and controlled substances, authorization must be obtained from the Office of Controlled Substances and the destruction must take place in the presence of another health care professional. Incineration is considered the ideal way to destroy narcotic and controlled substances, however they can be chemically adulterated by mixing them with bleach or an inert substance such as chalk, sawdust or cement. Such a mixture can be disposed of by a means that conforms to local municipal regulations.
Special Access Program for Veterinarians

Manufacturers usually seek approval to sell drugs only in countries where there is an expected market for their product. Many disease states are not common in Canada but the need to obtain drugs not approved in Canada to treat such conditions is recognized. In these situations, veterinary practitioners may submit a detailed explanation in applying to obtain an unapproved drug under the authorization of an Emergency Drug Release (EDR). There should be sufficient evidence of the safety and efficacy of the drug documented in the current scientific literature and the veterinarian may also have to submit this information with their EDR request. The reason for seeking an EDR should be for a serious or life-threatening illness or failure to respond to conventional available therapies. Lower cost of a drug is NOT an acceptable reason for requesting an EDR. The veterinarian is allowed to apply for up to six months supply of the drug for one patient. A charge of $50.00 applies for each EDR for companion animals and $100 for food animals. A follow-up report must be completed before requesting a new EDR or at the conclusion of the case.

Steps in Applying for an EDR

1. Call the manufacturer to confirm they will supply / sell you the drug on receipt of an EDR Authorization. The pharmaceutical company has the right to decide whether or not to provide the drug.

2. Fax completed EDR application to Veterinary Drugs Directorate.

3. VDD reviews the request and decides whether or not it is approved. If approved, a Letter of Authorization is sent to the manufacturer and to the practitioner. VDD personnel attempt to complete this process within 48 hours – which means in many cases the drug can be available to the veterinarian within about 4 days.

4. Complete the FOLLOW-UP REPORT documenting the EDR use, safety (potential adverse reactions) and efficacy for submission to VDD.

Granting of an EDR allows the practitioner to use the drug under the conditions described in the authorization (i.e.) for the patient and the condition. It does NOT mean the drug has been approved for sale in Canada. A practitioner cannot provide (sell / give) the drug to another practitioner, etc. because only the manufacturer has been authorized to sell or provide the drug in Canada and only under the terms of the EDR.
### EMERGENCY DRUG RELEASE APPLICATION AND FEE FORM

#### Veterinary / Billing Information

<table>
<thead>
<tr>
<th>Veterinarian, Practice Name, Address</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fax</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Billing Address (if different)</th>
<th>Billing Contact Person</th>
</tr>
</thead>
</table>

#### Patient Information

<table>
<thead>
<tr>
<th>Pet Name / Owner’s Name</th>
<th>Species</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Weight</th>
<th>Sex</th>
<th>No. of animals</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Disease / diagnosis / condition being treated</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Justification for use</th>
</tr>
</thead>
</table>

#### Emergency Drug Information

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Generic Name</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dosage form and strength</th>
<th>Route of administration</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Manufacturer name (include address, contact, phone, fax)</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Dose of drug and treatment regime</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date(s) drug will be used</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Quantity requested (see attached)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Clarify maximum for 6 months.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Previous follow up report: has been sent</th>
<th>is attached</th>
<th>other (explain)</th>
</tr>
</thead>
</table>

**SIGNATURE:** ___________________________ **DATE:** ___________________________

*** If applicable, please provide a written statement that animals to which this drug is administered will not be used in food for human consumption. ***

Please fax or email completed form to the above address/fax number.
An EDR for a non-food animal is $50.00; for a food animal is $100.00.
You will be invoiced by Health Canada for your EDR request.

<table>
<thead>
<tr>
<th>Customer no.</th>
<th>S.O. no.</th>
<th>Non food animal</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>EDR no.</th>
<th>Invoice no.</th>
<th>Food animal</th>
</tr>
</thead>
</table>
CHAPTER 10 – Prescriptions for Medicated Feeds

The Feed Act and Regulations (Feeds Act, R.S., c.F-7, s. 1) recognize that medications are ingredients allowed for use in livestock feeds and that these ingredients are controlled by authorities provided in another statute; Food and Drug Act and Regulations. The Feed Regulations (section 14, under "Standards") essentially set out parameters for compliance that recognize Food and Drugs Act and Regulations control measures for over the counter and other Food and Drugs Act and Regulations-sanctioned drug use applications in animal feeds (e.g. veterinary prescriptions). C.08.012

Veterinary prescription feeds are medicated feeds which are manufactured according to a written prescription supplied by a licensed veterinarian practicing in the province in which the feed is to be fed. Veterinarians may at times prescribe levels or combinations of medication different from those approved and set out in the Compendium of Medication Ingredient Brochures (CMIB). This should only be for a limited period in the treatment of a specific, diagnosed disease condition. General standards must be met and the withdrawal period as stated on the prescription must be such that there are no harmful residues or toxicity to humans or livestock.

When prescribing various drugs to be included in medicated feeds, veterinarians need to be aware not all drugs can be mixed together in the same feed.

Producers who wish to mix medicated feeds on-farm need to be made aware they are responsible for mixing errors and the dosing and withdrawal time errors that follow.

Veterinary prescription feeds are exempt from registration provided they meet certain conditions. The first condition is the feed be in compliance with Section C.08.012 of the Food and Drug Regulations, which requires that a feed manufacturer, using a medicating ingredient at a level or of a kind or for a purpose not listed in the CMIB, does so in accordance with a written prescription issued by a licensed veterinarian. The manufacturer must be sure of the following:

(a) The drug is prescribed for prophylactic or therapeutic purposes and not as a growth promotant.
(b) The drug has an identification number (DIN) under the Food and Drugs Act. A listing of drug identification number is available from Health and Welfare Canada.
(c) The animals are under the direct supervision of the veterinarian.

The veterinarian assumes full responsibility for extra-label use of any feed medication.

(a) The Feed Regulation (Section 5(2)(g)) requires the prescription from the veterinarian contains the following information:
(b) The date on which the prescription was written;
(c) The name and address of the person for whom the feed is to be mixed and intended for use;
(d) Name and level of medication ingredient(s);
(e) Name and amount of medicated feed;
(f) Number, kind, class, age or weight of livestock to be feed;
(g) Special manufacturing instructions, if any;
(h) Feeding directions, including period of time medicated feed is to be used. It is particularly important for the producer to ensure that this has been obtained;
(i) Any necessary Warning or Caution statements;
(j) Signature of the veterinarian;
(k) A statement signed by the person receiving and using medicated feed, indication that he has read and understands all pertinent instructions. (If the veterinarian, for practical reasons, issues the
prescription directly to the manufacturer and is satisfied that the person for whom the prescription was issued is aware of all pertinent instructions, then this statement is not necessary).

Feed manufacturers are not to accept a prescription which specifies more feed to be mixed than the animals being treated would normally consume during the treatment period.

A feed manufacturer should not accept any veterinary prescription calling for the addition of a substance—including a feed nutrient—unless the source of that substance has a drug identification number (DIN) issued by Health and Welfare Canada.

A copy of the prescription must be in the hands of the manufacturer prior to delivery of the feed.

Where to Find Detailed Information about In-Feed Medications

- **The Feeds Act and Regulations**, under Agriculture and Agri-Food Canada’s authority allows feed manufacturers to sell medicated feeds and veterinarians to prescribe medications for use in feeds.
- **The Compendium of Medicating Ingredients Brochures (CMIB)** lists the approved brands, use levels, claims, cautions, and warnings associated with each medication.
- **The levels listed in the CMIB are the only legal levels** that a commercial or on-farm manufacturer can incorporate into a commercial feedstuffs without a prescription.
- **Levels outside of those in the CMIB require a veterinary prescription**. It is as illegal to mix a feed with a drug level below that listed in the CMIB as it is to manufacture a feed with a higher level. (Food and Drug regulations C.08.012)

Veterinarians may find it useful to use a prescription order form similar to the example shown here.
## Sample Prescription form for Medicated Feed

<table>
<thead>
<tr>
<th>OWNER</th>
<th>ADDRESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>VETERINARIAN</td>
<td>ADDRESS</td>
</tr>
<tr>
<td>SPECIES</td>
<td>PROD. TYPE</td>
</tr>
<tr>
<td>No. ANIMALS</td>
<td>WT.</td>
</tr>
<tr>
<td>NAME of FEED</td>
<td>AMOUNT (kgs or tones)</td>
</tr>
</tbody>
</table>

### LEVEL of MEDICATING INGREDIENTS

<table>
<thead>
<tr>
<th>Names of Medicating Ingredients</th>
<th>Drug Trade Name (Optional)</th>
<th>Level of Medicating Ingredient in the Feed</th>
<th>Level of Drug in Feed (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### MIXING DIRECTIONS

<table>
<thead>
<tr>
<th>FEEDING INSTRUCTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

### CAUTIONS

<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

### MANUFACTURING INSTRUCTIONS

<table>
<thead>
<tr>
<th>REPEAT:</th>
<th>Once_____ Twice_____ or_____ times.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIGNED</td>
<td>___________________________, DVM</td>
</tr>
<tr>
<td>DATE</td>
<td>____________________________</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>OWNER’S SIGNATURE</th>
</tr>
</thead>
</table>

*
CHAPTER 11 – Selection and Prudent Use of Antimicrobial Drugs

Antimicrobial Therapy

In recent years there have been important changes in antimicrobial therapy. There are new antimicrobials available and there is a greater database of species-specific pharmacokinetic information available for antimicrobials used in veterinary medicine, which allows for more accurate drug dosing. Concerns over drug residues in food animals and continued development of bacterial resistance require a more measured and rational approach to the use of all antimicrobials.

Rational Use of Antimicrobial Agents

The following questions must be considered when developing an antimicrobial regimen:

1) **Does the diagnosis warrant antibiotic therapy?** Using antimicrobials to treat minor infections or purely viral or inflammatory diseases is irrational, expensive, can be hazardous to the patient and encourages antimicrobial resistance. Clients have come to expect antimicrobials for trivial infections or "just in case" an infection may develop. Equine practitioners must resist client pressure to use or prescribe unnecessary drugs.

2) **What organisms are likely to be involved?** For many infections, the likely organism can be successfully predicted from the history and clinical signs (e.g., urinary tract and skin infections in dogs, "strangles" in horses). In some cases laboratory confirmation would be appropriate.

3) **What is the in vitro antimicrobial sensitivity of the organism?** For many pathogens, the in vitro susceptibility can reliably predicted. For example, Streptococcus species are typically susceptible to penicillin. However, many Gram-negative bacteria have unpredictable susceptibilities and susceptibility testing is essential for determining appropriate drug therapy. Despite being predictably susceptible to many antimicrobials, mycoplasma polyarthritis in cattle is difficult to cure due the massive accumulation of fibrin and purulent material in affected joints that prevent effective antimicrobial concentrations.

4) **In what part of the body or tissue is the infection located?** Will the antimicrobial penetrate to the infection? Consideration of the pathophysiology of the infection will aid in selection of effective therapy. Treatment of sequestered infections such as mastitis or meningitis requires antimicrobials that readily cross membrane barriers. Antimicrobials characterized by low values for volume of distribution are unlikely to reach therapeutic concentrations in such sites.

5) **Will the antimicrobial be effective in the local environment of the organism?** For some antimicrobials the local infection environment reduces their efficacy. Sulfonamides are ineffective in purulent debris, as para-amine benzoic acid (PABA) released from decaying neutrophils serves as a PABA source for bacteria and reduces the competitive effect of the sulfonamide. Aminoglycosides are ineffective in an abscess due to the acidic, anaerobic environment along with the presence of nucleic acid material from decaying cells which inactivates the aminoglycosides.

6) **What drug formulation and dose regimen will maintain the appropriate antimicrobial concentration for the proper duration of time?** Label doses only apply to label pathogens. When treating "off-label", the dosage regimen must be adjusted for the antimicrobial susceptibility of the specific pathogen.

7) **What adverse drug reactions or toxicities might be expected?** Do the benefits outweigh the risks? The risks of adverse reactions from antimicrobials are often under appreciated. A serious adverse reaction may complicate treatment of the original problem and even be fatal. Failure to communicate the risks of adverse drug reactions to clients is a common cause of litigation.

8) **Can you choose an approved product? What affect will the product have on carcass quality?** If using an antimicrobial in an extra-label manner, can you determine appropriate withdrawal times?
Understanding the principles of drug elimination allows the practitioner to determine appropriate withdrawal times for competitive or food animals.

Document the Infection

A diagnosis must be established before any therapy can be administered. It is not always necessary to culture samples from all patients with infectious diseases in order to identify the organism involved. Often, the practitioner can base a diagnosis on clinical experience from similar cases. The signs of some infectious diseases are so obvious that the need for microbiological identification is minimal; but for those infectious diseases of unknown cause or for those attributable to organisms with irregular antimicrobial sensitivity, there is no substitute for isolation and identification of the causative agent. For these organisms, initial therapy while waiting for culture results must include an antimicrobial with a broad spectrum of activity. However, it may be prudent, under these circumstances when the responsible pathogens are not known, to avoid the use of critically important antimicrobials agents, such as fluoroquinolones, third-and fourth-generation cephalosporins, streptogramins, and new antimicrobial agents to avoid indiscriminate use of these. Remember, broad-spectrum drugs are usually more toxic and more expensive. The use of antimicrobials for relatively trivial infections encourages development of antimicrobial resistant organisms. Without evidence of a susceptible pathogen, antimicrobial use is irrational and exposes the patient to unnecessary risks.

Antimicrobial Dosage Regimen Design

Successful antimicrobial therapy relies on administering sufficient doses so that pathogens at the site of infection are killed or sufficiently suppressed that they can be eliminated by the host's immune system. The relationship between the host, the bacteria and the drug may be very complex. High plasma antimicrobial concentrations are assumed to be advantageous in that a large concentration of drug will diffuse into various tissues and body fluids. Drug concentration at the infection site is assumed to be of major importance in determining drug efficacy. Remember, drug diffusibility from the plasma to extravascular tissues depends on molecular size, lipid solubility, drug pKa, local pH, specific cellular transport mechanisms and degree of protein binding. The relationship between bacteria and drug in the laboratory is described by:

- **Minimum Inhibitory Concentration (MIC):** The lowest drug concentration that inhibits bacterial growth.
- **Minimum Bactericidal Concentration (MBC):** The lowest drug concentration that kills 99.9% of bacteria.

*Interpreting MICs*

By the National Committee on Clinical Laboratory Standards (NCCLS) definition, the MIC values are derived as serially doubling concentrations (in micrograms per ml). The MIC of a particular pathogen is reported as one of the following numbers: 0.06-0.12-0.25-0.5-1-2 4-8-16-32-64-128-256-512.
**Susceptible ("S"), Intermediate ("I") and Resistant ("R")**

Designations are derived from "breakpoints" assigned by the laboratory based on safely achievable plasma concentrations and results of clinical trials. When a pathogen is reported as susceptible, it means that the recommended dosage of the antimicrobial will reach plasma or tissue concentrations that will inhibit bacterial growth in vivo.

When a pathogen is reported as resistant, inhibitory antimicrobial concentrations are not safely attainable in the patient. If the pathogen is reported as intermediate, then administering the antimicrobial at higher than recommended doses may result in effective therapy. The relationship between drug concentration and microbial inhibition is not a linear prediction. As antimicrobial concentration increases in vitro, eventually all bacteria will be inhibited or killed. This should not be interpreted to mean that dosage regimens should target these concentrations. Susceptibility testing results predict which bacteria have intrinsic or acquired resistance mechanisms to a particular antimicrobial. In vitro tests do this because bacterial susceptibility usually clusters around a small range of MICs.

The bacterial inhibition of E. coli by amoxicillin has a bimodal distribution. E. coli requiring an amoxicillin concentration of 16 mcg/ml to be inhibited are likely to have intrinsic or acquired resistance mechanisms and amoxicillin is unlikely to be a successful treatment for patients with this infection. The large cluster of E. coli inhibited by amoxicillin concentrations of 0.5 to 16 mcg/ml are considered the normal range and 16 mcg/ml is considered the "breakpoint" of susceptibility. As the MIC value increases within the normal range, the probability of successful therapy with amoxicillin decreases; meaning some susceptible E. coli are more susceptible than others. In vitro susceptibility tests predict treatment outcome fairly well, considering that many variables in the host-pathogen relationship are not taken into account.

The "S", "I", "R" designations are assigned by the laboratory based on safely achievable plasma concentrations. Antimicrobial susceptibility data also does not account for:

1) **Host Defenses:** The interaction between the host and the pathogen are complex and not predicted by in vitro tests. Antimicrobial drug action takes place in concert with host defenses such as humoral and cell mediated immunity, complement components, and nonspecific antibacterial factors such as lactoferrin, lactoperoxidase and lysozyme.

2) **Drug Distribution in the Body:** The "S", "I", "R" designations assigned by the microbiology laboratory are based on safely achievable plasma concentrations. This does not take into account for extremely high concentrations of antimicrobials achieved in organs and fluids of excretion (kidney, urine, bile) or with local administration of high drug concentrations (e.g. ophthalmic ointments). Pathophysiology may alter drug distribution, and some antimicrobials, such as the tetracyclines, accumulate in pneumonic lung tissues.

3) **Growth Rates and Size of Inoculum at the Infection Site:** The incubator of the microbiology laboratory is an ideal world for bacterial growth. Conditions are managed to promote rapid growth, and rapidly dividing bacteria are more susceptible to antimicrobial drugs. Replication rates may be much slower at the infection site and MIC's are generally unreliable for slow growing bacteria. Standardized inoculums used in the laboratory may over- or under-represent pathogen numbers in infected tissues.

4) **Mixed Infections:** Separate susceptibility testing of pathogens in a mixed infection does not account for the pathological syngressis between bacteria. The byproducts of one species of bacteria may facilitate the establishment and growth of another.

5) **Infection Environment:** Many antimicrobials are inactive in purulent exudate, which is typically anaerobic, acidic and hyperosmolar. Some antimicrobials will have different activity in body fluids (plasma, milk, bile) than in nutrient-rich laboratory media. Deposition of fibrin may alter tissue penetration of antimicrobials. Many bacteria are capable of producing a polysaccharide slime capsule to protect them from host factors. Mastitis pathogens typically increase their replication rate when incubated in mastitic milk.
6) **In Vivo Synergism May Occur with Antimicrobial Combinations:** Despite predictions of resistance from susceptibility testing, therapy may be successful because of synergistic combinations of antimicrobials. Synergism between penicillins and aminoglycosides has been recognized for streptococcal, enterococcal and staphylococcal infections. The synergism is attributed to increased cellular uptake of the aminoglycoside after cell wall damage from the penicillin.

7) **Topically Administered Antimicrobials are not Tested:** Veterinary microbiology laboratories may not routinely do susceptibility testing for antimicrobials that are only used topically. Polymyxin B is one of the most effective antimicrobials for superficial Pseudomonas infections, but it causes neurotoxicity and nephrotoxicity if administered systemically, so it is rarely included in susceptibility testing. Bacitracin and mupirocin are other examples of topical antimicrobials are rarely tested for in diagnostic laboratories.

8) **NCCLs Breakpoints may be Inappropriate:** The NCCLs breakpoints were originally established with bacterial isolates from humans, using human pharmacokinetic data and clinical trials in humans. A veterinary subcommittee was only established in 1993 and has only recently proposed veterinary-specific guidelines for susceptibility tests for some antimicrobials. The true relevance of any in vitro MIC predicting the in vivo results of drug therapy is questionable. But by convention, drug dosage regimens use a target plasma drug concentration that is based on some multiple (2 to 10, most often 4) of the in vitro MIC.

**Bactericidal Versus Bacteriostatic Antimicrobials**

<table>
<thead>
<tr>
<th>Bactericidal</th>
<th>Bacteriostatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroquinolones</td>
<td>chloramphenicol</td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>tetracyclines</td>
</tr>
<tr>
<td>β-lactams</td>
<td>macrolides</td>
</tr>
<tr>
<td>trimethoprim/sulfas</td>
<td>sulphonamides</td>
</tr>
</tbody>
</table>

99.9% of the bacteria and the drug is considered bacteriostatic. For many drugs, the distinction between bactericidal and bacteriostatic is not exact, and may depend on the drug concentration attained in the target tissue and the pathogen involved. Specific situations in which a bactericidal drug may be preferred over a bacteriostatic drug include: immunosuppressed patients (neonates), bacterial endocarditis, meningitis and surgical prophylaxis.

**Post-Antibiotic Effect (PAE)**

<table>
<thead>
<tr>
<th>Long PAE (≥3 hr)</th>
<th>Intermediate PAE</th>
<th>Short PAE (&lt;1 hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram positives</td>
<td>Fluoroquinolones</td>
<td>Aminoglycosides</td>
</tr>
<tr>
<td></td>
<td>Macrolides</td>
<td>penicillins</td>
</tr>
<tr>
<td></td>
<td>Chloramphenicol</td>
<td>cephalosporins</td>
</tr>
<tr>
<td></td>
<td>tetracycline</td>
<td></td>
</tr>
<tr>
<td>Gram negatives</td>
<td>Fluoroquinolones</td>
<td>penicillins</td>
</tr>
<tr>
<td></td>
<td>Aminoglycosides</td>
<td>cephalosporins</td>
</tr>
<tr>
<td>Anaerobes</td>
<td>metronidazole</td>
<td>trimethoprim/sulphas</td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

For some bacteria-drug interactions, bacterial growth remains suppressed for a period after drug concentration has decreased below the MIC. The PAE may be the reason that dosage regimens that fail to maintain drug concentration above the MIC are still efficacious. The PAE is dependent upon the antimicrobial and the bacterial pathogen.


**Concentration of the Antimicrobial**

Bacterial kill-curve studies show that antimicrobials can be categorized as concentration dependent bacterial killers or time-dependent bacterial killers.

For antimicrobials whose efficacy is concentration-dependent, high plasma concentration levels relative to the MIC of the pathogen are the major determinants of clinical efficacy. These drugs also have prolonged PAEs, thereby allowing long dosing intervals with maximum clinical efficacy.

<table>
<thead>
<tr>
<th>Concentration-Dependent</th>
<th>Time-Dependent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminoglycosides</td>
<td>Penicillins</td>
</tr>
<tr>
<td>Fluoroquinolones</td>
<td>Cephalosporins</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Other “static” antimicrobials</td>
</tr>
</tbody>
</table>

**Example:** You are treating a valuable embryo transfer bull calf with a Klebsiella pneumonia with gentamicin. The MIC of gentamicin for Klebsiella is 2 mcg/ml. The desired plasma concentration would be ten times the MIC at 20 mcg/ml. The Vd of gentamicin in the calf is 0.3 L/kg. The dose calculated is: \( \text{Dose} = (300 \text{ ml/kg}) \times (0.02 \text{ mg/ml}) = 6 \text{ mg/kg} \)

For time-dependent bacterial killers, the time during which the antimicrobial concentration exceeds the MIC of the pathogen determines clinical efficacy. The time above the MIC should be at least 50% for most patients, and should be closer to 100% for bacteriostatic drugs and for patients that are immunosuppressed. The bactericidal activity of time-dependent drugs does not increase with increasing plasma concentrations, once the MIC of the bacteria is exceeded.

**Designing the Drug Dosage Regimen**

Utilizing the previous information, antimicrobial dosage regimens are designed in one of two ways; either to maximize plasma concentration or to provide a plasma concentration above the bacterial MIC for most of the dosage interval.

For concentration-dependent killers with a prolonged PAE it is suggested that the peak plasma drug concentration be 8- to 10-fold higher than the MIC of the pathogen. If the Vd of the antimicrobial is known (can usually be found in Plumb’s Veterinary Drug Handbook), a precise drug dosage regimen for the pathogen can be calculated from the following equation: \( \text{Dose} = (\text{Vd}) \times (\text{desired plasma concentration}) \)

**Example:** You want to treat a calf with an E coli septicemia with florfenicol. While the MIC of florfenicol for Pasteurella spp. is only 1-2 mcg/ml, for E coli the MIC is 16 mcg/ml. Obviously, the label dose for BRD complex (20 mg/kg q 48 hr) is too low to target an E coli septicemia, so you would need to adjust the dosage regimen. In calves, the Vd of florfenicol is 1 L/kg and the elimination half-life is 18 hr. Because this is a serious infection, you would use a dosing interval of 24 hours and target plasma concentrations four times the MIC for E coli.

\( \text{Dose} = (0.064 \text{ mg/ml})(1000 \text{ ml/kg}) \times (1.44)(18 \text{ hr}) = 60 \text{ mg/kg} \)

For time-dependent killers, the objective is to keep the average plasma drug concentration above the pathogen’s MIC for the duration of the dosage interval. Again, utilizing Vd and elimination half-life information, you can precisely calculate a dosing regimen:

\( \text{Dose} = (\text{desired average plasma concentration}) \times (\text{Vd})(\text{dosage interval}) ÷ 1.44(\text{t/2}) \)
Site of the Infection

The pathophysiology of the infection will influence the distribution and activity of the antimicrobial drug. Abscess formation is a significant therapeutic problem for antimicrobial activity. The abscess wall limits penetration by non-lipid soluble drugs. The acidic environment encourages weak bases to accumulate but the low pH and the presence of cellular debris within the abscess may interfere with the activity of the antimicrobial.

Effectiveness Within Abscesses

<table>
<thead>
<tr>
<th>Very Effective</th>
<th>Moderately Effective</th>
<th>Ineffective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifampin</td>
<td>erythromycin (pH)</td>
<td>aminoglycosides (pH, debris)</td>
</tr>
<tr>
<td>florfenicol</td>
<td>fluoroquinolones (pH)</td>
<td>β-lactams (penetration)</td>
</tr>
<tr>
<td>tetracycline</td>
<td></td>
<td>trimethoprim/sulpha, (debris)</td>
</tr>
</tbody>
</table>

Limit Concurrent Use of Additional Antimicrobials

Combination antimicrobial therapy is commonplace in veterinary medicine, but combination therapy has rarely been demonstrated as superior to single drug therapy though clinical trials. Use of multiple antimicrobial drugs should be limited to:
1) known synergism against specific organisms
2) prevention of rapid development of bacterial resistance
3) to extend antimicrobial spectrum of initial therapy of life-threatening conditions
4) to treat mixed bacterial infections
5) non-synergistic or antagonistic combinations should be avoided (penicillin plus tetracycline, procaine penicillin G plus trimethoprim/sulfas)

Examples where concurrent use two antimicrobials may be warranted:
- β-lactam antibiotics and aminoglycosides are synergistic for treatment of enterococcal endocarditis
- Erythromycin and rifampin are used in combination to treat Rhodococcus equi infections to prevent the development of resistance
- β-lactams are used in combination with aminoglycosides or fluoroquinolones for life threatening septicemia or meningitis
- β-lactams are used in combination with aminoglycosides or fluoroquinolones for horses with pleuropneumonia because it commonly involves Strep. zooepidemicus, Gram negative and anaerobic pathogens

Principles of Prophylactic Use of Antimicrobial Drugs

1. The relative risk of infection must warrant the use of prophylactic antimicrobials. The risks of the prophylactic drug must be less that the risk of development of disease and its consequences. In veterinary medicine, most of the risk of infection depends on the skill of the surgeon and handling practices in the hospital.
2. The organism(s) that are likely to cause the infection and their antimicrobial susceptibility should be known or accurately predicted. At the WCVM, Pseudomonas aeruginosa is the most common cause of nosocomial infections. Its susceptibility pattern is variable between isolates.
Chapter 11 – The Selection and Prudent Use of Antimicrobial

3. The drug must be administered and must distribute to the site of potential infection before the onset of infection. Consider drugs that can be given intravenously and have a high volume of distribution.

4. Drugs used prophylactically should not be those that would be used therapeutically.

5. The duration of antimicrobial prophylaxis should be as abbreviated as possible. Most of the time, a single pre-operative dose is sufficient.

6. Drugs used prophylactically should have minimal adverse effects.

7. Theoretically, the selected dosage regimen should be bactericidal rather that bacteriostatic.

8. The selected protocol should be cost effective.

(The above section dealing with “Antimicrobial Therapy” is courtesy of Dr. Patricia M. Dowling, Professor of Veterinary Pharmacology, Western College of Veterinary Medicine, Saskatoon.)

CVMA Guidelines

Veterinarians, animal owners and animal caretakers all share responsibility for minimizing the use of antimicrobial drugs to conserve drug efficacy. Antimicrobial treatment regimes should be designed to maximize therapeutic efficacy while minimizing bacterial resistance.

Antibiotics used in animals should only be used within the confines of a valid VCPR. Veterinarians should continually update their knowledge of methods of disease prevention, new therapeutics and of other issues such as drug resistance trends, to ensure the prudent use of antimicrobials.

All users of antimicrobials should be educated in the proper use of antimicrobials including administration, handling, storage, disposal and record keeping. Veterinarians have a responsibility to educate staff, clients and other animal handlers on the prudent use of antimicrobials and for ensuring such training occurs.

Specific Principles

All antimicrobials, even those not purchased directly through or on prescription of a veterinarian should be used within the confines of a valid VCPR.

Animal owners and caretakers should be instructed in and encouraged to implement management, immunization, housing and nutritional programs that prevent or reduce the incidence of disease and therefore antimicrobial use.

Antimicrobials should only be used therapeutically if a pathogen is demonstrated or anticipated to be present, based on clinical signs, history, necropsy examinations, laboratory data (including resistance testing), and if the pathogen is expected to respond to treatment.

The need for prophylactic antimicrobials should be regularly assessed. Prophylactic antimicrobials should only be used when an animal(s) is determined to be at risk and evidence indicates that such usage reduces morbidity and/or mortality. Surgical protocols should emphasize strict aseptic technique instead of prophylactic antibiotics.

Antimicrobials should only be used to promote growth and feed efficiency if such use does not compromise therapeutic use in animals and people. Only those products currently approved should be used as growth promotants.
Antimicrobial selection should be based on the known or suspected target organisms, their known or predicted antimicrobial drug susceptibility, the site of infection, knowledge of the drug including its pharmacokinetic and pharmacodynamic properties, and other factors such as host immunocompetence. Antimicrobials that specifically target the pathogen should be selected over broader-spectrum agents and local therapy should be selected over systemic therapy when appropriate. Antimicrobials with unique mechanisms of action or novel resistance profiles in human medicine should not be used in veterinary medicine, particularly food animals, unless other antimicrobials by use or sensitivity testing have been shown to be ineffective and use of the other antimicrobials is considered to be lifesaving in the animal.

Antimicrobials approved for the treatment of the diagnosed condition should be used whenever possible. The dose, frequency and duration stated on the label should be followed whenever possible.

Combinations of antimicrobials, compounding of active pharmaceutical ingredients and extra-label usage of antimicrobials should be avoided unless safety and efficacy have been documented.

Antimicrobials should be used for the shortest time period required to reliably achieve a cure. This minimizes exposure of other bacterial populations to the antimicrobial.

Appropriate withdrawal times for antimicrobials used in animals intended for food should be adhered to.

Animals treated with antimicrobials may shed resistant bacteria into the environment. If possible, steps should be taken to minimize environmental contamination.

Antimicrobial products should be handled and stored properly. This includes proper disposal to avoid environmental contamination by the antimicrobial drug.

Veterinarians should alert any person handling antimicrobials of any potential risk to themselves and other species.
CHAPTER 12 – Adverse Drug Reactions
Report Form

Health Canada’s Veterinary Drugs Directorate (VDD) encourages veterinarians to report:

Adverse or unintended symptoms in animals after labeled or extra-label drug use; adverse symptoms in human exposed to veterinary products; and resistance, lack of efficacy, or decreased effectiveness. A Causal relationship does not have to be established prior to reporting a suspected adverse drug reaction. Reports may be made either to the drug manufacturer or to the VDD.

Reporting by veterinarians is voluntary, but it is an important contribution to the most accurate and up-to-date information on the safety and efficacy of a veterinary drug. 1-877-838-7322
## Dispensing Manual for Veterinarians

### Health Canada

- **Vet Drug Name:** [Dispensing Manual for Veterinarians](#)
- **Vet Drug Code:** [Dispensing Manual for Veterinarians](#)
- **Lot No.:** [Dispensing Manual for Veterinarians](#)
- **Expiry Date:** [Dispensing Manual for Veterinarians](#)
- **Drug Name:** [Dispensing Manual for Veterinarians](#)
- **Drug Code:** [Dispensing Manual for Veterinarians](#)
- **Drug Use:** [Dispensing Manual for Veterinarians](#)
- **Drug Form:** [Dispensing Manual for Veterinarians](#)

### Veterinary Drug Database

**Dispensing Manual for Veterinarians**

1. **Brand Name:** [Dispensing Manual for Veterinarians](#)
2. **Generic Name:** [Dispensing Manual for Veterinarians](#)
3. **Manufacturer:** [Dispensing Manual for Veterinarians](#)
4. **Lot No.:** [Dispensing Manual for Veterinarians](#)
5. **Expiry Date:** [Dispensing Manual for Veterinarians](#)
6. **Drug Name:** [Dispensing Manual for Veterinarians](#)
7. **Drug Use:** [Dispensing Manual for Veterinarians](#)
8. **Condition of Product:** [Dispensing Manual for Veterinarians](#)

### Veterinary Drug Information

1. **Animal Species:** [Dispensing Manual for Veterinarians](#)
2. **Age:** [Dispensing Manual for Veterinarians](#)
3. **Weight:** [Dispensing Manual for Veterinarians](#)
4. **Sex:** [Dispensing Manual for Veterinarians](#)
5. **Route of Administration:** [Dispensing Manual for Veterinarians](#)
6. **Other:** [Dispensing Manual for Veterinarians](#)

### Veterinary Drug Reaction

1. **Reason for Reaction:** [Dispensing Manual for Veterinarians](#)
2. **Reaction Description:** [Dispensing Manual for Veterinarians](#)
3. **Reaction Date:** [Dispensing Manual for Veterinarians](#)
4. **Reaction Time:** [Dispensing Manual for Veterinarians](#)
5. **Reaction Type:** [Dispensing Manual for Veterinarians](#)
6. **Reaction Severity:** [Dispensing Manual for Veterinarians](#)
7. **Reaction Cause:** [Dispensing Manual for Veterinarians](#)
8. **Reaction Treatment:** [Dispensing Manual for Veterinarians](#)

### Veterinary Drug Administration

1. **Veterinarian Name:** [Dispensing Manual for Veterinarians](#)
2. **Veterinarian Address:** [Dispensing Manual for Veterinarians](#)
3. **Telephones:** [Dispensing Manual for Veterinarians](#)
4. **Signature:** [Dispensing Manual for Veterinarians](#)
5. **Date:** [Dispensing Manual for Veterinarians](#)
This two-page form is available online at:
CHAPTER 13 – Adverse Reactions to Veterinary Biologics Form

This form is available online at:

http://www.inspection.gc.ca/animals/veterinary-biologics/guidelines-forms/3-15e/eng/1328599858279/1328600476085
CHAPTER 14 – Useful Websites

- CFIA Table of Contents: www.inspection.gc.ca/english/toce.shtml
- Agriculture and Agri-Food Canada - Programs and Services: www.agr.gc.ca/progser/index_e.phtml
- Veterinary Biologics available in Canada http://www.inspection.gc.ca/animals/veterinary-biologics/licensed-products/eng/1305488042307/1320704013875
- Veterinary Biologics Section - CFIA: www.inspection.gc.ca/english/animals/vetbio/vbpbve.shtml
- Medicated Feed ingredients - CFIA: www.inspection.gc.ca/animals/medicated-feed/ingredients/mibtoce.shtml
- Canadian Animal Health Network: www.cahnet.org
- United States Food and Drug Information - Center for Veterinary Medicine: www.fda.gov/cvm/default.html
- Food Animal Residue Avoidance Database: www.cfard.usask.ca
- Health Canada Website: www.hc-sc.gc.ca
- Human Drug Information: www.rxmed.com/index.html
- Government of Canada Phone Listings: http://www.servicecanada.gc.ca/eng/common/contactus/

Note: Listing of the websites above does not constitute an endorsement of their contents or their accuracy by the Saskatchewan Veterinary Medical Association.