CANADIAN VETERINARY MEDICAL ASSOCIATION

L'ASSOCIATION CANADIENNE DES MÉDECINS VÉTÉRINAIRES

VETERINARY OVERSIGHT OF ANTIMICROBIAL USE – A PAN-CANADIAN FRAMEWORK OF PROFESSIONAL STANDARDS FOR VETERINARIANS

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OBJECTIVE

The objective of this document is to provide a template of professional standards to be used by the Canadian provincial and territorial veterinary regulatory (licensing) bodies when developing their own regulations, guidelines, or bylaws relating to the veterinarians' professional responsibilities in providing oversight of the use of antimicrobials in all circumstances. The professional standards suggested in this document are not in themselves binding. However, the template is intended to lead to consistent regulations across the country.

VETERINARY OVERSIGHT

Veterinary oversight is a key element of antimicrobial stewardship. It encompasses the professional involvement of licensed veterinarians in providing guidance or direction for appropriate use of antimicrobials in animals with the objective of ensuring prudent use and minimizing the emergence or spread of antimicrobial resistance.

Veterinary oversight is the entire process or mechanism whereby veterinarians, through their education, experience and accountability, provide guidance or direction for appropriate use and distribution of antimicrobials.

Effective implementation is aimed at preventing and controlling the spread of antimicrobial-resistant infections, maintaining access to effective antimicrobials for animal health, improving animal health and welfare, consumer confidence, and public safety and meeting of phyto-sanitary standards involving trade.

OVERSIGHT OF VETERINARIANS

Veterinary medicine is a provincially regulated profession.

Each jurisdiction undertakes regulatory activities including: verification of credentials, compulsory registration with annual renewal, quality assurance programs, oversight of continuing education, inspection and certification of veterinary practices and a process to receive complaints and discipline registered veterinarians.

These regulatory activities provide a mechanism to ensure that veterinarians possess required credentials and are held accountable to meet the acceptable professional standards when overseeing the use of antimicrobials. A pan-Canadian template for credential recognition exists in the form of a labour mobility agreement signed by 10 provinces and two territories.

Provincial regulatory bodies provide consistent oversight of veterinarians engaged in prescribing and dispensing antimicrobials and pharmaceuticals.

RECOMMENDATION 1:

Respecting the autonomy of the respective regulatory (licensing) bodies, it is recommended that provincial and territorial regulatory (licensing) bodies undertake compliance measures involving practice inspection and verification of standards around veterinary oversight.

Regulatory (licensing) bodies have the authority to take action in cases where the veterinarian's conduct falls below the accepted professional standards.

PLAN

The Canadian Council of Veterinary Registrars (CCVR) recognizes the pivotal role that the regulatory bodies will play in implementation of increased veterinary oversight of antimicrobial use.

The Canadian Veterinary Medical Association (CVMA) is the national organization that represents the veterinary profession, liaises with and lobbies federal authorities regarding legislation of interest to the veterinary profession, and provides support for the provincial veterinary regulatory bodies in the form of administrative services to the CCVR.

The Veterinary Pharmaceutical Stewardship Advisory Group (VPSAG) is appointed by the CVMA Council to develop a policy framework for review by CVMA Council.

The CCVR and CVMA recognize the need for national uniformity of the professional standards (provincial regulation, bylaws, guidelines, codes) for veterinary oversight of the use of antimicrobials, while acknowledging and respecting provincial jurisdiction.

The CCVR has agreed, by way of motion to work collaboratively with the CVMA to develop a national framework on antimicrobial use.

The objective of the framework is to provide guidance to provincial and territorial regulatory (licensing) bodies as they develop their own by-laws, policies and guidelines in accordance with provincial legislation that regulates veterinarians when treating animals. This includes diagnosing, prescribing, using antimicrobials, dispensing, maintaining medical records and other stewardship requirements.

This document is drafted by the CVMA - VPSAG in collaboration with the CCVR. The CCVR working committee has reviewed the document.

Other stakeholders, primarily the National Farmed Animal Health and Welfare Council (NFAHWC), Public Health Agency of Canada (PHAC) and Health Canada's Veterinary Drugs Directorate (VDD), the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC) and the Council of Chief Veterinary Officers (CCVO) have received the document for review.

Stakeholder input was received and considered through 2015 and early 2016. The revised draft was distributed and was the subject of the CVMA Summit, held in Niagara Falls in July 2016.

BACKGROUND

Antimicrobial drugs are defined as any natural, semisynthetic, or synthetic substance capable of killing or inhibiting the growth of microorganisms. There are many types of these drugs, including antibiotics, antibacterial, antivirals, antifungals and antiparasitics.

For the purposes of this report, the term antimicrobial is used in a limited sense to refer only to those drugs used for the treatment of bacterial infections. While the principles apply and are also important for other antimicrobials (e.g. antivirals, antifungals, and antiparasitics), the greatest urgency and focus of current efforts is on antimicrobials used for bacterial infections.

Health care professionals, both in human and animal health rely on antimicrobials to treat, prevent and control infections.

However, the effectiveness of antimicrobials is declining due to the development and spread of resistance. While resistance can develop to all types of antimicrobials, the World Health Organization (WHO) considers the development of bacterial resistance to antimicrobials to be an urgent global concern.

The WHO urges the development and implementation of a comprehensive national strategy in all countries that includes actions that help:

- Reduce antimicrobial use and improve stewardship in humans and animals,
- Improve surveillance of antimicrobial resistance and antimicrobial use,
- Prevent and control the spread of drug-resistant infections, and
- Stimulate antimicrobial research and innovation.

The OIE (World Organization for Animal Health) highlights the importance of national antimicrobial resistance strategies.

The OIE Terrestrial Animal Code Chapter 6.9 deals with "*Responsible and prudent use of antimicrobial agents in veterinary medicine"* and provides guidance with the aim of protecting both animal and human health as well as the environment. It defines the respective responsibilities of the Competent Authority (as defined in the Code) and stakeholders such as veterinarians, the veterinary pharmaceutical industry, animal feed manufacturers, distributors and food animal producers who are involved in the authorization, production, control, importation, exportation, distribution and use of veterinary medicinal products (VMP) containing antimicrobial agents.

Responsible antimicrobial use with appropriate veterinary oversight aims to minimize the risk of selection for antimicrobial resistance. Veterinary oversight alone will not prevent antimicrobial resistance, as any use of antimicrobials can select for antimicrobial resistance. Ultimately, reducing antimicrobial use reduces the selection pressure for antimicrobial resistance.

REGULATORY RESPONSIBILITIES

In Canada, responsibilities for the regulation and responsible use of antimicrobial drugs are shared among federal, provincial and territorial governments, as well as with professional organizations, private industry and non-governmental organizations.

Identifying antimicrobial resistance as one of the highest public health risks facing Canadians, in 2014 the Public Health Agency of Canada (PHAC) developed a federal framework to address antimicrobial resistance. However, according to the Auditor General's Report, PHAC needs to mobilize the provinces, territories and other stakeholders in identifying priority actions, clarifying roles and responsibilities, and establishing clear and realistic deadlines for the development of a pan-Canadian strategy. Integration and coordination of activities at the federal and national levels would enhance the effectiveness of efforts to combat the threat of AMR in Canada.

Health Canada is the federal department responsible for pre-market evaluation/assessment and authorization of antimicrobial drugs for sale in Canada, monitoring the safety and effectiveness of approved products, and for ensuring that product labels provide up-to-date information on how these drugs should be used. However, Health Canada has no authority or control over the use of human or veterinary drugs once they have been approved for sale. Health Canada has a role in determining labelling requirements for prescription-only versus over the counter antimicrobials.

In March 2015, the Public Health Agency of Canada released a Federal Action Plan on AMR and antimicrobial use which will require by December 2016 that all use of medically important antimicrobials (Categories I, II, and III) administered to food animals in the feed or water require veterinary oversight. While all new medically important antimicrobials approved for use in animals since 2004 are prescription only status; old antimicrobials approved prior to the launch of Microbiological Safety Guidelines (2004) will now require increased veterinary oversight. The requirement for veterinary oversight of the use of all medically important antibiotics (MIA) in food animals is a historic change for Canada and an important additional responsibility for veterinarians to demonstrate improved stewardship of antibiotics. These changes are parallelling changes in the United States.

This document addresses the meaning of veterinary oversight to harmonize understanding across the provinces and territories, not only in food animals but in all species.

Legislative and regulatory actions of veterinary medical practitioners lie with the provinces and territories. Implementation of the respective provincial and territorial professional legislation lies with professional regulatory bodies in each province and territory, empowered by the legislation to register and oversee the practice of their members.

While being respectful of the autonomy of provincial and territorial legislatures and the provincially legislated veterinary regulatory bodies, there is an identified need to develop a pan-Canadian framework for veterinary medical professionals in regards to antimicrobial stewardship. While implementation through by-laws and policies remains a provincial/territorial responsibility there is critical need for national agreement and uniformity. The harmonization of veterinary oversight of antimicrobial use in Canada serves to emphasize the national and international responsibility of the veterinary community in mitigating antimicrobial resistance.

ANTIMICROBIAL STEWARDSHIP

In October 2014, the Federal government released *Antimicrobial Resistance and Use in Canada: A Federal Framework for Action*. This document serves as a starting point for a national collaborative response to the threat of Antimicrobial Resistance (AMR). The goal of the Framework is: "To protect Canadians from the health risks related to antimicrobial resistance."

The framework identifies three pillars: Surveillance, Stewardship, and Innovation.

While veterinarians play an integral role in all three of these areas, antimicrobial stewardship is a primary responsibility of the veterinary profession which is regulated under provincial authority.

The term Antimicrobial Stewardship has been used to describe the multifaceted and dynamic approaches required to sustain clinical efficacy of antimicrobials by optimizing drug use through alternatives including vaccination, management changes, facility changes and antimicrobial alternatives. When antimicrobials are required, antimicrobial stewardship describes the optimizing of the choice, dosing, duration, and route of administration, while minimizing the emergence of resistance and other adverse effects. Stewardship is an active, dynamic process of continuous improvement, involving a 5Rs approach of: responsibility, reduction, refinement, replacement and review.

Stewardship-related actions are those that conserve the effectiveness and longevity of antimicrobials by ensuring use of the most appropriate antimicrobial use in each case, and by reducing unnecessary usage of antimicrobials in both humans and animals. While strong stewardship activities need to be practised by all relevant players, the veterinary profession has the obligation and capacity to support stewardship throughout the profession, in all provinces and territories.

Developing optimum stewardship practices is essential to animal and public health, maintaining access to and effectiveness of antimicrobials for the treatment and prevention of disease in animals and to upholding the integrity of the veterinary profession. Antimicrobial stewardship in veterinary medical practice is in the public interest and consequently needs to be a high priority for veterinary regulatory bodies that are charged with the responsibility of protection of the public.

ROLE OF THE VETERINARIAN IN ANTIMICROBIAL STEWARDSHIP

By virtue of their education, experience and accountability to the public through provincial registration, veterinarians are qualified to serve the public interest by providing for the health care needs of animals.

Veterinarians undertake the activities of disease prevention, diagnosing, prescribing and the use and dispensing of medications in the practice of veterinary medicine.

Veterinarians engage in various practice types, including private and public practice and provide care for an extensive number of animal species. In all situations, their professional practice activities must be cognizant of the principles of antimicrobial stewardship.

The obligations of veterinarians include, but are not limited to:

Disease Prevention and Control- The veterinarian's role of working with clients and their animals to ensure optimum health and thus reduce the need for antimicrobials embraces a wide range of consultation and services involving good animal husbandry, including: biosecurity, nutrition, vaccination protocols, housing, genetic selection, parasite and pest control programs, reproduction, neonatal management, weaning management and other essential activities. The veterinarian must obtain enough relevant information so as to be knowledgeable of imminent disease hazards prior to establishing a disease prevention plan and prescribing preventative medication.

Evidence Informed/Based Diagnosis of Disease -When presented with a sick animal (individual or herd/flock) the veterinarian must take the necessary steps to gather enough relevant medical knowledge and production or performance-related information to establish an evidence-based diagnosis or presumptive diagnosis.

Prescribing Treatment for Disease - When a disease is diagnosed, reasonably suspected or anticipated, based on professional evaluation of the evidence at hand, the veterinarian must prescribe the most appropriate treatment. This decision must consider whether antimicrobials are to be used or not. If antimicrobials are to be prescribed, the veterinarian must use professional judgment in determining the correct treatment. Such professional considerations include: relevant diagnostic information (including cultures and sensitivity where appropriate) which drug is most effective, a duration of treatment that is both as long as necessary and as short a time as possible, using the appropriate dosage, and using the appropriate route of administration. Prudent use considerations also include a decision cascade that balances usefulness to the patient with risk to public health and antimicrobial resistance, based on category of antibiotic chosen. The categories of medically important antimicrobials defined by Health Canada are described below on page 18.

The decision on treatment using an antimicrobial may be directed by the species specific CVMA Antimicrobial Prudent Use Guidelines 2008.

The responsibility of the veterinarian when prescribing treatment for an animal may be summarized as: Right Drug, for the Right Reason, to the Right Patient, at the Right Dose, by the Right Route, at the Right Time, for the Right Duration, and with the Right Records.

Follow up on Treatment - It is the responsibility of the prescribing veterinarian to ensure that the prescribed pharmaceuticals are used properly. This includes client training and education on appropriate use, handling and storage and being available in the event of treatment failure or adverse reactions.

Dispensing of Pharmaceuticals - Dispensing is a professional practice activity that is performed by a registered veterinarian. The professional dispensing the product must ensure the accuracy

and validity of the prescription as well as inform and educate the person receiving the prescribed medications.

Create and Maintain Records - Veterinarians are required to maintain records of all client and patient interactions. This includes the investigation undertaken to establish medical need and documentation of all field and/or laboratory test results and prescribing and dispensing activities. In the future, veterinarians will be expected to appropriately contribute data to official surveillance programs as required by legislation.

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VETERINARIAN CLIENT PATIENT RELATIONSHIP (VCPR)

WHAT IS A VCPR?

A legitimate VCPR is only considered to exist if medical records of the practice contain sufficient evidence of relevant and timely interaction between the veterinarian, animal owner and animal patients.

These interactions may include, but are not limited to: farm or home visits, clinic appointments, consultations, direct animal examinations (individual or herd/flock), laboratory reports, production record reviews, etc.

The VCPR is documented evidence that the veterinarian has undertaken the steps necessary to establish medical need and consequently prescribe and subsequently dispense pharmaceuticals.

The VCPR is not a signed contractual agreement but rather a working connection and interaction between veterinarian, client and specific animal patient or group of animals.

The VCPR is not in of itself an entitlement to prescribe and subsequently dispense.

PROVINCIAL AND TERRITORIAL DEFINITIONS OF VCPR

Each provincial and territorial veterinary statutory body has their own definition of VCPR in provincial legislation. A review of the various VCPR definitions has demonstrated that there are not significant differences in the meaning and intent of the VCPR.

For the purpose of this document and a national understanding of the meaning of VCPR, the following definition of VCPR, modified from the *CVMA Antimicrobial Prudent Use Guidelines (2008)* is considered to be consistent with provincial legislation and is accepted.

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

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

2. The veterinarian has sufficient knowledge of the animal(s) on which to base the assessment, diagnosis and treatment of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) are kept.

3. The client has agreed to follow the veterinarian's recommendations and prescription.

4. The veterinarian is available or has arranged for follow-up evaluation, especially in the event of adverse reactions or failure of the treatment regimen.

PRESCRIBING AND DISPENSING

A veterinarian has the professional responsibility to undertake the following practice activities when directing the use of all antimicrobial products, regardless of their classification by Health Canada or route of administration.

PRESCRIBING

Veterinarians are entitled to prescribe drugs pursuant to the federal *Food and Drugs Regulations*.

PRESCRIPTION DEFINITION

A prescription is an evidence-based or informed order by a veterinarian directing that a specific animal patient or group of animals, be administered a specified drug, via an appropriate route of administration, in a defined dosage for a limited time in order to treat or prevent an identified disease.

The term prescription must be used correctly. A prescription is not the actual drug that is dispensed nor is it the piece of paper upon which the registered veterinarian's orders are written.

SUGGESTED STANDARD 1:

All antimicrobial drugs that are dispensed by a registered veterinarian regardless of their designation as prescribed by Health Canada or route of administration shall only be dispensed pursuant to a valid prescription issued by a veterinarian.

Accepting that all medically important antimicrobial products in animals must only be used under veterinary oversight, the following standards must be adhered to.

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

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

1. Establish a Valid VCPR

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

2. Make an Evidence-Based Determination of Medical Need

It is the responsibility of the registered veterinarian to make an informed decision that a particular drug will be prescribed. This may require a change in the culture of use of antimicrobials where animal owners or producers may be accustomed to requesting a particular antimicrobial for prevention, control or treatment of disease.

It is expected that the decision to use an antimicrobial is evidence-based or informed and the evidence results from some appropriate form of investigation conducted by the veterinarian. The information that the veterinarian relies upon will vary considerably given the practice type, species and production system of the animals for which the antimicrobial is prescribed.

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

A registered veterinarian may use other forms of investigation and information related to antimicrobials to make or support an evidence-based diagnosis and decision on treatment. These include culture and sensitivity testing, laboratory reports, production data, necropsy results or histology, bacteriology or virology results, review of the scientific literature and data from in-house trials, and a review of past treatment records.

It is not necessary that an individual animal is examined in every instance that a veterinarian issues a prescription. Veterinarians may appropriately prescribe antimicrobials based on examination and/or knowledge of a group of animals. It is required that the veterinarian in every instance has relevant medical knowledge to determine the medical need.

NOTE: Treatment Protocol

A treatment protocol is not a prescription and does not authorize dispensing of pharmaceuticals.

An animal health protocol is a detailed series of specific steps to be undertaken as a result of a specific scenario. The protocol defines the disease condition, specific signs of the disease, steps to be undertaken to investigate further and any treatment(s) to be administered.

An animal health protocol may include a step that requires the administration of a prescription drug such as an antimicrobial. A legitimate prescription must be issued for the prescription drug.

An animal health protocol established by the veterinarian may be used to determine the medical need for a drug prescribed as part of the protocol.

3. Complete Appropriate Documentation in the Medical Record

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

SUGGESTED STANDARD 2:

Medical records created and maintained by veterinarians for all practice types shall contain sufficient information entered into the record regarding the history, consultations, laboratory

investigations and physical examination findings to justify the prescription and use of the antimicrobial. A precise diagnosis or purpose for use of the antimicrobial must be recorded.

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

- **All prescriptions generated (including feed prescriptions) for the specific animal or group of animals[1] , supported with specific evidence of establishment of medical need.**

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

- **All medication dispensed or sold for the animal or group of animals and evidence that a valid prescription is on file.**

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

Records that document individual animal treatments maintained on any farm, production or other group unit are only in addition to the medical records maintained by the veterinarian. Individual animal treatment records are not required to be duplicated in the veterinarians' medical records if a prescription is issued on a group or herd basis.

Individual animal record or herd records maintained on any farm, production or other group which are in addition to the medical records maintained by the veterinarian will not be subject to audit by the regulatory authority.

[1] *A group of animals may be defined by criteria such as the date of acquisition or arrival into the facility, sex, age, weight, location in a production facility, the source of the animals, health status or disease risk.*

DOCUMENTING THE PRESCRIPTION

The prescription must be specific to an individual animal or identified group of animals.

A prescription must be written, and the following information must be documented in the written prescription provided to the client and / or in the prescribing veterinarian's medical record.

- Prescribing veterinarian and certified veterinary facility, and contact information,
- Patient owner/agent (client),
- Date of prescription,
- Individual or group animal identification
- Disease diagnosed, or purpose of use
- Name of drug prescribed and concentration,
- Quantity of drug,
- Directions for Use, including Dose, Frequency, and Duration,
- Route of administration,
- Substitution (yes or no) of same drug (different brand name)[2],
- Number of refills (implies zero if not indicated),
- Withdrawal time,
- Signature of the veterinarian.

For prescriptions regarding medically important antimicrobials to be administered via feed, the following information is also required:

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

4. Provide Oversight of Use and Follow Up

The accepted definition of VCPR specifically dictates that the registered veterinarian who is responsible for making the medical decisions with regards to an animal or group of animals

must be available for follow up or have arranged a designated alternate. This obligation extends to the prescription of any pharmaceuticals including antimicrobials.

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

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

DISPENSING

DISPENSING DEFINITION

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

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

Dispensing is an activity that is separate and distinct from that of issuing a prescription (prescribing).

The acts of prescribing and dispensing are commonly performed as an integrated activity in veterinary practice.

SUGGESTED STANDARD 3:

The responsibilities to be performed by the registered veterinarian when dispensing are:

- **confirm the identification of the client and establish and maintain an appropriate dispensing record for each client/patient as part of the medical record,**
- **obtain and confirm the accuracy of the original prescription and refill information,**
- **maintain the original prescription in the dispensing record, (this may already be documented in the medical record),**
- **confirm the identity and registration of the prescribing veterinarian,**
- **confirm the validity or reasonableness of the prescription,**
- **immediately transcribe to a written prescription any prescription taken over the phone,**

- **reject the prescription and not dispense any medications if the prescription is not valid, not reasonable, or improper. The situation may be rectified by calling the prescribing veterinarian for clarification and confirmation of the prescription,**
- **confirm any substitutions of a specific medication for a generic medication with the prescribing veterinarian and animal owner,**
- **provide the client with all necessary information regarding the use, storage and safety of the product,**
- **maintain a declining balance of refills,**
- **forward available or remaining totals to other dispensing locations if requested by the client, and**
- **refuse to provide additional refills when the prescription is finished.**

LABELLING

All dispensed products must have dispensing labels in addition to the manufacturer's label.

SUGGESTED STANDARD 4:

All dispensed pharmaceuticals must be appropriately labelled. The following information must appear on the label affixed to dispensed products. The information may be provided on the dispensing label and/or the manufacturer's label.

- **The words "Veterinary Use Only" must appear on the main panel of both inner and outer package labels, immediately following or proceeding the proprietary or brand name, proper name or common name, in type not less than one half as large as the largest type on the label.**

- **The name of the client,**
- **The names of the facility and the veterinarian prescribing the drug,**
- **The names of the facility and the veterinarian dispensing the drug,**
- **Identification of the animal or group of animals,**
- **The name of the drug dispensed and its concentration,**
- **The Drug Identification Number (DIN),**
- **The quantity of the drug dispensed,**
- **Directions for Use in the identified animal or group of animals, including Dose, Frequency, and Duration as prescribed,**
- **Minimal withdrawal time (where applicable) as prescribed,**
- **Storage precautions,**
- **Any toxic warnings or other precautions appearing on the original label, and**
- **Any other information required by legislation.**

Each using unit of product must be labelled by the dispensing facility. If units of medication are dispensed by the bottle, each bottle must have a label. If units are dispensed in a case lot, each case must display the label.

The obligation to maintain records of dispensing including the labelling may be facilitated with the use of commercially available or proprietary computer software.

DISPENSING RECORD AUDIT

A veterinary regulatory (licensing) body may undertake audit of pharmaceutical sales from veterinary practices.

SUGGESTED STANDARD 5:

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

- **A dispensing record of the appropriate dispensing, including the labelling,**
- **A record of the prescription, either:**
  - **medical record entries if prescribed by a veterinarian in the same practice where the pharmaceutical was sold, or**
  - **the original prescription from another registered veterinarian**
- **A medical record of the investigation that was undertaken to determine the medical need if the prescribing veterinarian is working in the practice that dispensed the pharmaceutical.**

The veterinarian must be able to demonstrate that for each prescription drug appearing on an invoice as sold, there exists a valid prescription, which in turn has documented evidence of established medical need, as described in the section above.

TRANSPARENCY

TRANSPARENCY OF PRESCRIBING AND DISPENSING

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

Recognizing the potential conflict of interest that exists, the process of prescribing and dispensing of pharmaceuticals must be transparent. The client's choice to have a prescription filled wherever they may legally do so must be maintained and respected. Any action that would result in a client being forced or persuaded to purchase their pharmaceuticals from a particular location would justify claims of conflict of interest.

Veterinary pharmaceutical companies often offer purchase incentives to veterinarians through loyalty programs. Veterinarians should not be influenced by corporate loyalty programs offered by pharmaceutical companies when prescribing pharmaceuticals.

SUGGESTED STANDARD 6:

A registered veterinarian who has determined the medical need and appropriately issued a prescription must provide a copy of this prescription to the client if the client requests to access the medication from a legitimate source other than the prescribing veterinarian.

Veterinary regulatory (licensing) bodies will provide oversight of veterinary professionals prescribing and dispensing activities to identify and address unwarranted prescribing.

CATEGORIZATION OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS

Applying good stewardship practices to antimicrobial selection requires consideration of the Health Canada categorization of medically important antimicrobials.

First choice should be a VDD approved veterinary drug, on-label or ELDU. The drug that has evidence based efficacy and is in the category of least importance in human medicine should normally be selected as the first choice, unless medical requirements dictate otherwise. In instances where ELDU results in the use of a category of drug of lower importance to human medicine, ELDU may be preferable to on-label use.

Health Canada categorizes antimicrobial drugs based on their importance in human medicine. The principal criteria considered for this categorization process are the indication (use in human medicine, spectrum of activity and efficacy) and the availability of alternative antimicrobials for the treatment of infections in human medicine.

Version – April 2009

Category I: Very High Importance

These antimicrobials are considered of very high importance in human medicine as they meet the criteria of being essential for the treatment of serious bacterial infections and limited or no availability of alternative antimicrobials for effective treatment in case of emergence of resistance to these agents.

Category II: High Importance

Antimicrobials in this category consist of those that can be used to treat a variety of infections including serious infections and for which alternatives are generally available. Bacteria resistant to drugs of this category are generally susceptible to Category I drugs which could be used as the alternatives.

Category III: Medium Importance

Antimicrobials in this category are used for treatment of bacterial infections for which alternatives are generally available. Infections caused by bacteria resistant to these drugs can, in general, be treated by Category II or I antimicrobials.

Category IV: Low Importance

Antimicrobials in this category are currently not used in human medicine.

EXTRA-LABEL DRUG USE

In the interest of protecting animal health and welfare, veterinarians' right to prescribe extra-label drug use (ELDU) must be maintained. Situations where the treatment of animals requires ELDU may arise, and may include antimicrobials for use in animal species where an approved antimicrobial does not exist, or at a dose that is appropriate given the disease condition.

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

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

A prescription for a medically important antimicrobial to be administered via feed must be issued for medications in accordance with the indications, species, dosage, treatment durations and withdrawal times specified in the Medicating Ingredient Brochure (MIB).

A feed prescription issued for an antimicrobial or for other medications not listed in the Compendium of Medicating Ingredient Brochures (CMIB) or for a species, dosage, duration or withdrawal time not listed in the specified MIB, is considered extra-label drug use and must only be used in exceptional circumstances, such as minor species use where no MIB listing exists.

The veterinarian issuing any ELDU prescription for food-producing animals is required to comply with the CVMA Antimicrobial Prudent Use Guidelines (2008) which state:

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

The veterinarian may rely on other relevant information and advice.

SUGGESTED STANDARD 7:

Veterinarians may prescribe a Health Canada approved product (veterinary or human) for a species, at a dose or for an indication not on the label, provided there is no suitable on-label product available. It is recognized that ELDU is necessary to protect health and welfare in minor use species.

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

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

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

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

ACTIVE PHARMACEUTICAL INGREDIENTS (API)

ACTIVE PHARMACEUTICAL INGREDIENT (API) DEFINITION:

Health Canada defines APIs as a substance or a mixture of substances intended to be used in the manufacture of a drug after which they become "active ingredients" of the drug product. APIs are not approved to be used directly as drugs.

'Dose form' is considered to be the administration of a raw chemical directly to the animal without first manufacturing or compounding the chemical into an acceptable format for administration.

SUGGESTED STANDARD 8:

Veterinarians must not prescribe or use APIs in dose form.

COMPOUNDING

COMPOUNDING DEFINITION:

As defined in the CVMA Prudent Use Guidelines, *compounding is the combining or mixing together of two or more ingredients (of which at least one is a drug or pharmacologically active component) to create a final product in an appropriate form for dosing.*

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

Compounding of drugs is considered extra-label drug use.

When no approved products (veterinary or human) exist, veterinarians may prescribe that a drug be compounded for a specific animal or group of animals. Compounding drugs for inventory and subsequent sale is considered manufacturing and not in compliance with Health Canada regulations and consequently is not permitted.

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

SUGGESTED STANDARD 9:

When no appropriate approved products (veterinary or human) exist, veterinarians may prescribe that drugs be compounded for use for a specific animal or group of animals provided the veterinarian has adequate medical justification for the prescription.

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

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

Veterinarians must not prescribe or use active pharmaceutical ingredients (API) of medically important antimicrobials.

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

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

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

DECISION CASCADE FOR ANTIMICROBIAL USE

RECOMMENDATION 2:

That the CVMA and the CCVR work to develop a decision cascade for antimicrobial use to guide the veterinarians' decisions in prescribing antimicrobials in the best interest of human and animal health.

ANTIMICROBIAL USE SURVEILLANCE

Veterinarians are required to create and maintain medical records of all antimicrobial prescribing, use and dispensing as outlined in this document.

Surveillance of antimicrobial use is necessary for understanding and mitigating the risk of antimicrobial resistance.

SUGGESTED STANDARD 10:

Veterinarians will participate in programs of antimicrobial use surveillance required by legislation, and provide surveillance data in compliance with provincial or territorial legislation.

Veterinarians must ensure client confidentiality is protected.

The Federal Action Plan calls for the CFIA to take the lead on developing a National Antimicrobial Use Surveillance System. It is contemplated that provincial legislation will be required to permit veterinarians to disclose client information regarding antimicrobial prescribing and use. The details of an antimicrobial use surveillance system have not been established.

RECOMMENDATION 3:

The CVMA and CCVR work with the federal, provincial and territorial governments to explore a regulatory framework for mandatory reporting of antimicrobial use on the order of veterinarians to a provincial and/or national surveillance program.

CONTINUING EDUCATION

Veterinary statutory bodies are responsible for establishing the policy, guidelines and regulations for oversight of antimicrobials, and ensuring compliance.

Informing veterinarians of their responsibility to adhere to these standards and providing opportunities or requirements for education are essential to gaining compliance with these changes in veterinary oversight.

Veterinary regulatory bodies are encouraged to develop tools for stewardship education of veterinarians.

Veterinary regulatory bodies should verify the continuing education regarding antimicrobial prescribing and use by all veterinarians.

RECOMMENDATION 4:

The CVMA and CCVR develop appropriate continuing education opportunities for veterinary professionals regarding antimicrobial stewardship.

LIST OF RECOMMENDATIONS

RECOMMENDATION 1:

Respecting the autonomy of the respective regulatory (licensing) bodies, it is recommended that provincial and territorial regulatory (licensing) bodies undertake compliance measures involving practice inspection and verification of standards around veterinary oversight.

Regulatory (licensing) bodies have the authority to take action in cases where the veterinarian's conduct falls below the accepted professional standards.

RECOMMENDATION 2:

That the CVMA and the CCVR work to develop a decision cascade for antimicrobial use to guide the veterinarians' decisions in prescribing antimicrobials in the best interest of human and animal health.

RECOMMENDATION 3:

The CVMA and CCVR work with the federal, provincial and territorial governments to explore a regulatory framework for mandatory reporting of antimicrobial use on the order of veterinarians to a provincial and/or national surveillance program.

RECOMMENDATION 4:

The CVMA and CCVR develop appropriate continuing education opportunities for veterinary professionals regarding antimicrobial stewardship.

LIST OF SUGGESTED STANDARDS FOR VETERINARY REGULATORY BODIES

SUGGESTED STANDARD 1:

All antimicrobial drugs that are dispensed by a registered veterinarian regardless of their designation as prescribed by Health Canada or route of administration shall only be dispensed pursuant to a valid prescription issued by a veterinarian.

Accepting that all medically important antimicrobial products in animals must only be used under veterinary oversight, the following standards must be adhered to.

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

5. **Establish and meet conditions of a valid Veterinarian Client Patient Relationship (VCPR) in regards to the specific animal or group of animals**
6. **Make an evidence-based determination of medical need**
7. **Complete appropriate documentation in the medical record**
8. **Provide oversight of use and follow up**

SUGGESTED STANDARD 2:

Medical records created and maintained by veterinarians for all practice types shall contain sufficient information entered into the record regarding the history, consultations, laboratory investigations and physical examination findings to justify the prescription and use of the antimicrobial. A precise diagnosis or purpose for use of the antimicrobial must be recorded.

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

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

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

All medication dispensed or sold for the animal or group of animals and evidence that a valid prescription is on file.

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

Records that document individual animal treatments maintained on any farm, production or other group unit are only in addition to the medical records maintained by the veterinarian. Individual animal treatment records are not required to be duplicated in the veterinarians' medical records if a prescription is issued on a group or herd basis.

Individual animal record or herd records maintained on any farm, production or other group which are in addition to the medical records maintained by the veterinarian will not be subject to audit by the regulatory authority.

SUGGESTED STANDARD 3:

The responsibilities to be performed by the registered veterinarian when dispensing are:

- **confirm the identification of the client and establish and maintain an appropriate dispensing record for each client/patient as part of the medical record,**
- **obtain and confirm the accuracy of the original prescription and refill information,**
- **maintain the original prescription in the dispensing record, (this may already be documented in the medical record),**
- **confirm the identity and registration of the prescribing veterinarian,**
- **confirm the validity or reasonableness of the prescription,**
- **immediately transcribe to a written prescription any prescription taken over the phone,**
- **reject the prescription and not dispense any medications if the prescription is not valid, not reasonable, or improper. The situation may be rectified by calling the prescribing veterinarian for clarification and confirmation of the prescription,**
- **confirm any substitutions of a specific medication for a generic medication with the prescribing veterinarian and animal owner,**
- **provide the client with all necessary information regarding the use, storage and safety of the product,**
- **maintain a declining balance of refills,**
- **forward available or remaining totals to other dispensing locations if requested by the client, and**
- **refuse to provide additional refills when the prescription is finished.**

SUGGESTED STANDARD 4:

All dispensed pharmaceuticals must be appropriately labelled. The following information must appear on the label affixed to dispensed products. The information may be provided on the dispensing label and/or the manufacturer's label.

- **The words "Veterinary Use Only" must appear on the main panel of both inner and outer package labels, immediately following or proceeding the proprietary or brand name, proper name or common name, in type not less than one half as large as the largest type on the label.**

- **The name of the client,**
- **The names of the facility and the veterinarian prescribing the drug,**
- **The names of the facility and the veterinarian dispensing the drug,**
- **Identification of the animal or group of animals,**
- **The name of the drug dispensed and its concentration,**
- **The Drug Identification Number (DIN),**
- **The quantity of the drug dispensed,**
- **Directions for Use in the identified animal or group of animals, including Dose, Frequency, and Duration as prescribed,**
- **Minimal withdrawal time (where applicable) as prescribed,**
- **Storage precautions,**
- **Any toxic warnings or other precautions appearing on the original label, and**
- **Any other information required by legislation.**

Each using unit of product must be labelled by the dispensing facility. If units of medication are dispensed by the bottle, each bottle must have a label. If units are dispensed in a case lot, each case must display the label.

The obligation to maintain records of dispensing including the labelling may be facilitated with the use of commercially available or proprietary computer software.

SUGGESTED STANDARD 5:

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

- **A dispensing record of the appropriate dispensing, including the labelling,**
- **A record of the prescription, either:**
  - **medical record entries if prescribed by a veterinarian in the same practice where the pharmaceutical was sold, or**
  - **the original prescription from another registered veterinarian**
- **A medical record of the investigation that was undertaken to determine the medical need if the prescribing veterinarian is working in the practice that dispensed the pharmaceutical.**

SUGGESTED STANDARD 6:

A registered veterinarian who has determined the medical need and appropriately issued a prescription must provide a copy of this prescription to the client if the client requests to access the medication from a legitimate source other than the prescribing veterinarian.

Veterinary regulatory (licensing) bodies will provide oversight of veterinary professionals prescribing and dispensing activities to identify and address unwarranted prescribing.

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CANADIAN VETERINARY MEDICAL ASSOCIATION
L'ASSOCIATION CANADIENNE DES MÉDECINS VÉTÉRINAIRES

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LIST OF ABBREVIATIONS

AAF - Alberta Agriculture and Forestry
AAFC - Agriculture and Agri-Food Canada
ABVMA – Alberta Veterinary Medical Association
AMR – Antimicrobial Resistance
AMU – Antimicrobial Use
ANAC - Animal Nutrition Association of Canada
API - Active Pharmaceutical Ingredients
CCVO – Council of Chief Veterinary Officers
CCVR – Canadian Council of Veterinary Registrars
CFIA – Canadian Food Inspection Agency
CgFARAD – Canadian Global Food Animal Residue Avoidance Databank
CVMA – Canadian veterinary Medical Association
CVO – College of Veterinarians of Ontario
DIN - Drug Identification Number
ELDU – Extra Label Drug use
MIA – Medically Important Antimicrobials
CMIB – Compendium of Medicating Ingredient Brochures
NFAHWC – National Farmed Animal Health and Welfare Council
OIE - World Organization for Animal Health
OMVQ – Ordre des médecins vétérinaires du Québec
OUI – Own Use Importation
PHAC – Public Health Agency of Canada
VCPR – Veterinarian Client Patient Relationship
VDD – Health Canada's Veterinary Drug Directorate
VMP – Veterinary Medicinal Products
VPSAG – Veterinary Pharmaceutical Stewardship Advisory Group
WHO – World Health Organization