

## Federal Policy Changes re: Antimicrobial Prescription Drugs

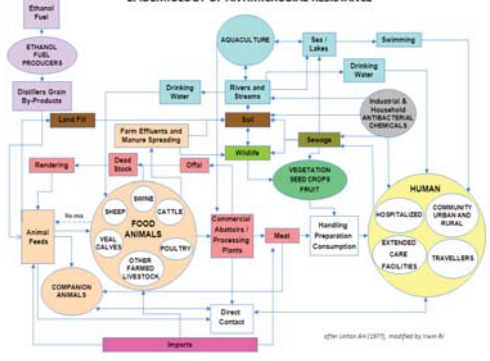


Dr. Keith Lehman  
Alberta Agriculture and Forestry  
November 3, 2018

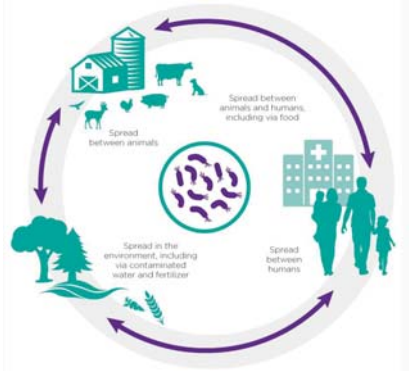
## Outline

- **Background and What's Changing**
  - One Health Challenge
  - Terminology
  - What is AMR and why is it important?
  - What changes are happening?
  - What will this mean to producers?
- **Veterinary Oversight**

### EPIDEMIOLOGY OF ANTIMICROBIAL RESISTANCE



### One Health Challenge



## Antimicrobial Resistance (AMR)

- **Antimicrobial = antibiotic**
  - Drugs that treat bacterial infections
- **Medically Important Antimicrobial (MIA)**



## Medically Important Antimicrobials

Category	Preferred choice for serious human infection	No or limited alternatives available	Examples
I – Very High Importance	Yes	Yes	ceftiofur, enrofloxacin
II – High Importance	Yes	No	tylosin, penicillin, lincomycin, streptomycin, tylothromycin
III – Medium Importance	No	No/Yes	tetracyclines, sulfas, florfenicol
IV – Low Importance	Not applicable	Not applicable	ionophores

Source: Health Canada Veterinary Drugs Directorate

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## Antimicrobial Resistance (AMR)

- **Antimicrobial resistance (AMR)**
  - When bacteria resist the killing effects of antimicrobials
- **Antimicrobial use selects for resistant bacteria/resistance genes**
  - More use can translate to a higher proportion of resistant bacteria in the population

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## Antimicrobial Resistance (AMR)

- 1 Bacteria cause an infection
- 2 Antibiotics are given to kill the bacteria
- 3 Some bacteria that cause illness resist the antibiotic treatment
- 4 Resistant bacteria continue to multiply and cause infection requiring antibiotics to treat and stop the spread of infection

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## AMR – Sir Alexander Fleming

- **Regarding Penicillin – 1945 Nobel Prize speech:**
  - *“The time may come when penicillin can be bought by anyone in the shops. Then there is the danger that the ignorant man may easily underdose himself and by exposing his microbes to non-lethal quantities of the drug make them resistant.”*

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Review on Antimicrobial Resistance

**By 2050, report estimates:**

- Annual burden of deaths from AMR = 10 million
- Cumulative cost of AMR to global economic output of \$100 trillion (USD)

**TACKLING DRUG-RESISTANT INFECTIONS GLOBALLY: FINAL REPORT AND RECOMMENDATIONS**

THE REVIEW ON ANTIMICROBIAL RESISTANCE  
CHAIRIED BY JIM O'NEILL

amr-review.org

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## Maryn McKenna Ted Talk:

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## World Health Organization (WHO)

- Mitigate adverse human health consequences
- Evidence based recommendations and best practices

WHO GUIDELINES ON USE OF MEDICALLY IMPORTANT ANTIMICROBIALS IN FOOD-PRODUCING ANIMALS

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## WHO Recommendations

- **overall reduction** in use of all classes of medically important antimicrobials **in food-producing animals**
- **complete restriction** of use of all classes of medically important antimicrobials in food-producing animals **for growth promotion**
- **complete restriction** of use of all classes of medically important antimicrobials in food-producing animals for **prevention of infectious diseases** that have not yet been clinically diagnosed

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## WHO Recommendations

- antimicrobials classified as **critically important** for human medicine should **not be used for control of the dissemination** of a clinically diagnosed infectious disease identified within a group of food-producing animals
- antimicrobials classified as **highest priority critically important** for human medicine should **not be used for treatment of food-producing animals** with a clinically diagnosed infectious disease

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## Health Canada Changes

November 13, 2017

1. **Increasing oversight over importation**
2. Access to low risk veterinary health products

May 17, 2018

1. Increasing oversight over active pharmaceutical ingredients

March 31, 2019

1. Mandatory reporting of sales volumes

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## Health Canada Changes

December 1, 2018

1. Removing growth promotion claims
2. **Moving all medically important antimicrobials to the prescription drug list**



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## Responsible Use Logo



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## What will this all mean?

- Effective December 1, 2018, producers will require a veterinary prescription to obtain all medically important antimicrobials.
- Pursuant to a prescription, those drugs will be available through veterinary clinics, pharmacies, and commercial feed mills in the case of medicated feeds.



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## In Feed Use

- Prescription signed by a veterinarian will be required to be presented at the Feed Mill before the sale of MIA medicated feed
- DIN Drug vs Micro/Macro-mix; Complete Feed
- Allow manufacturing and floor stocking of medicated feed containing MIAs if done pursuant to HC approvals (CMIB)



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## Thank You

- [www.agriculture.alberta.ca/ocpv](http://www.agriculture.alberta.ca/ocpv)
- [www.ohab.ca](http://www.ohab.ca)



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## VETERINARY OVERSIGHT OF ANTIMICROBIAL USE ALBERTA LAMB PRODUCERS

Dr. Phil Buote, Deputy Registrar  
November 3, 2018



## OUTLINE

- Veterinary Oversight
- Prescribing
- Veterinarian-Client-Patient-Relationship (VCPR)
- Extra Label Drug Use
- Dispensing
- Oversight of veterinarians and verification of compliance

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## WHAT IS VETERINARY OVERSIGHT?

- Canadian Veterinary Medical Association (CVMA)
- Veterinary Pharmaceutical Stewardship Advisory Group (VPSAG)
- Canadian Council of Veterinary Registrars (CCVR)

*“Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards for Veterinarians (December 2016)”*



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## VETERINARY OVERSIGHT

- Veterinary oversight is a key element of **antimicrobial stewardship**.
- Professional involvement of licensed veterinarians in providing direction for appropriate use of antimicrobials in animals
- Objective of ensuring prudent use
- Veterinarians, through their education, experience and accountability, provide guidance or direction for appropriate use and distribution of antimicrobials.

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## PRESCRIBING AND DISPENSING

ABVMA COUNCIL GUIDELINES REGARDING PRESCRIBING, DISPENSING, COMPOUNDING AND SELLING PHARMACEUTICAL,

- Provide the guidance for veterinarians and veterinary practices in Alberta
- The expected professional standards for veterinarians
- Verification through PIPS Inspections
- Compliance Approach
- Enforceable through the complaints and discipline process

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## PRESCRIBING

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

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

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## VETERINARY-CLIENT-PATIENT RELATIONSHIP

A VCPR exists when all of the following conditions have been met:

1. The veterinarian has assumed responsibility for making clinical assessments and recommendations regarding the health of the animal(s) and need for medical treatment,
2. The veterinarian has sufficient knowledge of the animal(s) on which to base the assessment, diagnosis and treatment of the medical condition of the animal(s). This means that the veterinarian:
  - is professionally acquainted with the keeping and care of the animal(s), and
  - has documented relevant and timely interaction between the veterinarian, animal owner or caretaker and animal patients, and
  - has documented medically appropriate information and knowledge about the animal(s)
3. The client has agreed to follow the veterinarian's recommendations and prescription.
4. The veterinarian is available or has arranged for follow-up evaluation, especially in the event of adverse reactions or failure of the treatment regimen.

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## DETERMINATION OF MEDICAL NEED

### Requirement for prescribing

- Registered veterinarian makes an informed decision that a particular drug will be prescribed
- Establishes the medical needs of the patient - individual animal or group of animals
- Pertinent medical history and conducting a physical examination
- Not necessary that an individual animal is examined in every instance
- Veterinarian **MUST** have relevant medical knowledge to support the establishment of medical need.

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## ANIMAL HEALTH PROTOCOL

- An animal health protocol is a series of steps to be undertaken following an indication.
- Veterinarians may establish animal health protocol(s) in advance or anticipation of the animal health event
- Establishes the medical need for issuing a prescription.
- An animal health protocol is not a prescription
- When an animal health protocol includes a step that a drug be administered to an animal or group of animals, a legitimate prescription must be issued before pharmaceuticals are dispensed.

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## DOCUMENTATION

### Requirement for prescribing

- Investigation conducted
- Information upon which the veterinarian relies to determine the medical need
- History
- Physical examination findings
- Consultations
- Laboratory investigations
- All prescriptions must be specific to drug, quantity, indication, route of administration, duration of administration, withdrawal time (if relevant) and number of refills available.

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## DOCUMENTATION

### Requirement for prescribing

- Clearly document the intention to prescribe a specific product (trade name) with no substitution or
- The chemical name of the drug which would allow the dispenser to dispense the product (trade name) of their choice.
- All medication dispensed or sold for the animal or group of animals and evidence that a valid prescription is on file.
- Medical records shall document the diagnosis or purpose of use,
- Communication regarding progress of care, patient response to treatment including treatment failures and any adverse reactions.

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## PRESCRIPTION

### Medical record of prescribing must document:

- Prescribing veterinarian and certified veterinary facility, and contact information
- Patient owner/agent (client)
- Date of prescription
- Identification of individual animal or group of animals
- Name of drug prescribed and concentration
- Quantity of drug
- Directions for use, including dose, frequency, and duration
- Route of administration
- Substitution (yes or no) of same drug (different brand name)
- Number of refills (implies zero if not indicated)
- Withdrawal time
- Signature of the veterinarian

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## PRESCRIPTION FOR IN-FEED ADMINISTRATION

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

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

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## OVERSIGHT OF USE AND FOLLOW UP

### Requirement for prescribing

- Must be available for follow up or have arranged a designated alternate.
- It is the responsibility of the prescribing veterinarian to ensure that prescribed pharmaceuticals are used properly.
  - client training and education on appropriate use, handling and storage, withdrawal time
- available in event of treatment failure or adverse reactions.
- Prescribing veterinarian is responsible for oversight of appropriate use of prescribed medications.

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## EXTRA LABEL DRUG USE (ELDU)

- Any approved drug that is administered in a manner not explicitly stated on the approved label in regard to **indication, dosage regimen, route or frequency of administration, duration of treatment, or target species.**
- Any drug approved for human but not veterinary use, active pharmaceutical ingredients (API's), and compounded drugs.
- A pharmaceutical product in a manner that is not in accordance with Health Canada's approved label, package insert, or registration by the Canadian Food Inspection Agency or Health Canada.

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## 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.
- Veterinarians will encounter cases where the treatment of animals requires ELDU
  - in a species for which approved antimicrobial does not exist, or
  - use of an antimicrobial at a dose that is appropriate given the disease condition.

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## EXTRA LABEL DRUG USE

When prescribing ELDU, the veterinarian assumes the responsibility to:

- ensure avoidance of drug residues and food safety,
- ensure that use of the product in the animal(s) is safe and effective,
- consider the potential contribution to development of resistance,
- effect on the environment,
- obtain client informed consent from the animal owner (associated risks, particularly safety, efficacy and residue avoidance)

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## DISPENSING

Professional activity within scope of practice of veterinary medicine

Veterinary Profession Act

### Definitions

1 In this Act, ...

(p) "veterinary medicine" means a medical service performed with respect to an animal and includes the following:

- (i) surgery;
- (ii) obstetrics and ova and embryo collection;
- (iii) prescribing, compounding, **dispensing** and selling drugs.

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## LABELLING

Dispensing Label Information

A dispensing label that includes prescription specific information must be affixed or confirmed by a registered member working at the dispensing VPE.

The dispensing label must include:

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

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## DISPENSING

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.

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## DISPENSING

Expected professional standards

- Establish the identity of client and create medical record
- Establish the identity of prescriber
- Determine the validity of the prescription
- Maintain prescriptions on file and manage available refills
- Appropriate delegation of dispensing
- Label according to PIPS Bylaws and provide Information to client
- Substitute medications only if appropriate
- Transcribe prescriptions taken over the phone
- Store and display pharmaceuticals in accordance with the PIPS Bylaws.

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## SHIPPING PHARMACEUTICALS

- Veterinary practice entities may ship appropriately prescribed and dispensed pharmaceuticals.
- Appropriately prescribed and dispensed pharmaceuticals may only be shipped by a veterinary practice.
- Drop shipping, or shipping of pharmaceuticals from the distributor or manufacturer directly to a client's place of residence or business, does not constitute appropriate dispensing.
- Acceptable process for shipping is detailed in the Guidelines

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## OVERSIGHT OF VETERINARIANS

- Veterinary medicine is a self regulated profession
- Authority to self regulate is granted by the Government of Alberta
- ABVMA is the professional regulatory organization responsible for the regulation of veterinary medicine in the province of Alberta
- Regulate in the public interest

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## ALBERTA VETERINARY MEDICAL ASSOCIATION (ABVMA)

Mission: Serving the public by regulating, enhancing, and providing leadership in the practice of the profession of veterinary medicine in Alberta.

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## REGULATION

- Authority provided by the provincial government through the *Veterinary Profession Act*
- Accountable to the Ministry of Labour
- Public Member Oversight
- Regulate
  - Registration
  - Mandatory Continuing Education
  - Establish Practice Standards
  - Veterinary Practice Quality Assurance – Inspections
  - Complaints and Discipline process

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## PROFESSIONAL ENHANCEMENT

- Educate and Inform members and the public
- Communication
  - Social Media, websites
- Promote veterinary medicine to the public
- Continuing Education events
- Interest of the public

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## VERIFICATION OF COMPLIANCE

- Ensure that veterinarians and veterinary practices undertake prescribing and dispensing activities in accordance with the expected professional standards
- Accountability
- Expectation of the public and other stakeholders
- Veterinarians will be under scrutiny

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## QUESTIONS:

*“If veterinarians are providing oversight of antimicrobial use, who is providing oversight of the veterinarians?”*

*“If I comply with the guidelines and refuse a request for an antimicrobial, what is stopping my client from going down the street to the next veterinary practice and buying it there?”*

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## COMPLIANCE APPROACH

### ABVMA steps to ensure compliance with Guidelines

- Profession establishes the professional standards
- ABVMA informs members – publishes notices / website
- Advise members of the expected professional standards / answer question
- Undertake verification activities - Practice Inspections and record audit
- Enforcement in cases of non-compliance - Practice Review Board and discipline process

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## DISPENSING AUDIT

### 'Veterinary Oversight of Antimicrobial Use – a Pan-Canadian Framework of Professional Standards for Veterinarians'

#### 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 labeling,
- 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. [www.abvma.ca](http://www.abvma.ca)



## NON-COMPLIANCE

### Practices that fail to meet the standards

- Practices that are non-compliant may be referred to the Practice Review Board
- Complaints

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## THANK YOU

Questions?



### Follow us:



### Websites:

[www.abvma.ca](http://www.abvma.ca)  
[www.albertaanimalhealthsource.ca](http://www.albertaanimalhealthsource.ca)

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