

Qualification Certificate Home Study Manual

Authorized Medicine Sales Regulation
Alberta Regulation 131/2014

Revised December 2014

Inspection and Investigation Branch

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QUALIFICATION CERTIFICATE HOME STUDY MANUAL

TABLE OF CONTENTS

Introduction

Chapter 1 Production Animal Medicine and the Law

Chapter 2 Disease and its Causes

Chapter 3 Drug Information Basics

Chapter 4 Drug Formulations

Chapter 5 Drug Administration Routes

Chapter 6 Drugs Licensed for Sale through Authorized Medicine Outlets

Chapter 7 Drug Interactions and Adverse Reactions

Chapter 8 Responsibilities of Qualification Certificate Holders and
AMSO Licensees

Appendix A Answers to Review Questions

Appendix B *Authorized Sales Medicine Regulation A.R.131/2014 (Animal
Health Act)*

Appendix C Units of Measure

INTRODUCTION

Livestock medicines contribute to production animal health and the production of safe food and food products that originate from agricultural animals. The proper use of drugs or medicines is beneficial in alleviating animal suffering through the treatment and prevention of disease. On the other hand, the improper use of drugs may cause harm and unnecessary suffering in animals. For example, antibiotics must be carefully selected and used in order to treat bacterial infections effectively. Consumer protection also plays a role in the regulation of livestock medicines because consumers expect and demand that food products be wholesome, and free of disease or drug residues.

At all times, livestock producers are encouraged to work with and under the guidance of a registered veterinarian so that their animals are in the best possible health. As animal health experts, veterinarians play an important role in the diagnosis and treatment of animal disease and health maintenance. In the event a producer has any concerns or is unsure of how a production animal should be cared for or its health maintained, the producer should always consult with a veterinarian registered with the Alberta Veterinary Medical Association (ABVMA).

The *Authorized Medicine Sales Regulation (AMSR)* supports animal health and safe food production from animals in two ways. First, it regulates the wholesale distribution of authorized medicine to authorized medicine sales outlets (AMSOs), and second, the AMSR also regulates the manner in which authorized medicine may be sold to the public. Only certain types of veterinary medicines may be distributed or sold over the counter, rather than by way of a prescription written by a registered veterinarian. Production animals include not only those animals that are used for slaughter for food or food products, but also horses and other animals used in the pollination of crops.

All premises or outlets where the authorized medicines are sold must be licensed as Authorized Medicine Sale Outlets (AMSO). Each AMSO must have at least one person who is licensed as a “Qualification Certificate” (QC) holder to be present or available for consultation at all times during regular business hours. A person may obtain a QC license upon demonstrating, to the satisfaction of government regulators, a basic understanding of the proper use of authorized production animal medicines by way of examination. In this way, public confidence in both authorized medicine sales and its role in supporting both animal health and food safety is maintained.

The roles and responsibilities of QC holders and AMSO licensees have limitations. **QC holders and AMSO shall not provide livestock producers with specific information pertaining to disease diagnosis or drug prescription.** Rather, such matters come exclusively within the role of the registered veterinarian. For this reason, this manual will not describe specific disease conditions or recommend treatments.

Persons who purchase animal health products at AMS outlets are expected to know what products they require. A QC holder has a responsibility to refer persons who do not have a clear knowledge of what authorized production animal medicine they require to a veterinarian registered with the ABVMA.

This manual is written with a twofold purpose. First, it is a learning tool designed to provide information that is necessary for those who are interested in becoming QC holders. Questions on the QC examination are based on the review questions at the end of each section of this manual. Answers to the review questions may be found in Appendix “A”.

The second objective of this manual is that it will serve as a convenient resource that informs and educates QC holders who dispense drugs at AMSOs in the proper use and handling of drugs in order that they may assist livestock producers in ensuring a safe food supply.

PRODUCTION ANIMAL MEDICINES AND THE LAW

OBJECTIVE:

To familiarize the reader with Federal and Provincial legislation relevant to the sale and distribution of authorized medicines for production animals in the Province of Alberta.

PRODUCTION ANIMAL MEDICINES AND THE LAW

The sale of veterinary drugs in Alberta is regulated by both federal and provincial laws. Laws are written instruments that are collectively referred to as legislation.

- Federal legislation sets minimum national standards.
 - ◆ All provinces and territories within Canada must comply with these minimum standards so that all Canadian legislation on a subject, such as authorized production animal medicines, is consistent with each other. When this happens, the legislation is said to be “harmonized”.
- Provincial legislation may meet or exceed national standards so that they are harmonized and work together with federal and other provincial legislation.
- In the unlikely event that federal and provincial conflicts on a particular subject matter, then federal legislation will take precedence over provincial legislation.

LAWS THAT APPLY TO ANIMAL MEDICINES IN ALBERTA

Federal

- A. *Food and Drugs (Canada) Act*
- B. *Feeds Act (Canada)*
- C. *Controlled Substances Act (Canada) and Narcotics Control Regulation*

Provincial

- A. *Pharmacy and Drug Act*
- B. *Veterinary Profession Act*
- C. *Animal Health Act*
- D. *Authorized Medicine Sales Regulation*

I. FEDERAL LEGISLATION

A. *FOOD AND DRUGS (CANADA) ACT (FDA)*

- The FDA and regulations made under its authority are administered by Health Canada and the Canadian Food Inspection Agency (CFIA).
- Its purpose is to protect human and animal health by prohibiting the sale of foods or drugs containing any harmful substances.
- The FDA establishes the conditions and standards under which drugs are manufactured and offered for sale in Canada.
- Production animal medicines are considered to be “Products for Veterinary Use” administered by Health Canada.
- Health Canada maintains a Prescription Drugs List (PDL) for humans and animals.
 - ◆ The PDL provides a list of generic drugs that require a prescription in order to be obtained for treatment or therapeutic purposes.
 - ◆ Drugs containing these compounds listed in the PDL are marked as prescription drugs and are not authorized for sale at AMS outlets.
- All drugs offered for sale in Canada must qualify for a “Notice of Compliance”.
 - ◆ Here, drug manufacturers must submit to regulatory authorities details of their marketed products for review and approval. Drug potency, purity, and quality are reviewed, as well as manufacturer quality control procedures, toxicity test results, residue information, and clinical trial results.
 - ◆ Compliance with the FDA ensures that drugs marketed in Canada, are safe, effective, and that the labels contain all necessary warnings re toxicity, contraindications and withdrawal times.
- The FDA also dictates specific labelling requirements for drugs, including any warnings. Warnings may include information about
 - ◆ side effects
 - ◆ adverse reactions
 - ◆ contraindications
 - “Contraindications” refers to other drugs that may interfere with the effectiveness of the particular marketed medicine if they are taken together or as a part of general therapy.
 - ◆ withdrawal times for production animal medicine
 - If a medicine has been administered to a production animal that will be slaughtered for food, then there needs to be a waiting, or withdrawal time before slaughter occurs so that drug residues will not be present in the animal’s system. Otherwise, drug residues may be present in the food product.
 - ◆ Toxicity
- Compliance with the FDA ensures that drugs marketed in Canada are safe and effective and that the labels contain all necessary warnings.

B. FEEDS ACT (CANADA) (FA)

- The FA is administered by the Plant Products Division of the CFIA.
- Its purpose is to establish the conditions under which drugs can be put in the feed of livestock intended for food production.
- Feed manufacturers may sell medicated feed provided that the medicating ingredients that have been added to livestock feed are permitted under the FA regulations. The CFIA publishes a Compendium of Medicating Ingredients Brochure that lists permitted medicating ingredients.

NOTE: The *Authorized Medicine Sales Regulation* **does not apply to medicated feeds**. Medicated feeds are regulated by federal legislation under the *Feeds Act*.

C. CONTROLLED SUBSTANCES ACT (CANADA) AND NARCOTICS CONTROL REGULATION

- Controlled drugs and narcotics are legislated by the Controlled Drugs and Substances Act (Canada) and Narcotics Control Regulations. Over the counter (OTC) sales of controlled drugs and narcotics are strictly prohibited. Controlled drugs and narcotics may lawfully be obtained by prescription, but special reporting measures and precautions are taken when the prescription is filled.

II. PROVINCIAL LEGISLATION

In addition to the federal legislation, each province makes its own legislation governing the sale of medicines for both humans and animals. Alberta has three such pieces of legislation: the *Pharmacy and Drug Act*; the *Veterinary Profession Act*, and the *Authorized Medicine Sales Regulation*.

A. PHARMACY AND DRUG ACT (PDA)

- The PDA is administered by the Alberta College of Pharmacists.
- Its purpose is to regulate the sale of drugs in the Province of Alberta.
- The PDA lists a number of activities that are within the exclusive scope of the practice of pharmacy. These activities include, but are not restricted to, dispensing drugs, selling drugs by retail and re-packaging of drugs in larger or smaller quantities for re-distribution or retail sale.
- Only a pharmacist can engage in the practice of pharmacy.
 - ◆ However, exceptions to this rule are made for registered veterinarians and the sale of livestock medicine in accordance with the *Authorized Medicine Sales Regulation*.

B. VETERINARY PROFESSION ACT (VPA)

- The VPA is administered by the Alberta Veterinary Medical Association (ABVMA).
- Only veterinarians registered with the ABVMA may practice veterinary medicine, which includes prescribing and dispensing drugs. Again, registered veterinarians are exempted from restrictions in the PDA concerning the practice of pharmacy
- Registered veterinarians must possess the qualifications listed in the VPA.

C. AUTHORIZED MEDICINE SALES REGULATION (AMSR)

All AMS licensees and Qualification Certificate holders must be thoroughly familiar with the contents of this regulation and their responsibilities under it. A copy of the AMS Regulation can be found in appendix “B” of this study guide.

- The AMSR was made under the authority of the Animal Health Act and is administered by the Inspection and Investigation Branch of the Animal Health and Assurance Division of Alberta Agriculture and Rural Development.
- The AMSR is important because it permits Authorized Medicine Sales Outlets (AMSOs) to be licenced and lawfully to sell authorized livestock animal medicines. Without it, the sale of production animal medicines through licenced outlets would not be possible.

NOTE: A separate AMS Outlet licence is required for each retail outlet. All sales must take place through a licenced outlet.

- **Section 14** of the AMSR identifies specific authorized medicines and classes of authorized medicines that may be sold by AMS outlets.
 - ◆ Specific medicines include certain vaccines.
 - ◆ Classes of medication identify types of medication that may be used for therapeutic prevention or treatment of disease.

NOTE: **If a drug or class of drugs is not listed under section 14 of the AMS regulation then an AMS outlet is not allowed to possess or sell it.**

NOTE: **Drugs listed on the Prescription Drug List - Products for Veterinary Use** cannot be sold or stored at an AMS outlet. They may only be obtained through a prescription from a registered veterinarian.

- Drugs listed in Section 14 AMSR are also called OTC or “**Over the Counter**” AMS authorized drugs.
 - ◆ OTC drugs can be purchased without a prescription and they can be used without veterinary supervision.
 - ◆ Because OTC medicines are allowed to be used without veterinary supervision, **the label of all OTC medicines must give clear, understandable directions for use.**
 - ◆ Antibiotics may only be sold in person at the outlet’s permanent place of business.
 - ◆ Outlets may only sell authorized medicine:
 - ◆ in person at the outlet’s permanent place of business
 - ◆ by telephone sales, or
 - ◆ online or by other electronic means
 - ◆ The exception to the above is that **antibiotics are not permitted for sale by telephone, online or by other electronic means.**

NOTE: Section 19(4) exempts Disinfectants, udder washes, teat dips and sanitizers from the OTC requirements.

Review Questions

Introduction and Chapter 1

1. Name two objectives that the *Authorized Medicine Sales Regulation* (AMSR) supports.

2. Can an AMS Outlet sell medicines containing generic drugs included on the Prescription Drug List – Products for Veterinary Use? Why or why not?

3. Who can legally sell drugs in the Province of Alberta and what qualifications must they possess?

4. What is an “OTC” drug?

5. In what manner are Outlets only permitted to sell authorized medicine? What is the exception?

DISEASE AND ITS CAUSES

OBJECTIVES:

To provide:

Basic disease information; and

To familiarize the reader with examples of types of drugs which AMSOs may sell OTC to prevent or treat disease.

DISEASE AND ITS CAUSES

The *Veterinary Professions Act (VPA)* states that **animal disease diagnosis and treatment prescription is the exclusive responsibility of a registered veterinarian.**

- The Authorized Medicine Sales Regulation (AMSR) specifically prohibits the holder of a wholesale or outlet authorized medicine licence from diagnosing a disease and prescribing treatments.

NOTE: Section 22(5) (b) AMSR states that

No licensee shall diagnose disease, disorder or condition of an animal, prescribe medicine or otherwise contravene section 2(1) of the *Veterinary Profession Act*.

Section 2 of the VPA states that only registered veterinarians may practice veterinary medicine.

- **Practicing veterinary medicine, pharmacy, or engaging in unauthorized sales of medicine or selling authorized medicines without being authorized to do so are offences.** Under the AMSR, the Director may suspend or even cancel a licence if the licensee has contravened the VPA, or the *Pharmacy and Drug Act*, the *Veterinary Profession Act*, the *Food and Drugs (Canada) Act*, or any Act of the Parliament of Canada relating to the sale or distribution of medicine.
- Nevertheless, AMS Qualification Certificate holders and licensees do need a basic understanding about causes of disease and why particular classes of drugs may or may not be indicated as being suitable in its treatment.

Definition of Disease

Cause of Disease

- Infectious
- Non-infectious

I. DEFINITION OF DISEASE

- **For the purposes of this manual, the term “disease” refers to any departure from a normal state of health which results in a disturbance of normal body functions of the animal.**
 - ◆ Under this definition, a disease may be
 - a very mild condition which only affects a small part of the body i.e. a cut or an abscess
 - generalized and life threatening i.e. blackleg
- The *Alberta Animal Health Act* defines disease as
 - ◆ a pathological abnormality or a distinct group of symptoms or behaviours,
 - ◆ any syndrome, or
 - ◆ the condition of carrying a disease-causing agent.

A disease may have one or more causes.

II. CAUSES OF DISEASE

All diseases are either:

1. Infectious
- Or
2. Non – infectious

A. INFECTIOUS DISEASES

- Infectious diseases are caused by organisms, such as bacteria, viruses, fungi or parasites. They may be contagious or non-contagious.
- Contagious diseases spread easily from animal to animal, usually through direct contact.
- Non-Contagious diseases do not spread directly from one animal to another.
- There may be other non-disease causing factors that may pre-dispose animals to disease, such as injury or lower resistance to disease (immunity).

Although an infectious agent may be non-contagious, several animals in a herd could be affected if they are all subjected to the same predisposing factors.

Example:

Lump jaw is caused by a bacterium in the soil and it does not spread directly from animal to animal. However, if the herd is given coarse feed, several animals may develop mouth injuries, which may in turn compromise the resistance of animals to disease. The mouth injuries may be a predisposing factor that allows the lump jaw bacterium to enter the deeper tissues of the jaw and cause disease.

- Living organisms causing infectious diseases can enter the body in various ways.

Types of Infectious Agents

- Bacteria
- Viruses
- Fungi (molds)
- Parasite

1. Bacteria

- Bacteria are microscopic, single celled **organisms** that do not require a living host cell to multiply.
- Many types of bacteria can reproduce and remain in the environment or an animal's body for long periods of time.
- Not all bacteria cause disease. Many are essential for proper digestive function, particularly in ruminants (animals with a rumen such as cattle and sheep).
- **Bacteria that cause disease are called pathogenic bacteria.**
- Pathogenic bacteria often produce toxins or poisons which cause signs of depression in affected animals.
 - ◆ Examples of common livestock diseases caused by bacteria include:
 - Blackleg in cattle
 - Erysipelas in pigs
 - Mastitis
 - Foot Rot
 - Abscesses, etc.

- **Most pathogenic bacteria may be treated with antibiotics** or antibacterial drugs providing that the correct drug is chosen and treatment starts early in the course of the disease.
 - ◆ Pathogenic bacteria may respond differently to various types of antibiotic or antibacterial drugs. Some antibiotics target specific bacteria, while broad spectrum antibiotics may be used to treat multiple types of bacteria.
- **Antibiotics not listed on the Prescription Drug List – Products for Veterinary Use** may be sold through AMS outlets.
 - ◆ They are available for application in a number of forms, such as injectables, topicals, boluses, and udder infusions.

2. Viruses

- Viruses are microscopic infectious agents. They are smaller than bacteria and can only reproduce when they are in a living host cell.
- Although they cannot reproduce outside of the animal's body, **some viruses are capable of surviving in the environment for extended periods of time.**
 - ◆ Examples of common livestock diseases caused by viruses include:
 - Bovine Virus Diarrhoea (BVD)
 - Infectious Bovine Rhinotracheitis (IBR)
 - Parvovirus abortions in pigs
 - Several types of interstitial pneumonia

The use of antibiotics to treat viruses is not recommended because

VIRUSES ARE NOT AFFECTED BY ANTIBIOTICS

- As viruses reproduce they destroy body cells. It is the destruction of body cells that causes symptoms of viral infection.
- Vaccination is the only effective way of preventing diseases caused by viruses.
 - ◆ Antiviral drugs are not licenced for use in food producing animals

The sale of “Live” or “Modified Live” virus vaccines are not allowed for sale at AMS outlets.

- Mixed viral and bacterial infections can occur.
 - ◆ The best example of this is the “Shipping Fever” complex in cattle.
 - Shipping fever is usually caused by a sequential occurrence of stress, infection with one or more viruses, and then a subsequent bacterial infection which leads to the development of pneumonia.

3. Fungi or Molds

- Fungi are a large group of organisms, such as yeasts or molds, belonging to the kingdom Fungi, which is distinct from plants, animals, bacteria and viruses. Some are microscopic, while others are visible to the eye. Some fungi are capable of causing disease.
- Ringworm is the only fungal disease of practical significance to AMS licensees.

4. Parasites

- Parasites are members of the animal kingdom. Some are microscopic single celled organisms (i.e. coccidia). Most parasites are more complex organisms and are visible to the naked eye. Examples of complex parasites include lung and intestinal worms, lice, mange mites, warbles, and horse bots.
- Ivermectin is a common antiparasitic drug in current use, but many others may be sold at AMS outlets.

B. NON-INFECTIOUS DISEASE

- Non-infectious diseases are conditions caused by non-living agents.

General Causes of Non-infectious Disease

- Nutritional
- Poisoning
- Physical Agents
- Metabolic
- Genetic
- Endocrine Disorders
- Allergies

1. Nutritional Diseases

- Most nutritional diseases are caused by a lack of an essential nutrient such as protein, energy, minerals or vitamins.
- Nutritional diseases can also be caused by overeating
 - ◆ i.e. bloat, grain overload,
- Various mineral and vitamin preparations are available for sale through AMS outlets.
 - ◆ Most of these preparations are specifically designed to prevent nutritional deficiencies but some are available for the treatment of deficiency diseases.
 - i.e. injectable selenium, iron supplements, B vitamin, vitamins A & D
- Other products relating to nutritional problems or digestive upsets include various laxatives and bloat medications.

2. Poisoning

- Lead is the most common cause of poisoning in livestock, particularly cattle.
 - ◆ Chewing and licking on old batteries is the most common source of lead for cattle.

- Toxic plants may also cause disease in certain geographical areas during certain times of the year.
- Treatments or antidotes for poisoning are specific for the cause.

Antidotes to toxins are NOT available through AMS outlets.

- In the event of a suspected poisoning, the following measures need to be taken.
 - ◆ Cases should be referred to a registered veterinarian.
 - ◆ Incidents must be reported to the Chief Provincial Veterinarian within 24 hours of detection. Reporting is mandated by the Reportable and Notifiable Disease Regulation, made under the authority of *Animal Health Act*.
 - ◆ To report a suspected poisoning, call the telephone numbers below:
 - (780) 427 3448 during business hours or
 - 1 (800) 524 0051 outside of business hours

3. Physical Agents

- This category includes animal health problems related to excessive cold (freezing), excessive heat (burning), excessive sunlight and traumatic injuries such as cuts, abrasions, and fractures.
- Various ointments, creams, and wound preparations are the main products available at AMS outlets for these types of disease.

4. Metabolic Diseases

- Metabolic diseases are conditions caused by biochemical abnormalities in the body.
 - ◆ Milk fever, grass tetany and ketosis are the most commonly encountered metabolic diseases in cattle.
- Injectable calcium, phosphorus, magnesium, glucose solutions and oral propylene glycol are the main products sold in AMS outlets for the treatment of metabolic diseases.

5. Genetic Diseases

- Genetic diseases are inherited conditions. Most genetic diseases are present at birth and are generally manifested by physical deformities.
 - ◆ They are of no practical significance to AMS outlets.
 - ◆ There are no specific medications for genetic problems.

6. Endocrine Diseases

- Endocrine diseases may be caused by an over production, under production, or imbalance in body hormones.

- The diagnosis and treatment of endocrine disorders is very complicated and many hormones have serious side effects.
 - ◆ Generally, injectable hormones are not allowed to be sold at an AMS outlet, The only exception is epinephrine (adrenalin), an injectable hormone which can be sold at an AMS outlet.
- Hormones in the form of implants or feed additives, **which are labelled by the manufacturer for use in production animals**, may be sold by AMS outlets.

7. Allergies

- Allergies are diseases caused by an overreaction of the body's immune system.
- There are several causes of allergies, including adverse reactions to drugs or other allergens.
- Allergic reactions may vary in severity. For example, a mild reaction may result in a mild skin conditions, but a severe reaction may be life threatening, especially if it leads to a constriction of airways and accumulation of fluid in the lungs of the affected animal.
 - ◆ Allergic reactions that cause constriction of the airways and fluid accumulation in the lungs are commonly called **anaphylactic** reactions.
 - ◆ Anaphylactic reactions can occur in a very short time following the injection of almost any drug.
 - ◆ Epinephrine is the treatment of choice for anaphylactic reactions and is licenced for sale through AMS outlets.

NOTE: Purchasers of injectable drugs should be advised about the possibility of allergic reactions.

- In summary this section was intended to give a brief overview of the types of agents that cause disease in animals and to give examples of products that can be sold at AMS outlets for the treatment or prevention of these diseases.
- **It cannot be emphasized enough that AMS licensees or their employees MUST NOT become involved in the diagnosis of disease or the recommendation of specific treatments.**

Do not hesitate to refer customers to a registered veterinarian if the customer does not appear to know what he or she requires.
Remember, an accurate diagnosis is essential to determine what drug should be used.

Review Questions Chapter 2

1. Define “disease”.

2. What is the difference between an infectious and non-infectious disease?

3. What is the difference between a contagious and non-contagious disease?

4. What are the differences between viruses and bacteria?

5. List five common parasites of livestock.

DRUG INFORMATION BASICS

OBJECTIVE:

To understand drug packaging and labelling in order to

- explain why drugs are packaged in certain ways
- read and understand all sections of a drug label
- define “DIN”
- define extra label use of a drug.

GENERAL DRUG INFORMATION

- Purchasers of authorized medicines may rely on the ability of a QC holder or AMSO licensee to convey knowledge of the types of authorized medicines that may be used to prevent or treat disease in a production animal in order that the purchasers may make their own informed choice about what drugs they will purchase.
 - ◆ Therefore AMS Qualification Certificate (QC) holders and outlet licensees have a responsibility to be aware of and understand the information provided by drug manufacturers.
 - ◆ Licensees or AMSOs and QC holders are accountable for any information or misinformation they may provide to a purchaser of authorized medicine about a drug.

Remember: A QC holder acts as conduit of information and does not diagnose, treat disease, or prescribe any authorized medicines.

If a buyer of authorized medicine is unsure about the type, appropriateness, and effectiveness of a drug that he or she should use, then a QC holder has a responsibility to refer the buyer to a veterinarian.

WHAT IS A DRUG?

- *The Food and Drugs Act* (FDA) states that a drug is any substance or mixture of substances that is 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 animal, or
 - ◆ disinfection of premises in which food is manufactured, prepared, or kept

DRUG PACKAGING AND LABELING

- Drug packaging and labelling are both regulated under the FDA.

Packaging

- Various packaging methods are used to protect drugs from deterioration caused by the effects of light, moisture and physical damage.

Protecting Against Light

- Many drugs will deteriorate if exposed to light for variable periods of time.
 - ◆ Light sensitive drugs are packaged either in brown glass bottles or with an outer opaque package. Typically, cardboard is used for the outer packaging.
 - ◆ All drugs should be stored in their original containers and out of direct sunlight.

Protecting Against Moisture

- Many tablets, boluses, and powders are particularly sensitive to moisture.
 - ◆ Manufacturers place small packages of desiccants (chemicals which absorb moisture) in containers of tablets, boluses and powders.
 - These materials must be left in the drug containers.
 - Moisture sensitive drugs should be stored in areas of low humidity.

Protecting Against Physical Damage

- Vibration of medicines, which often occurs while in transit, will cause pills and boluses to chip or fracture.
 - ◆ Cotton is commonly used as a filler to minimize the effects of vibration.
 - ◆ Boluses are often packaged in individual slots within a larger container.

Drug Labelling

- Drug labelling requirements ensure that sufficient information about a particular drug is provided for its safe use and handling.

MAIN SECTION OF A DRUG LABEL

| | |
|-------------------------------------|-----------------------|
| 1. Generic Name | 7. Warning |
| 2. Trade (Brand Name) | 8. Caution |
| 3. Drug Identification Number (DIN) | 9. Lot Number |
| 4. Contents | 10. Expiry Date |
| 5. Indications | 11. Precautions |
| 6. Dosage and Administration | 12. Contraindications |

- AMSO licensees must be familiar with label components because they have a responsibility to draw to the attention of purchasers of authorized medicines information about
 - ◆ Precautions that need to be taken concerning withdrawal times.
 - The withdrawal time is the period of time that must elapse after the last treatment before the animal can be slaughtered or before any product from the animal, such as milk, can be used for human consumption.

- ◆ Information on the drug label regarding
 - Appropriate dosage
 - The species of production animal for which the drug is approved
 - Method of drug administration
 - The drug's expiry date
 - Toxicity warnings and
 - Any drug precautions that need to be taken.
- Additionally, AMSOs must provide notice concerning the safe use and handling of authorised medicines. In particular, attention must be drawn to the
 - ◆ importance of proper use of authorized medicine, and
 - ◆ contact information of a staff person who holds a qualification certificate in the event for clarification of any questions regarding the safe and proper use of authorized medicine.
 - For in person sales, the AMSO must display a sign including information about the safe and proper use of drugs and the contact information of a staff QC holder, in a form determined by the Minister, in a prominent location within the licensee's permanent place of business.
 - For sales by telephone, online or other electronic means, the licensee must provide the buyer with a written notice with the information listed above.

EXAMPLE OF HOW TO READ AND UNDERSTAND A LABEL

Below is a sample label, which illustrates most of the components of a drug label.

3 DIN 02239151 **2**

**VETERINARY
USE
ONLY**

Propen LA

Sterile Injectable Suspension
A Long Acting Antibiotic



Net 100 mL


| | | | |
|----------|--------------------------|---------------|----------|
| 1 | Active ingredient | per mL | 4 |
| | Penicillin G Procaine | 300 mg | |

7 **WARNINGS:**
Do not administer to lactating dairy cattle.

Subcutaneous administration:
Cattle must not be slaughtered for use in food for at least 14 days after the latest treatment with this drug.

Intramuscular administration:
Cattle must not be slaughtered for use in food for at least 21 days after the latest treatment with this drug. Pigs must not be slaughtered for use in food for at least 10 days after the latest treatment with this drug.


Injectable


Code 01420  **Vétoquinol**

Figure 1 – Sample Label – part 1

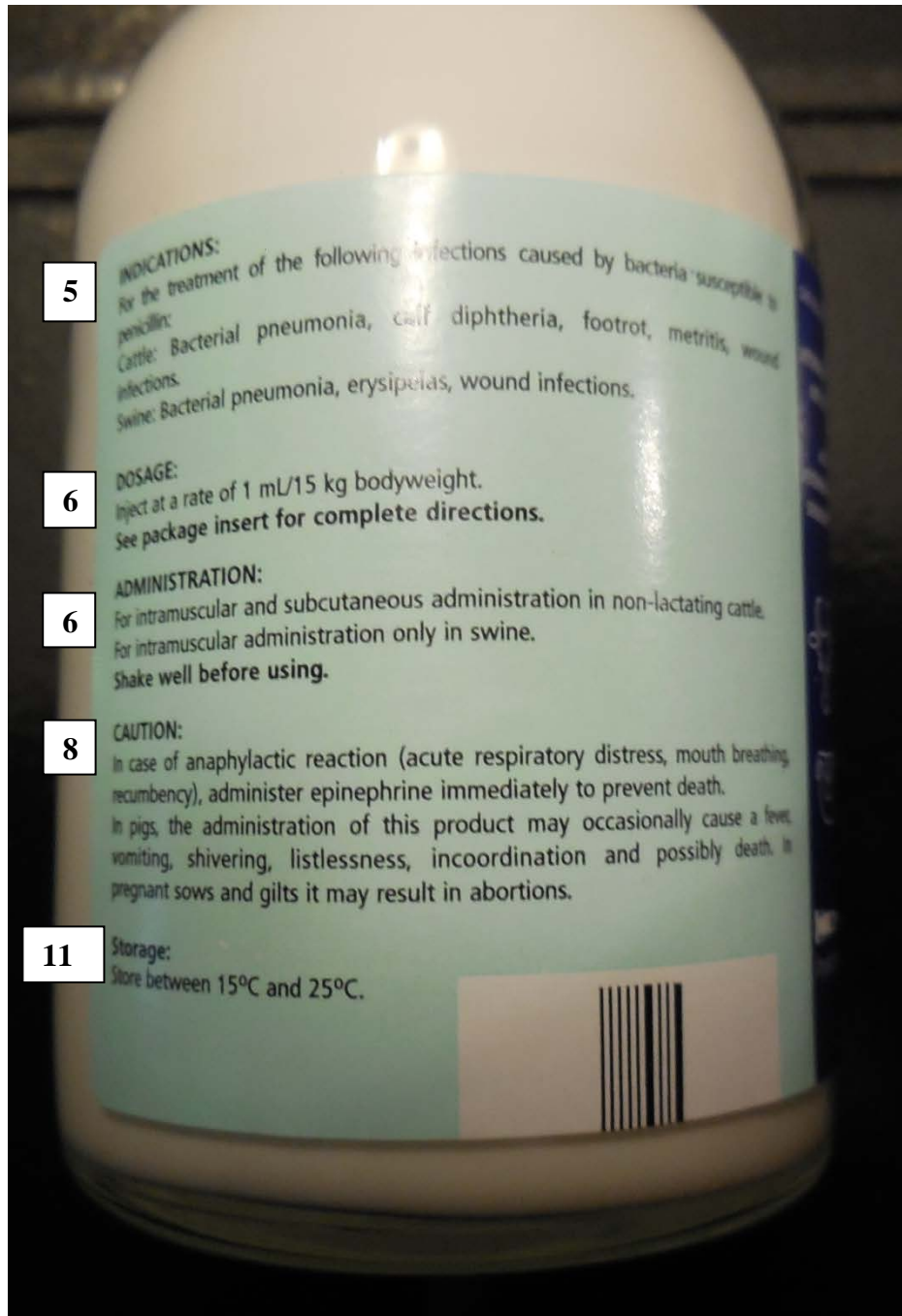


Figure 2 – Sample Label – part 2

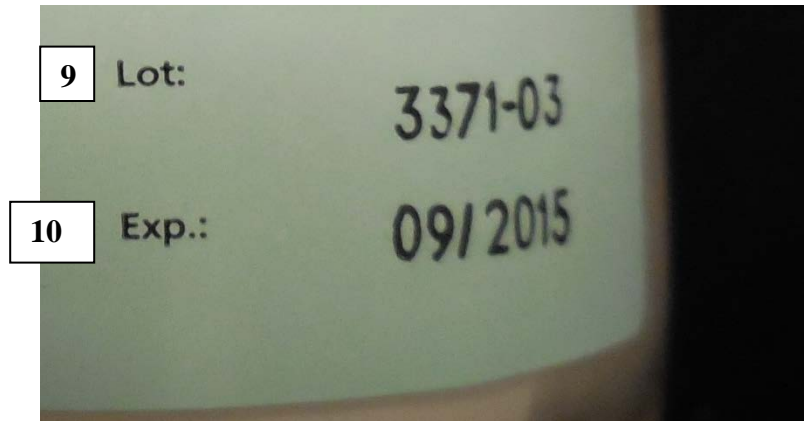


Figure 3 – Sample Label – part 3

- All drugs have a **GENERIC** name and a **TRADE or BRAND** name.
 - ◆ Both names will appear on a proper drug label.
 - ◆ The trade name will be given prominence and the generic name will usually be in smaller type.

1. Generic Name

- The **generic name is the common chemical name** of the active ingredient in a drug product.
 - ◆ It is usually found below the Trade Name.

In Figure 1 - Sample Label, “Penicillin G Procaine” is the generic name, (Item #1).

2. Trade or Brand Name

- **The trade or brand name is the name chosen, by the drug company,** for their particular product. (The term “Trade Name” will be used from this point on).
 - ◆ In some cases, the trade and generic names may be the same, but in most instances they are not.

In Figure 1 - Sample Label, “Propen LA” is the trade name (Item #2)

- Another example which illustrates trade and generic names is “Liquamycin” and “Oxyvet”.
 - ◆ **Liquamycin** is Zoetis’ trade name while **Oxyvet** is the trade name used by P.V.U. for the generic drug **oxytetracycline hydrochloride**.
 - ◆ The generic name tells you that Liquamycin and Oxyvet are actually the same drug.
- Because the trade name is given prominence in advertising, it may be difficult to convince clients that products with the same generic name are actually the same drug.
- Special symbols are placed on the drug label to indicate what schedules of the FDA they are listed. For example,



Prescription drug as per the Prescription Drug List – Products for Veterinary Use

Controlled substance as per the *Controlled Substances Act*

Narcotic under Narcotics Control Regulations

NOTE: Products with a prescription, controlled or narcotic drug designation are not allowed to be sold or stored at an AMS outlet.

NOTE: There are no special designations or symbols on the labels of OTC products

3. Drug Identification Number (DIN)

- All drugs that are licenced for sale in Canada have a **Drug Identification Number** or a **DIN** which is assigned by Health Canada.

In Figure 1 - Sample Label, the DIN is 02239151 (Item #3).

NOTE: The **DIN** must be present on the label of every drug that is sold in Canada.

- Health Canada maintains the Drug Product Database (DPD)¹. The DPD is a searchable database that contains specific information for drugs approved for use in Canada.
 - ◆ It can be searched by Brand or Trade Name, the manufacturer, the active ingredient (generic name) and by a numerical listing of the *DIN* Number.
 - ◆ By referring to the numerical listing of the *DIN* on this website, anyone can quickly determine what active medicinal and non-medicinal components are in a drug.
- In the event of accidental human poisoning, an attending physician who looks up the *DIN* of the offending product can get immediate information on the active ingredients and recommend treatments from Poison Control Centres.
- Using the *DIN* prevents the possibility of mistakes that might occur through the use of only the trade or generic name.

¹ <http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp>

NOTE: For the purposes of the AMSR, the presence of a DIN is a defining characteristic of an authorized medicine, with the exception of biologicals.

- **Any product with a *DIN*** that is **not listed in Section 14** of the AMS Regulation **cannot be sold** at an AMS outlet.
- **Biologicals** (e.g. vaccines) are drugs derived from biological sources. They are licenced by the Canadian Food Inspection Agency under the authority of the *Health of Animals (Canada) Act* and regulations made under it.
 - ◆ Biologicals do not have a DIN. Instead, the CFIA assigns an Establishment Licence Number (ELN)
 - This is often abbreviated, on a drug label, as Ag. Can. Est. Lic. No.

NOTE: The DIN or ELN must be visible.
Therefore, AMS outlets must keep drugs in their original packaging.
An exception may be made for the sale of individual boluses.
Where drugs are stored in alternative containers, the DIN should be marked on the container.

Section 22(6) still requires the presence of a DIN on the alternative container.

4. Content and Concentration

- This section contains a listing of the active ingredients, preservatives and carriers.
 - ◆ It also identifies the concentration of each ingredient.

In Figure 1 - Sample Label, the label indicates that there are:

- ◆ 300 mg

in each cc or ml of product. (Item #4).

- Drug concentrations are expressed in different ways for various drug forms as follows:
 - ◆ Solutions
 - The concentration is expressed as the number of milligrams (mg) contained in each millilitre (ml) or cubic centimetre (cc) of product.
 - ◆ Powders
 - The concentration is expressed as the number of mg of active ingredient per gram (g) of powder.
 - ◆ Boluses/Bollettes or Tablets
 - The concentration is expressed as the number of mg per bolus.

- ◆ Vitamins and some other drugs
 - The concentration of vitamins and some other drugs, such as penicillin, are expressed in International Units (I.U. or U.) per ml.

NOTE: See Appendix “C” for Units of Measure.

- The concentration of a drug has a direct effect on dosage recommendations. i.e. Liqueamycin could contain 100 or 200 mg of the active ingredient oxytetracycline in each ml (cc). The dosage in cc’s or ml’s for the product with the 200 mg concentration would be half the dose of the 100 mg concentration.

5. Indications

- This section of the label states (indicates) what disease conditions the drug is intended for.
 - ◆ It will also indicate the species of animals the product is to be used on.

In Figure 2 - Sample Label (Item #5), the label states that Propen LA is used for the treatment of the following infections caused by bacteria susceptible to penicillin:

Cattle: Bacterial pneumonia, calf diphtheria, footrot, metritis, wound infections.

Swine: bacterial pneumonia, erysipelas, wound infections.

NOTE: A customer should always be referred to a registered veterinarian if he or she is unsure what a particular drug is needed for the treatment of the condition of the animal.

- The indications stated on the label should meet the purchaser’s needs; otherwise the desired results will not be achieved.
- Examples of indications from actual drug labels:
 - ◆ For use in the treatment of thrush, hoof punctures, cracked hooves in horses and foot rot and ringworm in cattle and sheep.
 - ◆ For infections caused by susceptible bacteria.
 - ◆ For the treatment and prevention of ketosis.
 - ◆ An insecticide for the treatment and prevention of fly maggots in wounds on beef cattle and horses.
 - ◆ For the prevention and treatment of scours in pigs, cattle, sheep and horses.

6. Dosage

- Dosage involves more than just the amount given in a single injection.
 - ◆ It is best to think of what is called a “**Dosage Regime**”.

A dosage regime includes:

- ◆ Amount to be given at one time
- ◆ Route of administration
- ◆ Frequency of administration
- ◆ Duration of treatments

A. Amount

- The amount of a solution to be given by injection or oral administration is generally expressed as the number of millilitres (ml) or cubic centimetres (cc) per kilogram (kg) of body weight.
- Powdered or solid drug doses are generally expressed as the number of grams (g) or number of tablets/boluses per kilogram (kg) of body weight.
- Dosages for drugs used in the feed or water will be expressed as the number of grams (g) or millilitres (ml) per litre (l) of water or per kilogram (kg) of feed.

B. Route of Administration

- The route of administration states how to give the drug, e.g. oral, intramuscular, subcutaneous, intravenous, etc. (See Chapter 5 for drug administration routes)

C. Frequency of Administration

- The frequency of administration or **dosage interval** is expressed by terms such as: *one time only, *once a day, *morning and night, *every 6 hrs, etc.

D. Duration of Treatment

- The duration of treatment is expressed by terms such as: *every 24 hours for at least 3 days, or *maximum duration of treatment should not exceed 5 days.
 - ◆ Failure to treat for the minimum length of time increases the risk of relapse.
- Exceeding the duration of treatment can have undetermined effects on safe withdrawal times (see below “7. Warning”).
 - ◆ Specific dosage regimes have been tested to determine withdrawal times.
 - ◆ Any deviation from label recommendations means that the withdrawal times are no longer valid.
- Besides increasing the risk of increasing the withdrawal time, exceeding the recommended dosage carries the risk of poisoning the animal.
 - ◆ This is particularly true for toxic drugs such as selenium.

NOTE: It is important for the producer to know the weight of the animal being treated.

- ◆ Guessing weights can lead to over or under dosing.
- ◆ Use of a scale or weigh tape is highly recommended.

In Figure 2 - Sample Label (Item #6): the injection dose is 1mL per 15 kg of body weight.

- ◆ Non-lactating cattle: the route may be either intramuscular or subcutaneous.
- ◆ Swine: the only route is intramuscular.
- ◆ The frequency and duration of treatment are not covered on the package label. More information regarding the mg/kg body weight dose, frequency, duration and volume per injection site limitations are listed in the package insert (as referred to on the package label).

E. Dosages for Vaccines

- The effectiveness of a vaccine requires the injection of a minimum amount of antigen regardless of the size of the animal.
 - As a result, for a given vaccine, the same dose is recommended for all animals regardless of age or size.

NOTE: Vaccine doses are standard, regardless of the size or age of the animal.

7. Warning

- **This is the section where warnings about *human health hazards* are given.**
 - ◆ In some instances animal health hazards may also be listed here.
- The **WITHDRAWAL TIME** will be stated in this section.

In Figure 1 - Sample Label (Item #7):

- ◆ The drug cannot be given to lactating dairy cattle.
- ◆ The cattle withdrawal for subcutaneous administration is 14 days after the last treatment.
- ◆ The cattle withdrawal for intramuscular administration is 21 days after the last treatment.
- ◆ The swine withdrawal for intramuscular administration is 10 days after the last treatment.

NOTE: An outlet licensee must draw to the attention of a purchaser of authorized medicine any precautions to be taken with respect to the minimum withdrawal time before

- ◆ slaughtering an animal
- ◆ using animal products or by-products from the slaughtered animal for human ingestion.

The withdrawal time stated on a drug label only applies if all its directions are followed exactly in respect of the administration of the drug to the specified species of animal for which the drug is intended.

- If anything is changed pertaining to increasing the dosage, route of administration, or species of animal, safe withdrawal times are no longer known.
 - ◆ These deviations increase the chance that the animal, or its products, may contain drug residues which could be potentially harmful to humans.
- Examples of warning statements from other drug labels:
 - ◆ Danger, Poison, Inflammable
 - ◆ Do not apply to teats or lactating animals
 - ◆ Always store out of the reach of children
 - ◆ Avoid contact with skin
 - ◆ If human or animal poisoning should occur, immediately consult a physician or veterinarian.

8. Caution

- This section of the label **draws attention to any potential adverse reactions** that may occur **in the animal.**

In Figure 2 - Sample Label (Item #8), the following cautions are brought to the attention of the user:

- ◆ In case of an anaphylactic reaction, administer epinephrine immediately to prevent death.
- ◆ In pigs, the administration of this product may occasionally cause a fever, vomiting, shivering, listlessness, incoordination and possible death.
- ◆ In pregnant sows and gilts it may result in abortions.

- This information is found in a separate section to draw attention ensure that the user is aware of these potential reactions and is prepared to respond in a proper manner.
- If the handling of a drug is potentially hazardous to a human, warnings may also sometimes be stated in this section.
 - ◆ In most cases human health hazards are listed in the Warning section.
- Other examples of caution statements include:
 - ◆ Do not inject more than 5ml at any one site
 - ◆ Harmful if swallowed or inhaled
 - ◆ Wash hands with soap and water after using
 - ◆ Administer slowly
 - ◆ Cease administration if adverse symptoms occur
 - ◆ Use only if clear

9. Lot Numbers

- By law most drugs require a lot number.

In Figure 3 - Sample Label, the Lot number is stated as 3371-03 (Item #9)

- All AMS outlet licenses are required to record lot numbers on sales receipts.
- In the event of a drug recall, public announcements will be made.

NOTE: It is the responsibility of AMS licensees and the purchaser of medicines to check lot numbers in their possession if a drug recall is issued.

AMS outlets may be asked by an ARD inspector to provide a list of purchasers of the type of medicine over a certain time period regardless of the lot number.

10. Expiry Date

- Expiry dates provide the purchaser with a **guarantee, from the manufacturer**, that the drug will contain a minimum amount of activity, providing it has been stored properly.
- AMS outlet licenses are required to record expiry dates on sales receipts.

In Figure 3 - Sample Label, the expiry date is stated as **09/2015**. This means that this product expired on the last day of September of 2015.
(Item #10)

- If administered to an animal, expired drugs may not be effective, even when used as directed. The AMSR prohibits the sale of expired drugs.
- It is important to check expiry dates when drugs are received from a wholesaler.
 - ◆ If the drug does not have a reasonable expiry date you may get stuck with unsold expired product.
- Selling short dated drugs to customers is not a good practice because the customers may not be able to use the product before the expiry date.
- Stock should be rotated.
 - ◆ This means that new stock, with a longer expiry date, should be placed behind older stock with a shorter expiry date.
- Outdated drugs must be removed from the shelf.
 - ◆ Speak to the supplier or distributor of the expired drug to determine if it can be returned for credit.

NOTE: The sale of outdated drugs is prohibited by the AMSR.

- Expiry dates can be expressed in different ways.
- One way of stating the expiry date is to use a sequence of numbers designating the specific date.
 - ◆ For drugs packaged in Canada the designation 21/12/14 (dd/mm/yy) means that the drug expires on Dec. 21, 2014.
- Americans use month/day/year (e.g. 12/21/2014). There can be confusion between American and Canadian drugs when the day of expiry is less than 12.
e.g. 3/8/14 would mean August 3, 2014 under the Canadian system but March 8, 2014 for an American product.
- If the expiry date is indicated using year and month only it is understood that the expiry date corresponds to the last day of the month.

11. Precautions

- This section gives the storage requirements.

In Figure 2 - Sample Label, the storage instructions simply state “Store between 15-25⁰ C” (Item #11).

- **All drugs must be stored according to the manufacturer’s recommendations.**
 - ◆ This will ensure that the product retains its effectiveness until the expiry date.
- In addition to being responsible for the proper storage of medicines at their place of business, AMS licensees and QC holders also have a responsibility to alert the purchaser of any storage precautions on the label or package insert of medicines.
- If shipments received from a supplier do not appear to have been properly stored then the product should not be accepted.
 - ◆ For example:
 - John receives a drug that requires refrigeration but there is no indication or evidence that the supplier placed cold packs in the shipment.
 - John should return the product.
 - ◆ Similarly, if there is any suggestion that a drug has been exposed to excessive heat or may have been frozen it should not be accepted.
- Similarly, for safety reasons, AMS Outlets should not accept the return of drugs from customers who have purchased them because there is no way of knowing whether they were stored properly.
- Examples of “Precaution Statements” from drug labels:
 - ◆ Store in a Dark, Cool Place
 - ◆ Do Not Freeze
 - ◆ Do Not Store Open Vials
 - ◆ Store at 20 C, etc.

12. General Storage Recommendations

- Drugs must be stored at the temperature recommended on the label, and they should never be frozen. If no temperature is indicated on the label then the following guide lines may be used:
 - ◆ Refrigerate means 2-8⁰ C.
 - ◆ Store in Cool Place means 8-15⁰ C.
 - ◆ Protect from excessive heat” means store below 40⁰ C.
- All drugs, unless otherwise specified must be protected from moisture and light. Drugs should not be stored in direct sunlight.
 - ◆ Drugs which are particularly susceptible to the effects of light are bottled in brown glass.
 - ◆ Placement of the bottle in a cardboard box or other type of opaque container also serves to protect the drug from the effects of light.

13. Contraindications

- Special circumstances under which the drug should not be administered will be stated in the section of the label called “Contraindications” or on the package insert.

In Figures 1-3 - Sample Label does not have a contraindications section.

- Examples of Contraindications:
 - ◆ Do not administer to pregnant animals
 - ◆ Do not administer to animals with liver or kidney disease

Package Inserts

- Package inserts generally provide supplementary information to the label. e.g. Package inserts will often contain information on the chemical composition of the drug and the way in which it is metabolized in the body.
- It may contain more detailed information about dose, route, frequency and duration of treatment.
- The insert may replace the label if the package is too small to meet the labelling requirements of the *Food and Drugs Act*.

NOTE: Package inserts should be given to the customer.

Extra Label Use

- “Extra label use” means using a drug in any manner other than what is specifically recommended on the label. Any deviation from the label dosage amount, frequency, duration, route or species of use is considered extra label use.
- **Only registered veterinarians can recommend “Extra Label Use”.** This practice is considered a prescription and the veterinarian is responsible and liable for any adverse consequences of “**Extra Label Use**”.

NOTE: Using a drug in any manner other than as specifically stated on the label, by anyone other than a registered veterinarian, is illegal as per *the Food and Drug Act* (Canada).

- Calculations of withdrawal times are based on the recommended label dosage amount, frequency, duration and route of administration and do not apply to Extra Label Use.
 - ◆ When a drug is used in any manner other than as recommended, there is no way of knowing what the withdrawal time may be.

Summary of Sections Commonly Found on a Drug Label

- | | |
|---|--|
| <input type="checkbox"/> Generic Name | <input type="checkbox"/> Warning |
| <input type="checkbox"/> Trade (Brand Name) | <input type="checkbox"/> Caution |
| <input type="checkbox"/> Drug Identification Number (DIN) | <input type="checkbox"/> Lot Number |
| <input type="checkbox"/> Contents | <input type="checkbox"/> Expiry Date |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Precautions |
| <input type="checkbox"/> Dosage and Administration | <input type="checkbox"/> Contraindications |

**AMS LICENSEES AND QC HOLDERS HAVE A
RESPONSIBILITY TO ADVISE ALL CUSTOMERS TO
READ THE LABEL THOROUGHLY BEFORE THEY USE
THE DRUG.**

Review Questions Chapter 3

1. Name three physical agents that may damage drugs.

2. What measures do manufacturers of drugs take to protect drugs from damage?

3. What is the generic name of a drug?

4. What do these symbols mean?



5. Can an AMS outlet handle or store a drug that has any of the symbols listed in Question 4?

6. What is the DIN and what is its significance?

7. Do all livestock medicines handled in AMS outlets have a DIN? If not, which products do not have one and what do they have instead?

8. a) What do the following terms stand for? mg; g; ml; cc; kg

b) Which of the above, if any, are the same measure?

9. a) A producer has a calf which he claims weighs 770 pounds. He purchases a product from you and wants to know how many cc's he should give to his animal. The label states that this product has 500 mg of product per ml. The dosage is expressed as 50 mg per kg. There are 2.2 pounds in a kg. How many cc's would you tell the producer to give this calf?

b) What would the dose be if the concentration of this drug was 250 mg rather than 500 mg?

10. What does the indication section of a drug label tell you?

11. What are the four main components of a dosage regime?

12. What is the major difference in dosage rates for a vaccine compared to other drugs?

13. What is the withdrawal time and where would you find this time on a drug label?

14. What activities could affect the withdrawal time as stated on the label?

15. Why are lot numbers and expiry dates important?

16. What is meant by the term “contraindication”?

17. What is meant by the term “Extra Label Use” and under what conditions is it legal?

18. What is the withdrawal time for “Extra Label Use”?

DRUG FORMULATIONS

OBJECTIVE:

To describe different types of drug formulations and give examples of why different formulations are needed and how they are used.

NOTE: For the purpose of completeness, this section includes supplementary information for AMSO Licensees or Qualification Certificate holders.

PHYSICAL DRUG FORMS

Drugs come in many formulations, each of which is designed for a specific purpose and/or route of administration.

Basic Drug Formulations

- Liquid
- Semi – Solid
- Solid

I. LIQUID DRUGS

- Liquid drugs come in two forms
 - ◆ Solutions
 - ◆ Suspensions

A. Solutions

- Solutions are the simplest form of liquid drug preparations.
- A **solution** is a preparation which **contains** one or more **solutes** (solids) completely dissolved **in a solvent** (liquid).
 - ◆ i.e. In a sugar solution, sugar is the solute and water is the solvent.
- Solutions are clear because the particles in the solution are completely dissolved thus they are not visible.
- In an “Aqueous Solution” water is used as the solvent.
 - ◆ Most aqueous solutions are non-irritating and can be given by any route.
- Propylene glycol is commonly used as a drug solvent.
 - ◆ Propylene glycol solutions are too irritating to give subcutaneously.
 - Small doses can be given by intramuscular injection.
- In a “Tincture” solution, alcohol is used as the solvent.
 - ◆ Tinctures should only be applied topically when a drying effect is desired.
 - Tincture of iodine, which is used to disinfect navels, is the only tincture likely to be handled by an AMS outlet.
- Solutions are available for oral, topical, parenteral or ophthalmic use. Please refer to Chapter 5 for more information about this.

- ◆ Solutions for oral and topical use do not have to be sterile or free from particulate material.
- ◆ Solutions for parenteral or ophthalmic (eye) administration (see Chapter 5) **must** be sterile and free from particulate material.

Solutions are liquid preparations

that contain one or more solutes completely dissolved in a solvent.

Suspensions are liquid preparations

where the solutes is only suspended in the solvent.

B. Suspensions

- **Suspensions** are liquid preparations where the **solute is suspended rather than dissolved** in the solvent.
 - ◆ The solute **will eventually settle out**, unless an emulsifying agent has been included in the preparation.
 - ◆ When the solute settles out, solid material will be seen in the bottom of the vial and clear liquid will be on top.
 - ◆ In order to re-suspend the solute, **suspensions need to be well shaken prior to use**.
 - Injectable penicillin products and bacterins are common examples of suspensions handled by AMS outlets.
 - Bacterins are suspensions of killed bacteria or live bacteria whose virulence has been reduced for use as a vaccine

NOTE: Suspensions cannot be used for intravenous injection because they are too thick

II. SEMI-SOLID DRUGS

- Semi-solid drugs come in four forms:
 - ◆ Ointments
 - ◆ Creams
 - ◆ Pastes and poultices
 - ◆ Suppositories

A. Ointments

- Ointments are semi-solid preparations which have an oil base.
 - ◆ They are intended for topical use, including ophthalmic use.
- Ointments form an occlusive film which serves to prevent the loss of moisture from an injured area.
 - ◆ Because they have an oily base, ointments tend to float off of wet wounds.
- The most common ointments sold by AMS outlets are ointments intended for the topical treatment of wounds.

B. Creams

- Creams are very thick emulsions using less oil and more water.
 - ◆ Propylene glycol is often used as the carrier.
 - ◆ Because creams mix well with body fluids, they are recommended, rather than an ointment, for wet or weeping lesions.

C. Pastes and Poultices

- Pastes and poultices are similar to ointments, but they are thicker.
- They are used topically.
 - ◆ They often contain medications intended to alleviate inflammation.

D. Suppositories

- Suppositories are semi-solid drug preparations intended to be inserted into a body opening.
 - ◆ They melt at body temperature.
 - ◆ They are seldom, if ever, used in production animals.

III. SOLID DRUG PREPARATIONS

- Solid drugs come in the following forms:

- | | |
|------------|------------|
| ▪ Tablets | ▪ Resins |
| ▪ Boluses | ▪ Powders |
| ▪ Capsules | ▪ Granules |
| ▪ Implants | |

A. Tablets, Boluses and Bolletes

- Due to their small size, tablets are not commonly dispensed by AMS outlets. They are primarily intended for humans, cats and dogs. However, boluses/bolletes (below) may be dispensed by AMS outlets for use in livestock.
- Boluses are large tablets for large animals. A bollete is a small bolus.
- Boluses consist of compressed powdered drugs and a binding agent.
 - ◆ Some have a film coating to prevent crumbling or protection from stomach acid.
- Most boluses and bolletes are intended for oral administration.
 - ◆ A balling gun should be used to give boluses or bolletes orally.
- Boluses intended for placement in the uterus of large animals, to prevent infections following birth, or as a treatment for retained placentas are also available.

B. Capsules

- Capsules are made out of gelatin and the active ingredient(s), usually a powder or a granule, is put inside the capsule.
 - ◆ Capsules are primarily designed for humans, and small animals, such as cats or dogs.

C. Implants

- Implants are hard cylindrical pellets which are given by subcutaneous injection.
 - ◆ They dissolve slowly, thus the active ingredients are released over a long period of time.
 - ◆ Most implants contain hormones which are intended to improve feed efficiency and enhance growth rates, i.e. Synovex® implants for cattle.

D. Resins

- Resins are preparations in which the drug is incorporated into a resin or plastic like substance.

E. Powders

- Powders are a very simple form of a solid drug.
 - ◆ A variety of drug powders are on the market.
 - ◆ Most are intended to be mixed in the feed or water.

F. Granules

- Granules are modified powders where the drug particles have been coated with various materials to mask the taste or improve solubility.

Review Questions Chapter 4

1. List the three basic types of drug formulations.

2. Name the only type of drug formulation that may be given by the intravenous route.

3. What special properties must be present in a solution that is injected into an animal or placed in its eye?

4. What is the difference between a solution and a suspension?

5. What is the advantage of using a cream rather than an ointment for weeping or wet wounds?

6. Name the types of solid drug preparations that are most likely to be handled by an AMS outlet.

DRUG ADMINISTRATION ROUTES

OBJECTIVE:

To gain a basic understanding of drug administration and how different routes may affect drug effectiveness and safety.

DRUG ADMINISTRATION ROUTES

- The route of administration refers to the way a drug is given to an animal. **It is very important that drugs are administered correctly!**
 - ◆ The use of administration routes, other than those recommended by the manufacturer, may affect **drug effectiveness, safety and withdrawal times**.
 - ◆ The use of administration sites other than the ones recommended may result in delayed drug absorption, drug failure, severe tissue reactions, shock or death.
- **If a purchaser is unsure about the effectiveness, safety, or administration of any authorized medicine, always refer them to a registered veterinarian.**
- Various on-farm food safety organizations make “Codes of Practice” available that are relevant to their area of specialty. Codes of Practices outline preferred administration routes, withdrawal times, and dosage per site for various medication types. Examples of participating organizations and their sphere of expertise include:
 - ◆ Canadian Quality Milk - for dairy cattle
 - ◆ Alberta Beef Quality Starts Here - for beef cattle
 - ◆ Canadian Quality Assurance for - swine

AMS outlets handle authorized medicines for which the following routes of administration may be followed:

- ◆ Oral
- ◆ Parenteral
- ◆ Topical
- ◆ Intramammary
- ◆ Ophthalmic
- ◆ Intrauterine

I. ORAL ADMINISTRATION

- **Oral administration means giving a drug by mouth.** This method of administration is also called “Enteral Administration” which means via the enteric system (digestive tract).
 - ◆ Many different drugs are available for oral administration in a variety of forms (i.e. powders, liquids, pills, boluses, etc.)

A. Advantages

1. Ease of Administration

- Most methods of oral administration are quite easy particularly when the drug is added to the feed or water.

2. Safety

- The oral route is the least likely route to cause serious adverse reactions such as anaphylactic shock (severe allergic reaction).
 - ◆ This increased safety is due to slower absorption rates and lower peak blood levels.

B. Disadvantages

1. Slower onset of action

- The onset of action is slower than other routes due to slower absorption.

NOTE: Because of slow absorption, the oral route is often used following initial treatment by one of the other administration routes that provide quicker drug absorption.

2. Erratic or incomplete absorption

- Variations in stomach and intestinal motility and the amount of filling of the gut affect the rate and completeness of absorption.

3. Inactivation

- Drugs may be inactivated by the acid of monogastric (single stomach) animals, i.e. pigs.
 - ◆ Drugs intended for oral use in monogastric animals are formulated to protect the drug from the stomach acid.

4. Sick Animals

- Sick animals may not get enough of a drug by the oral route because they are not eating or drinking enough.
 - ◆ Often the oral route is better suited for disease prevention rather than treatment.

5. Special Equipment and Skills

- Oral administration of drugs by methods other than through the feed and water requires good restraint, specialized equipment and physical skills.

6. Inadequate dosing/overdosing (when giving via feed/water)

- Dosing in feed or water requires precise calculations to make sure the concentration of drug in the feed (mg drug per kg of feed) or water (mg drug per L of water) is correct to allow for correct dosing. This is dependent on animals consuming normal amounts of feed/water in a day.
- Animals that are sick may consume less feed/water, reducing the dose of drug they take in.
- Small or large animals may eat less/more feed, impacting their mg/kg drug dose that is taken in.

C. Methods of Oral Administration

1. Putting the Drug in the Feed or Water

- **Putting the drug in the feed or water is the least obtrusive method** of oral administration resulting in the least distress to the animal.
- The dosage is regulated by the amount the animal will eat or drink.
- Drugs may be mixed into prepared feeds or crumbles or powders may be sprinkled on top of the feed.
- Most powdered drugs do not dissolve readily in cold water, thus, they will settle out (precipitate) if placed directly into the trough.
 - ◆ To prevent settling out, it is best to dissolve the drug in a small quantity of warm water before adding it to the drinking water.
- Automatic medicators are available for use with automatic watering systems.

2. Stomach Tube

- **Stomach tubes are used when there is a need to administer large volumes of liquid medication by the oral route.**
- Care must be taken to ensure that the tube does not enter the trachea (windpipe).
 - ◆ Accidental administration of liquid medications, into the trachea, can result in the development of “aspiration pneumonia”, which is often fatal.
 - ◆ Producers should be referred to a registered veterinarian to learn proper stomach tubing technique.
- Medication can be forced through the tube by a stomach pump or it may be allowed to run in by gravity with the use of a funnel.

3. Drenching

- **Drenching refers to the administration of small quantities of liquid medication** by mouth using a long necked bottle or a rubber bulb dose syringe.
- Care must be taken to avoid injury to the lining of the mouth or throat when using a dose syringe.
- When an animal is drenched, its head should be kept relatively level.
- Medication should be given slowly to give the animal a chance to swallow.
 - ◆ Administration must be stopped if coughing occurs.
- Particular care has to be exercised when drenching with mineral oil.
 - ◆ Mineral oil is smooth and tasteless and does not stimulate a normal swallowing reflex. This increases the risk of aspiration.
 - ◆ Because of the risk of aspiration, **it is best to administer mineral oil through a stomach tube** rather than as a drench.

4. Balling Guns

- **Balling guns are instruments designed to give boluses or bollettes by mouth.**
- Balling guns come in two standard sizes.
 - ◆ Large metal balling guns are used for larger calves, yearling and adult cattle.
 - ◆ Smaller plastic balling guns are used for small calves, sheep and goats.
 - ◆ The proper size should be chosen, considering the size of bolus and the size of animal.
 - Large boluses should not be given to calves, lambs or kids.
- The bolus or bollette must be placed at the back of the tongue, but not so far back that it accidentally enters the trachea (windpipe).
 - ◆ Care must be taken to prevent injury to the lining of the mouth or throat.
- Dehydrated animals may not be able to swallow a bolus. Placing a small amount of lubricating jelly on the bolus will assist swallowing in these cases.

NOTE: Customers who do not know or are unsure of how to perform the required oral treatment method should be referred to a registered veterinarian for proper instruction.

NOTE: All methods of oral administration, other than administration in the feed or water, require suitable restraint to allow for proper administration and to minimize the chance of injury to either the animal or the handler.

II. PARENTERAL ADMINISTRATION

- Parenteral administration is a general term which refers to all routes that are not by the enteral (oral) route, which generally require the drug to be injected with a syringe and needle.
 - ◆ In Greek “Para” means “alongside of” or “parallel”.
 - ◆ “Enteron” means “intestinal”.
 - ◆ “Parenteral” literally means “alongside of (not in) the gut”.
- General Advantages of Parenteral Administration
 - ◆ More rapid response than oral
 - ◆ More reliable response
 - ◆ Greater accuracy of dosing
 - ◆ Suitable for drugs that cannot be administered orally

Commonly used terms in parenteral drug administration

Sterile
Isotonic
Buffered

Sterile

- Sterile means freedom from any microscopic organisms including those capable of causing disease.
 - ◆ Sterility is very important because parenteral injections bypass some, or all, of the natural defence systems of the body.

NOTE: Under ideal conditions the site for any parenteral injection would be prepared by removing the hair and washing and disinfecting the skin. This is not practical under most farm and ranch conditions, but care should be taken to give injections in areas that are clean and free from dirt or manure.

- Producers must be made aware that sloppy or dirty injection techniques including failure to properly prepare the site and injecting several animals with the same needle carries an increased risk of abscesses at the site of injection.

Isotonic

- Isotonic means the same concentration as body fluids.
 - ◆ It is particularly important for intravenous drugs to be isotonic.
- **Suspensions** (i.e. most injectable penicillin preparations) **must not be given intravenously** because they are simply too thick to place in the blood stream and can cause severe complications if given intravenously.

Buffered

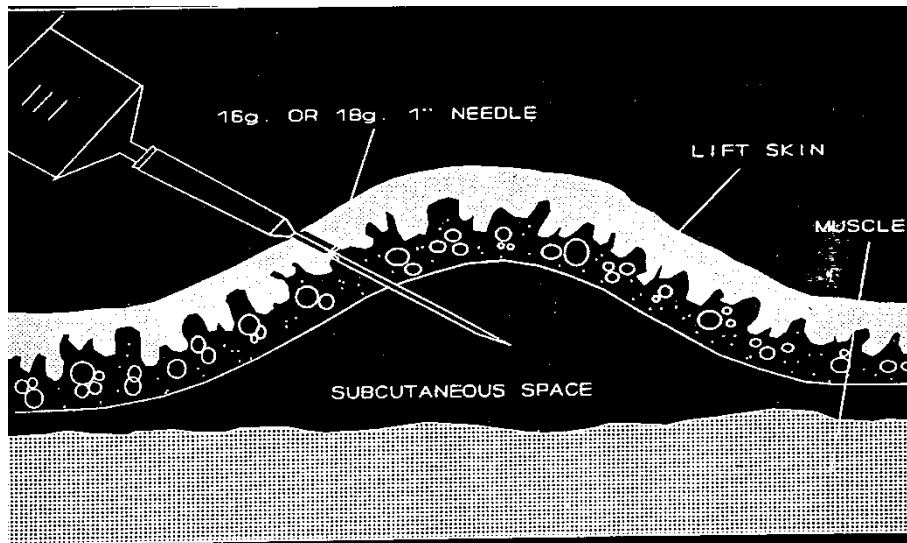
- Buffered means the drug is chemically balanced so that it does not affect the acid base balance of the body.

There are many different parenteral routes, but only three are commonly used by livestock producers.

Subcutaneous Injection
Intramuscular Injection
Intravenous Injection

A. Subcutaneous Injection (S.C. or S.Q.)

- **“Subcutaneous” means under the skin**, therefore S.Q. administration means placing the drug just under the skin and **not into the deeper tissue**.
- Of the three common parenteral routes of administration **absorption of the drug is slowest from a subcutaneous injection**.
- The S.Q. route is generally chosen if a slow continuous absorption is desired or there is a moderately high risk of an allergic reaction.
- S.Q. administration is preferred whenever possible to avoid carcass damage and subsequent trim loss at the packing plant.
- Many vaccines are given by the subcutaneous route.
- Subcutaneous injections can be given at designated sites.
 - ◆ Horses, cattle and sheep: the best site is the side of the neck, just ahead of the shoulder.
 - ◆ Pigs, calves and sheep: the loose fold of skin behind the elbow.
 - ◆ Cattle – alternative site: the loose skin on the side of the chest.
 - ◆ Pigs – alternative site: the skin at the base of the ear.
 - ◆ Hormone implants: the skin at the base of the ear is used for hormone implants because this part of the carcass is not used for food.
 - This eliminates the risk of implants getting into the food chain.
 - In pigs, the neck is not a suitable area for subcutaneous injections because of the heavy layer of fat immediately below the skin.
 - Drugs injected into fat are poorly absorbed because of the reduced blood supply.



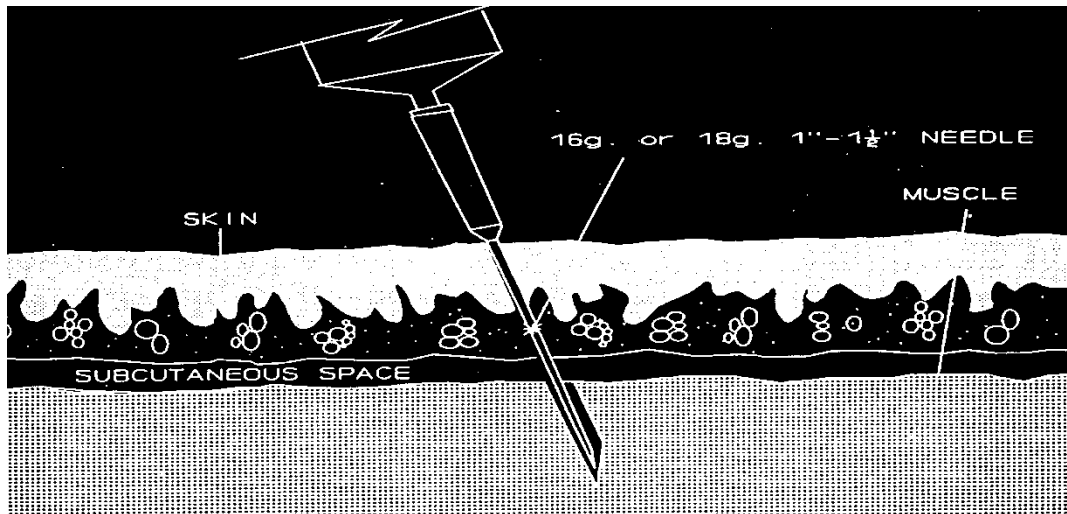
Subcutaneous Injection

- A subcutaneous injection is performed by picking up a loose fold of skin, inserting the needle through the skin then running it parallel, to the surface of the skin, after penetration has been achieved.
- An alternative method is to use a short needle (no more than 1.25 cm or ½ inch) and injecting it straight through the skin. This type of needle often used to vaccinate cattle with an automatic syringe.
- Because of the rich nerve supply, **irritating drugs should not be given by the S.Q. route.**

B. Intramuscular Injection (I.M.)

- “**Intramuscular**” means into the muscle, therefore an I.M. injection consists of placing the drug directly into the muscle tissue.
- The absorption rate of an **intramuscular injection is faster than subcutaneous but slower than intravenous.**
 - ◆ Some vaccines and most antibiotics are given by the intramuscular route.
 - ◆ Intramuscular sites are also used for the administration of depot preparations, such as
 - drugs formulated for slow release from the muscles, i.e. long-acting penicillin
 - various injectable mineral and vitamin preparations.
- Deep intramuscular injections have a faster absorption rate than shallow injections because of better blood supply in the deeper tissues.
 - ◆ In most animals a 1½-inch needle will be long enough providing the injection is perpendicular (at a 90° angle) to the skin.
- For large bulls and pigs that have a thick layer of subcutaneous fat, a 2 inch needle may be required.

- Drugs that are more irritating may be given by the intramuscular route versus the S.Q. route because there are not as many sensory nerve endings in muscle tissue.



Intramuscular Injection

- As a general rule, no more than 10 cc of an irritating drug should be given at one injection site.
 - ◆ In larger animals, or when non irritating preparations are being injected, up to 20 cc can be given at one site.
 - ◆ When more than one site is used, the sites should be at least 10 cm apart.
- In theory, any muscle mass can be used for an intramuscular injection.
- Because some drugs cause permanent damage to the meat, and because any injection has a slight risk of infection or tissue damage, it is recommended that intramuscular injections be given on the side of the neck to avoid blemishes in the more expensive cuts of meat in the rump or ham.
- There is also a possibility of nerve damage occurring at some injection sites. Using the neck minimizes these risks.
- There is always a chance of accidentally hitting a blood vessel when attempting an intramuscular injection. There are two ways to avoid this:
 - ◆ the needle can be put in without the syringe attached or,
 - ◆ with the syringe attached, the operator can pull back on the plunger before pushing it in to inject the drug.
 - If blood is observed, in either situation, the needle should be removed and re-inserted into another site in the muscle.

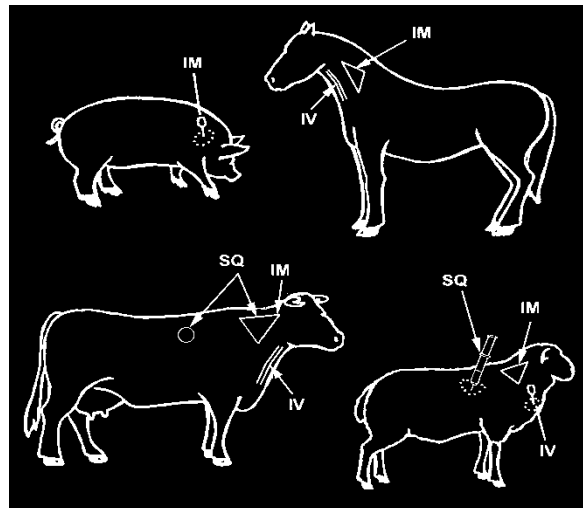
Customers who are uncertain of how to administer an intramuscular or subcutaneous injection should be referred to a registered veterinarian.

C. Intravenous Injection (I.V.)

- **“Intravenous”** means injecting into a vein.
 - ◆ In farm animals, the jugular vein is commonly used.
 - It is readily accessible in the lower part of the neck.
- Because absorption is instantaneous, intravenous injections are used when an immediate effect is required,
 - ◆ i.e. giving calcium to a cow with milk fever.
- The I.V. route is also useful for injecting a large volume of liquid medication that is formulated for intravenous administration,
 - ◆ i.e. electrolytes, calcium and dextrose solutions.
- A syringe can be used to give small amounts of medication by the I.V. route.
- Intravenous injections must be done slowly.
 - ◆ Rapid injections can cause fatal shock reactions.
 - ◆ The chance of a severe allergic reaction is also higher with intravenous injections.
- The I.V. route bypasses all of the body’s natural defense mechanisms against infectious agents; therefore **drugs for intravenous injection must be sterile.**

Many producers do not possess the skills required to perform an intravenous injection.

- These individuals should be advised to consult with a registered veterinarian.



Schematic for injection sites

D. General Guidelines for Injections

1. Recommended Routes

- If there is a choice on the label, use a subcutaneous injection rather than an intramuscular one.

2. Avoid injections in high value cuts

- Choose muscle tissue of lesser value such as the neck rather than the rump.
- Negative reactions may lower the value of the carcass.

3. Use clean or sterile technique as follows:

- Clean the top of multiple use vials with alcohol swabs.
- Do not use alcohol or any other chemical disinfectant on a “live” or “modified live” vaccine vial. This could kill the “live” vaccine agent, making it ineffective.
- Place a separate needle in the bottle top.
 - ◆ Remove this needle before putting an open bottle back into storage.
- Use sterile disposable needles and syringes.
 - ◆ Ideally, a separate needle should be used for each animal.
 - An accepted alternative is to disinfect the needle between animals and limit the use of the same needle to 10-12 animals.
 - i.e. when using automatic injectable syringes to administer vaccines
- Clean and sterilize non disposable equipment before and after use.
 - ◆ Do not use chemical disinfectants for vaccination equipment.
- Keep drugs and equipment in a clean working area.
- Choose an area of clean dry skin on the animal to minimize the chance of infection.
- Always wash hands before and after handling drugs.

4. Proper needle size

- The choice of needle depends on the route of administration, size of the animal and consistency (thickness) of the drug.
- Two measurements must be considered when choosing a proper needle; these are length and thickness (gauge).

NOTE: The smaller the gauge the greater the thickness.

- ◆ The length is measured in centimetres or inches.
- ◆ The gauge or thickness is expressed as a number.
 - 14, 16 and 18 gauge needles are the most common sizes used and of these the 16 gauge needle is used most frequently.
- Common needle lengths range from 1.25 cm (½”) to 5.0 cm (2”).

- The following factors must be considered when choosing needle size:
 - ◆ thickness of the drug,
 - ◆ size of the animal,
 - ◆ route of administration.
- Although 18 gauge needles are suitable for drugs with a watery consistency they will bend or break more easily than a 16 or 14 gauge needle when used on animals with thick hides such as cows, bulls and large pigs.
- Use of an 18 gauge needle is usually restricted to calves, sheep, small pigs, and occasionally horses.
- A 16 gauge needle will handle moderately thick drugs.
 - ◆ They are less likely to break in cows.
- A 14 gauge needle should only be considered for use in bulls or when the drug is very thick.
- 16 gauge, 1.25 cm (1 inch) needles are the best choice when an automatic syringe is used for subcutaneous injections.
 - ◆ Needles longer than 2.5 cm (1 inch) should not be used for subcutaneous injections.
- The proper length for intramuscular injections will vary from 2.5 (1 inch) to 5.0 cm (2 inches).
 - ◆ A 3.75 cm (1½”) needle is the most common length in general use, but may be too long for calves, piglets, etc., and may be too short for mature bulls and fat pigs.
 - ◆ Remember, the intent of an intramuscular injection is to place the drug deep into the muscle.

5. Restrain the animal to prevent:

- injury to the animal,
- injury to the drug administrator and
- broken needles.

All methods of injection require suitable restraint to allow for proper administration and to minimize the chance of injury to either the animal or the handler.

6. Do not inject too much drug at any one site

- **Follow the directions on the label.**
- If there are no specific label instructions use the following guidelines:
 - ◆ no more than 10 ml at a single intramuscular site, or
 - ◆ no more than 20 ml at a single subcutaneous site.

7. Choose different injection sites for repeat treatments

- Use opposite sides of the neck when using repeating treatments over a number of days.

E. Injection Safety for the Drug Administrator

- Any producer who is not comfortable administering an injection by any route should be directed to a registered veterinarian for training.
- Insertion of the needle into the animal should be done with confidence and in one motion. Glancing insertion by a drug administrator who has reservations about inserting the needle is more likely to result in discomfort to and reaction from the animal.
- Used needles should be disposed of in an approved sharps container.
- Once a needle is used, the needle cap should not be placed back on the needle. This increases the chance of needle-stick injury.
- Proper restraint of the animal helps prevent injury of the drug administrator.

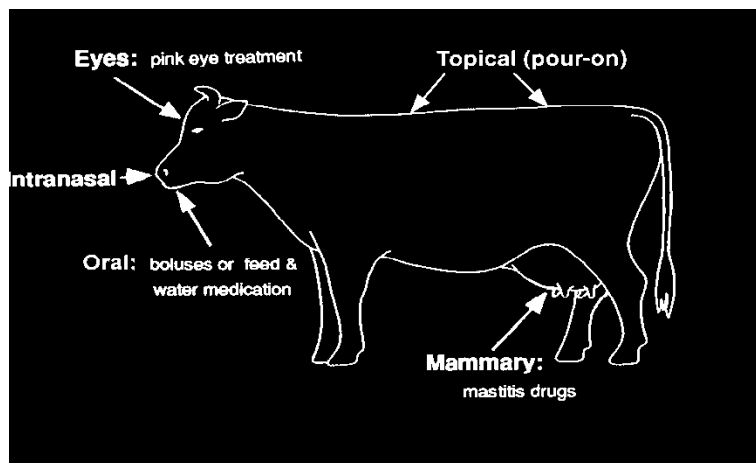
III. TOPICAL ADMINISTRATION

- **Topical administration** refers to the application of a drug to the surface of the skin.
 - ◆ This route can be used for a localized effect, i.e. antibiotics in a wound ointment, or for a generalized (systemic) effect from drugs that are absorbed through the skin, i.e. Ivomec (pour-on).

NOTE: Care must always be taken when using drugs that are capable of penetrating the skin.

Since any drug with the ability to penetrate the hide of an animal can also penetrate human skin, proper protection must be taken when appropriate.

(i.e. wear gloves).



IV. INTRAMAMMARY ADMINISTRATION

- “**Intramammary**” means placing a drug into the udder by insertion through the teat canal.
 - ◆ Antibiotic preparations for the treatment of mastitis are given in this way.
 - Cleanliness is extremely important as the chance of introducing infection into the udder is very high.
 - Only individual treatment syringes (one syringe per teat) should be used to reduce the chance of infection.
- The end of the teat should be cleaned and disinfected before inserting the cannula.
 - ◆ The cannula should only be inserted far enough to enter the teat cistern.
 - It should not be inserted to its full length.
 - The recommended depth of insertion is approximately 0.6 to 0.9 cm (1/4 to 3/8 of an inch).
 - ◆ A disinfectant teat dip should be used following treatment.

NOTE: Drugs infused into the teat will be absorbed into the blood stream. Small quantities will gain access to the other quarters, thus **all milk from treated animals should be discarded**, until the appropriate withdrawal time has elapsed, **even if only one quarter is treated**.

Remember always to follow label instructions.

V. OPHTHALMIC ADMINISTRATION

- This is a special form of topical administration where a drug is placed on the surface of the eye.
 - ◆ Only drugs that are specifically formulated for ophthalmic administration should be used.
 - The primary use of this route, in production animals, is the treatment of pink eye in cattle.

VI. INTRAUTERINE ADMINISTRATION

- “**Intrauterine**” means into the uterus.
- Uterine boluses, which are placed in the uterus after birth are the most likely type of intrauterine preparation to be sold at an AMS outlet.
- It is strongly recommended that the lips of the vulva and surrounding area be thoroughly cleaned and that the producer use clean plastic gloves when placing uterine boluses.
 - ◆ This is done to prevent both animal and human infection.

Review Questions Chapter 5

1. What is meant by the oral administration of drugs?

2. What are the advantages of oral drug administration?

3. What are the disadvantages of oral drug administration?

4. What is the best method to give the following types of medication by mouth?

a) large volumes of fluid?

b) small volumes of fluid?

c) boluses?

d) powder or granules?

5. What are the most commonly used routes for the parenteral administration of drugs?

6. List some common locations on the body where subcutaneous injections may be given.

7. Explain two ways of giving a subcutaneous injection.

8. When giving an intramuscular injection, how can you determine that the needle is actually in the muscle rather than in a blood vessel?

9. Where should intramuscular injections be given and why?

10. What general guidelines should be considered when administering any type of injection?

11. What is the difference between a 14 gauge and an 18 gauge needle?

12. What special precautions should be taken when injecting a drug into the udder?

13. What precautions should be taken when placing boluses into the uterus?

14. What precautions should the handler take when using a pour-on treatment?

DRUGS LICENCED FOR SALE THROUGH AUTHORIZED MEDICINE SALES OUTLETS

OBJECTIVE:

To provide a brief overview of the types of drugs that can be sold at an Authorized Medicine Sales outlet (AMSO).

NOTE: Drugs listed in this section appear in the same order as they are listed in Section 14(2) of the *Authorized Medicine Sales Regulation*.

DRUGS LICENCED FOR SALE THROUGH AUTHORIZED MEDICINE SALES OUTLETS

- **Only Authorized Medicine Wholesalers and Authorized Medicine Outlet licensees are permitted to sell authorized medicine for production animals.**
- Wholesalers are only permitted to sell authorized medicine to outlet licensees; they are not permitted to sell to producers.
- Producers can only buy authorized medicine from an Authorized Medicine Sales Outlet (AMSO).
- However, an exemption is made for veterinarians and pharmacists: the AMSR does not apply to any person who is authorized by the Veterinary Profession Act or the Pharmacy and Drug Act and who sells production animal medicine under the authority of those two Acts.
- Authorized medicines that may be sold in Alberta are specifically listed in the Authorized Medicine Sales Regulation (AMSR).
- In order to be an authorized medicine, a medicine that is listed in the AMSR must also meet the following criteria:
 - ◆ It is a veterinary biologic that, under federal law (*Health of Animals Act*(Canada)), has been
 - authorized for manufacture or import into Canada, and
 - approved for sale in Canada
 - ◆ It has been assigned a Drug Identification Number (DIN) under the Food and Drugs Act (Canada)

Or

 - ◆ It is a product that is registered under the Pest Control Products Act (Canada) and is used for direct application to a production animal
 - This includes insecticide impregnated ear tags.
- The following types of drugs appear as they are listed in section 14(2) of the Authorized Medicine Sales Regulation.

Types of Licenced Drugs

- Veterinary Biologicals
- Antibiotics
- Anti-Parasitics
- Oral preparations
- Wound preparations
- Skin preparations
- Vitamins
- Minerals
- Hormones for growth promotion
- Anaphylactics
- Solutions for metabolic disease and nutritional deficiencies
- Anti-cannibalism compounds
- Topical liniments, counter irritants or poultices
- Oral & topical antitussives, decongestants, bronchodilators or expectorants
- Acetylsalicylic acid boluses
- Disinfectants, udder washes, teat dips and sanitizers

NOTE: IF A DRUG DOES NOT FIT INTO ONE OR MORE OF THE CATEGORIES LISTED IN THIS SECTION, THAT **DRUG IS NOT AUTHORIZED** FOR SALE AT AN AMS OUTLET.

It is also **illegal to store** drugs at an AMS outlet that are not listed in the *AMSR*.

I. VETERINARY BIOLOGICALS – section 14(2)(a)

- Biologicals are drugs (e.g. vaccines) derived from living organisms.
 - ◆ They are used to confer either an active or passive immunity.
- Section 14(2)(a) authorizes AMS Outlets to sell all biologicals other than ***Brucella*, rabies, anthrax vaccines and modified live and live virus vaccines for mammals.**
 - ◆ **Section 15(2) restricts the sale of modified live and live virus vaccines for poultry to hatcheries permitted under the *Health of Animals Regulations* (Canada)**

A. Vaccines

- The term **vaccine** generally refers to a preparation of a weakened or killed viral immunizing agent for viral diseases (live or dead) and products containing live bacteria.

- ◆ **Bacterin is a special term for killed or weakened bacterial immunizing agents against bacterial diseases.**

To understand immunization one has to know the difference between an antigen and an antibody.

- **Antigens are protein molecules** from disease causing viruses or bacteria.
 - ◆ Each bacterium or virus has many different antigens.
 - ◆ Antigens vary in their ability to stimulate an immune response.
- **Antibodies are also protein molecules in an animal which**, when present in the blood or tissues in sufficient quantities, **protect the animal from exposure to the virus or bacterium that produced them.**
 - ◆ When an animal is exposed to a **specific antigen**, either from natural exposure or vaccination, **specific antibodies** will be produced.
 - ◆ It takes at least two weeks for the animal to develop protective levels of antibodies.
 - ◆ Because it takes time to develop antibodies, **vaccines are used to prevent rather than treat** disease.
- When an animal is re-exposed to the same antigen it will respond by producing higher levels of antibodies, in a shorter time period.
 - ◆ This is the reason for giving “**booster**” vaccinations.

NOTE: Booster vaccinations are not different products; they are simply a second or third injection with the same vaccine.

- Vaccines may contain a single organism, e.g. Erysipelas vaccine, or they may contain several e.g. IBR, PI3, BRSV vaccine.
 - ◆ Most vaccines contain the entire organism, alive or dead.
 - These preparations contain all of the antigens from the organism(s) in the vaccine.
 - ◆ Some vaccines only contain the antigens which have been shown to stimulate immunity.

1. Active Immunity

- Vaccines and bacterins stimulate “**Active Immunity**”.
 - ◆ “**Active Immunity**” means that an **animal has developed its own antibodies** against a particular antigen.
 - ◆ **When an animal has developed enough antibodies** to protect itself from a pathogenic organism, **it is said to be immune** to that disease.
 - ◆ The length of time that an animal will retain its “**Active Immunity**” varies with the antigen and frequency of exposure.
 - ◆ Single exposures to some antigens can produce a life-long immunity while other antigens produce much shorter periods of immunity that require boosters to maintain.
 - It is generally accepted that most live vaccines produce a stronger immunity than killed vaccines or bacterins.

2. Killed Vaccines

- The bacteria or viruses, in these products have been killed through irradiation, heat treatment or chemical inactivation.
 - ◆ Killed vaccines come ready for use and pose less risk to animals than live, or modified live vaccines.
- All killed virus vaccines and bacterins can be sold at an AMS outlet.

3. Live Vaccines

- Live vaccines are lyophilized (freeze dried) in a powder form to preserve the viability of the micro-organism.
 - ◆ The lyophilized portion consists of a dry wafer of material.
 - It is contained in a separate vial from the diluent or liquid portion.
 - ◆ Prior to being used live vaccines have to be **“reconstituted”**
 - Reconstitution of a vaccine consists of injecting a sterile diluent into a vial of freeze dried (lyophilized) material.

NOTE: All live vaccines must be used shortly after reconstitution (usually within hours).

Producers should use the entire contents of a vial before reconstituting another vial.

Modified Live Vaccines

- These vaccines consist of **living organisms** which have been **“modified” to the point where they will no longer cause disease.**
 - ◆ This is done by passing the virus, or bacteria, through other species of animals, or tissue cultures, several times and by using methods in the lab to minimize the virulence of the micro-organism.
- **Modified live virus vaccines for mammals CANNOT BE SOLD AT AN AMS OUTLET.**
- Some live bacterial vaccines, such as Erysipelas vaccine can be sold.
- Chemical sterilization of syringes or needles will inactivate live vaccines.
 - ◆ Only heat should be used to sterilize syringes and needles used for vaccination.

B. Toxoids

- Toxoids are immunizing agents in which the antigen is derived from the toxin or poison produced by a micro-organism rather than from the micro-organism itself.
- The toxin is chemically neutralized.
- Toxoids also stimulate an “Active Immunity”.
- The most commonly sold toxoid is tetanus toxoid.

NOTE: Vaccines and toxoids are used to **prevent** disease. They are not intended for treatment of disease.

Open vials of vaccine should not be stored for future use.

C. Antiserums and Immunoglobulins

- **Antiserums** and Immunoglobulin preparations **contain antibodies, rather than antigens.**
- **Antiserums** consist of serum from the blood of animals that have been repeatedly vaccinated with a particular antigen.
 - ◆ Because of the repeated vaccinations, the serum will have high levels of antibodies against whatever antigen(s) were in the vaccines.
 - ◆ Tetanus antitoxin is a good example of an antiserum.
 - ◆ Colostrum is an example of an **immunoglobulin** product.
 - ◆ Colostrum and similar products are used as a replacement for colostrum for newborn animals.
 - Colostrum is the mother's first milk that is rich in antibodies. It is very important for any animal to receive colostrum within the first 24 hours of life to protect them from disease. After this, the newborn gut can no longer absorb the antibodies from colostrum into the bloodstream.
 - Many heifers do not produce enough colostrum to provide sufficient immunity for their calves.
- Antiserums and Immunoglobulins confer a "**Passive Immunity**".
 - ◆ Antiserums and immunoglobulins provide immediate protection because they contain preformed antibodies.
 - Because protection from passive immunity is immediate, antiserums are useful in the treatment of certain conditions, e.g. tetanus.
 - The degree of protection drops off quickly as the antibodies are used up.
 - Most immunoglobulin preparations will provide protection for approximately two weeks.

NOTE: All biological products must be refrigerated.

II. ANTIBIOTICS AND ANTIBACTERIAL AGENTS – section 14(2)(c)AMSR

- **Antibiotics/antibacterial agents** are defined as drugs, obtained from living organisms or a synthetic or semi-synthetic process, that are capable of killing or inhibiting bacteria.
 - ◆ e.g. Penicillin comes from a mold or fungus called Penicillium.
 - ◆ Other names for antibacterial agents include "chemotherapeutic" or "antimicrobial".
 - By strict definition, antibiotics/antibacterial agents are one type of antimicrobial.

NOTE: The term antibiotic is used throughout the section below, but the material also refers to antibacterial agents.

- Antibiotics are used for the treatment of infectious diseases caused by bacteria.
- **Antibiotics on the Prescription Drug List are prohibited from sale** at an AMS outlet.

A. Mode of Action

- **Bactericidal antibiotics** actually **kill** bacteria.
 - ◆ Bactericidal antibiotics are most effective against organisms that are actively multiplying therefore they usually work best if given early in the course of a disease.
 - Penicillin is an example of a bactericidal antibiotic.
- **Bacteriostatic antibiotics** only **suppress** bacterial growth.
 - ◆ The body defenses will have a better chance of overcoming the infection when the bacterial growth rate is kept in check.
 - Tetracyclines are an example of a common bacteriostatic antibiotic.
- **Bacteriostatic and bactericidal antibiotics should not be used together.**
 - ◆ Interference with bacterial growth by the bacteriostatic antibiotic will interfere with the action of the bactericidal antibiotic.

B. Range of Action

- **“Broad Spectrum Antibiotics”** are effective against a wide range of types of bacteria.
- **“Narrow Spectrum Antibiotics”** are only effective against a smaller range of types of bacteria.
- A narrow spectrum antibiotic will not affect as many types of bacteria when it is used. This is generally preferable to prevent the development of antibiotic resistance (see below).
- Under ideal conditions, the choice of which antibiotic to use would be based on an antibiotic sensitivity test, which should be interpreted by a registered veterinarian.
- An **“Antibiotic Sensitivity Test”** is a laboratory test where the micro-organism causing the disease is grown and the effects of different antibiotics are observed to determine what drug will be effective against the bacterium being treated.

NOTE: Customers that are not sure of what antibiotic they require should be referred to a registered veterinarian.

- **“Antibiotic/Antimicrobial Resistance”** refers to the ability of bacterial populations to develop resistance to the killing effects of a particular antibiotic.
 - ◆ Currently there is great concern that the agricultural use of antibiotics may lead to the development of resistance in bacteria in animals that are capable of causing disease in humans.

- Using the recommended dose amount, frequency and route for the proper length of time reduces the chance that resistance will develop.
- Label recommendations pertaining to the amount, route of administration, dosing frequency and length of time for treatment should always be observed.
- **Under no circumstances should the label recommendations be exceeded.**
 - ◆ **Withdrawal times are only valid for the recommended label dose.**
- **Any antimicrobial might cause “Hypersensitivity” (Allergic) reactions.**
 - ◆ Producers should have epinephrine on hand to treat any adverse reactions.

NOTE: UNDER NO CIRCUMSTANCES should the label recommendations be exceeded except under the direction of a registered veterinarian.

QC holders should draw the customer’s attention to the label and in particular, cautions, including a caution not to exceed the recommended dosage.

NOTE: **Antibiotics/antibacterial agents are not effective against viral infections**

III. ANTI-PARASITICS (PARASITACIDES) – section 14(2)(d) AMSR

- Parasitacides are a class, or group, of drugs that kill, or inhibit, a wide range of internal and external parasites.
 - ◆ Many of these products, particularly the insecticides, are registered federally under the *Pest Control Products Act*.
 - ◆ They are authorized for sale through AMS outlets under section 14(1)(c).
 - ◆ Examples of general types of parasitacides include:
 - Anthelmintics
 - Insecticides
 - Anti-coccidial drugs

A. Insecticides

- These are chemicals which kill biting or sucking insect parasites or pests.

B. Anti Coccidial Drugs

- These are compounds which are effective in the treatment of intestinal parasites called coccidia.

C. Parasiticide Spectrum of Activity

- Similar to antibiotics, **the spectrum** of activity of a **parasiticide** may be very **broad** or quite **narrow**.
 - ◆ Ivermectin is broad spectrum – it is effective against worms, lice, warbles, bots and mange mites, but does not have any effect on coccidia.
 - ◆ Tramisol is narrow spectrum – it is only effective against worms.
- Drug labels or package inserts must be read carefully to determine the spectrum of activity of any particular parasiticide.
- Parasiticides are also available in a wide variety of physical forms including:
 - ◆ Injectables, e.g. Ivermectin
 - ◆ Powders for topical use, e.g. Louse Powders
 - ◆ Pour-ons, e.g. Ivomec or Eprinex
 - ◆ Oral liquids, e.g. Safeguard 10% suspension
 - ◆ Oral pastes, e.g. Eqvalan
 - ◆ Oral powders, e.g. Piperazine

NOTE: Ivermectin injectable cannot be given to horses.

NOTE: AS FOR ALL DRUGS, WHEN IN DOUBT ABOUT A PARASITACIDE READ THE LABEL.

If a customer is still unsure about what drug to use or how to administer it, refer him or her to a registered veterinarian.

IV. ORAL PREPARATIONS – section 14(2)(e) AMSR

- Section 14(2)(e) of the *Authorized Medicine Sales Regulation* allows oral preparations labelled by the manufacturer for the prevention or treatment of diseases of the digestive system in production animals including, bloat, colic, indigestion, diarrhea, constipation and impaction to be sold at AMS outlets.
 - ◆ A wide range of drug preparations including solutions, powders, boluses, etc., fall into this category.
 - ◆ Rather than being a true drug classification, this category is literally a “grab bag” of drugs based on the route of administration and the reasons for use.
- Products such as antibiotic boluses for the treatment of scours, in young animals, could just as easily fit into this category as under antibiotics.

V. WOUND AND SKIN MEDICATION – sections 14 (2)(f) and 14 (2)(g) AMSR

- These two groups are based on use rather than on a true drug classification.
 - ◆ Many wound and skin preparations contain antibiotics.

NOTE: Skin or wound preparations containing an **antibiotic are prohibited from sale** at an AMSO.

NOTE: The Federal government has prohibited the use of products containing nitrofurans in food producing animals.

A production animal, according to section 1(h)(i) of the AMSR, is an animal whose products or by-products may be used for food by humans, and includes horses.

- If horses were not classified as production animals, AMSO licensees would not have any authority to sell authorized medicine for horses.

The AMSR does not apply to any person who is authorized by the *Veterinary Profession Act* or the *Pharmacy and Drug Act* and who sells production animal medicine under the authority of those two Acts.

VI. VITAMIN AND MINERALS – sections 14 (2)(h) and 14 (2)(i)AMSR

- Both oral and injectable vitamins and minerals are authorized for sale under Section 14(2)(h) and 14(2)(i) of the *Authorized Medicine Sales Regulation*.
 - ◆ Vitamins and minerals are nutrients which should be available in adequate amounts in properly balanced feeds.
- There are no restrictions on what types of vitamins or minerals can be sold for oral use BUT
 - ◆ Injectable vitamin products are limited to a maximum of:
 - 500,000 international units (I.U.) of Vitamin A per ml and
 - 75,000 I.U. of Vitamin D per ml.
- All Vitamin B preparations can be sold at an AMS outlet with the exception of Vitamin B12 containing the “Intrinsic Factor Concentrate”.

NOTE: Selenium and iron are the only injectable minerals that are authorized for sale under the *AMSR*.

VII. HORMONES – sections 14(2)(j) & 14 (2)(k) AMSR

- Hormones are chemicals produced by the endocrine glands of the body.
 - ◆ Hormones regulate many body functions, including but not limited to the regulation of growth, metabolism, reproduction, etc.

- **HORMONES ARE PROHIBITED FROM SALE IN AMS OUTLETS, with the exception of:**
 - ◆ **growth promotants and hormones** in the form of implants and feed additives labeled by the manufacturer for use in production animals.
 - ◆ **injectable epinephrine** (adrenaline) for the treatment of anaphylactic reactions in production animals.

NOTE: Epinephrine (adrenaline) is the only injectable hormone that can be sold at an AMSO outlet.

VIII. SOLUTIONS FOR METABOLIC DISEASE – section 14(2)(l) AMSR

- A limited number of solutions for the treatment of metabolic disease and nutritional deficiencies in debilitated production animals are authorized for sale under section 14(2)(l).
- Examples of specific products that are allowed to be sold under this section are:
 - ◆ dextrose, calcium, phosphorus and magnesium preparations for the treatment of milk fever and grass tetany
 - ◆ oral propylene glycol for the treatment and prevention of acetonemia (ketosis)
 - ◆ amino acid solutions for debilitated animals.

IX. ANTI-CANNIBALISM COMPOUNDS FOR POULTRY – section 14(2)(m) AMSR

- The presence of a DIN technically classifies these products as drugs.
- This subsection is needed to allow the sale of any of these types of products that have a DIN.

X. OTHER TYPES OF AUTHORIZED MEDICINES – sections 14(1)(n, o, p, q)AMSR

- Topical liniments, counter - irritants or poultices for the treatment of joint pain, swollen ligaments tendons or muscles. (s. 14(2)(n))
- Oral or topical preparations labelled by the manufacturer as antitussives, decongestants, bronchodilators or expectorants. (s. 14(2)(o))
- Acetylsalicylic acid boluses for horses and cattle. (s. 14(2)(p))
- Disinfectants, udder washes, teat dips and sanitizers. (s. 14(2)(q))
- At this time the Chief Provincial Veterinarian has not authorized the sales of other medicines (s. 14(2)(r))

Review Questions Chapter 6

1. What are biologicals and what are they used for?

2. What is the difference between active and passive immunity?

3. What is a vaccine?

4. What is a “booster” vaccination?

5. What is an antiserum or immunoglobulin preparation?

6. What types of vaccines are not allowed to be sold through AMS Outlets?

7. Why are vaccines and toxoids recommended for the prevention of disease rather than for treatment?

8. Live vaccines must be reconstituted. What does this mean?

9. What could happen to a live vaccine if a chemical sterilizing or cleaning agent, such as alcohol, was used on the syringes or needles that were going to be used to inject a live vaccine?

10. What is an antibiotic and what is its primary use?

11. What is the difference between a bactericidal and bacteriostatic antibiotic?

12. Antibiotics, antibacterial agents and parasitacides are said to have a spectrum of activity. What does this mean?

13. What does the term “antibiotic resistance” mean? What precautions can be taken to help prevent it when giving an antibiotic?

14. Name the three general types of parasitacides that are licensed for sale at an AMS outlet.

15. What type of wound and skin medication would be prohibited from sale in an AMS outlet?

16. Name the two injectable minerals that can be sold at an AMS outlet?

17. Name the only injectable hormone (other than growth implants) that is allowed to be sold at an AMS outlet.

DRUG INTERACTIONS AND ADVERSE REACTIONS

OBJECTIVES:

To provide basic information on drug interactions and adverse reactions.

To provide information on how to handle any customer reports of adverse reactions.

DRUG INTERACTIONS AND ADVERSE REACTIONS

I. DRUG INTERACTIONS

A. General

- Unexpected results can and do occur when various drugs are mixed or used together.
 - ◆ Some occurrences are **beneficial**.
 - Acceptable drug combinations in common use include using supportive treatments, such as electrolytes or glucose solutions in combination with antibiotics and administering vitamin or mineral preparations, parasite treatments and vaccinations at the same time.
 - ◆ Some are neutral.
 - ◆ Some are definitely detrimental.

The focus of this chapter will be incompatible drug interactions that result in adverse reactions in production animals.

B. Incompatibilities

- Incompatibilities refer to detrimental chemical interactions, which may occur when drugs are mixed together prior to administration.
 - ◆ i.e. mixing an acidic and a basic drug causes neutralization.
 - ◆ Other incompatibilities include the failure of oil and water based solutions to mix and the precipitation of solutes.
 - Precipitation is a common problem when drugs are mixed together.

NOTE: DRUGS SHOULD NOT BE MIXED TOGETHER, UNDER ANY CIRCUMSTANCES, PRIOR TO ADMINISTRATION UNLESS ON THE ADVICE OF A REGISTERED VETERINARIAN.

AMSO LICENSEES AND QC HOLDERS ARE NEITHER QUALIFIED NOR AUTHORISED TO RECOMMEND DRUG COMBINATIONS.

ALL QUESTIONS REGARDING DRUG COMBINATIONS SHOULD BE REFERRED TO A REGISTERED VETERINARIAN OR A PHARMACIST.

II. ADVERSE DRUG REACTIONS

- **Adverse drug reactions are defined as any unexpected side effects** associated with the clinical use of a drug, including injuries, toxicities or sensitivity reactions, **or any unusual failure of a drug to perform as expected.**

A. Allergic Reactions

- Allergic reactions may be manifested by the development of skin rashes or by more severe anaphylactic reactions.
 - ◆ **Anaphylactic reactions are severe allergic responses including rapid swelling of tissues in the throat and accumulations of fluid in the lungs.**
 - Anaphylactic reactions usually occur within minutes of administering a drug and if they are severe enough the animal may die.

B. Shock

- Shock is caused by circulatory collapse. This may be caused by the drug itself or from giving an I.V. injection too fast. A severe shock reaction may kill an animal.

C. Swellings

- Most injection site swellings are due to infection because of unsanitary injection techniques.
- Some swellings may be caused by the drug.
 - ◆ Drug induced swellings are the type that should be reported. It is also advisable to report cases where an unusual number of animals develop abscesses or infections continue to occur following adjustments to sanitary injection techniques. These occurrences could be due to bacterial contamination of the drug.

III. REPORTING ADVERSE REACTIONS

A. What Should be Reported

- A producer should report any of the following adverse drug reactions.
 - ◆ **All unexpected reactions** which cause undesirable patient responses that are **not** consistent with the side effects **listed on the label or package insert.**
 - ◆ **All reactions which are more severe, or more frequent, than would be expected** from the information on the label or in the package insert.
 - ◆ **All suspected adverse reactions in recently marketed drugs** (7 years or less)

- ◆ **Failure of the drug to perform as expected when it was used according to the label recommendations** for species, dose, indications and route of administration
- Producers should report all adverse reactions as soon as possible after the occurrence.

B. To Whom Should Reports be Made?

- Livestock producers should be advised to report any adverse reaction to one of the authorities listed below.
- If informed of an adverse reaction, a QC holder should advise the producer to report the event to one of the following authorities:
 - ◆ The product manufacturer,
 - ◆ The producer's registered veterinarian, who will then report to the manufacturer or appropriate federal government department, or
 - ◆ Directly to the appropriate federal government department:
 - For **veterinary drugs**: The Veterinary Drugs Directorate (VDD) of Health Canada
 - For **biologics**: The CFIA
 - For **pesticides**: the Pest Management Regulatory Agency
- **Contacts for reporting adverse reactions are listed in the box on the next page.**
 - ◆ A QC holder or AMSO should be able to provide a producer with the contact information of the appropriate federal government department to report an adverse reaction if requested.
 - ◆ When in doubt, the producer should be referred to a registered veterinarian.

Adverse reactions to veterinary drugs should be reported to the Veterinary Drugs Directorate of Health Canada.

Adverse Reaction Officer:
Tel: 1-877-838-7322
Fax: (613) 946-1125
General Tel: (613) 954-5687
Submission and Knowledge Management Division, VDD
Fax: (613) 946-1125

Veterinary Drugs Directorate
Health Products and Food Branch
Health Canada
Holland Cross Complex
Tower A, Ground Floor
11 Holland Avenue
Ottawa, Ontario K1A 0L2
Address Locator - 30000A

See also http://www.hc-sc.gc.ca/dhp-mps/vet/faq/dar-rim_program-eng.php

Please note: The Veterinary Drugs Directorate deals **only** with suspected adverse reactions to veterinary drugs.

Suspected adverse reactions to veterinary biologics (vaccines, bacterins, etc.) should be reported to:

Canadian Food Inspection Agency
Animal Products Directorate
Animal Health and Production Division
Veterinary Biologics Section
59 Camelot Drive
Ottawa, ON K1A 0Y9

Suspected adverse reactions to veterinary pesticides (i.e. Topical treatments for external parasites) should be reported to:

Director
Pest Management Regulatory Agency
2250 Riverside Drive
A.L. 6606D2
Ottawa, ON K1A 0K9
Tel: 1-800-267-6315

Review Questions

Chapter 7

1. Producers may wish to mix two or more drugs together, for convenience, prior to injecting them into an animal. What could go wrong if they do this? Can a QC holder advise a producer on mixing medications?

2. What are the main types of adverse reactions?

3. What is the responsibility of a Qualification Certificate holder when told about an adverse drug reaction?

RESPONSIBILITIES OF QUALIFICATION CERTIFICATE HOLDERS AND AMSO LICENSEES

OBJECTIVE:

To summarize the responsibilities of AMSO licensees and Qualification Certificate holders.

REPONSIBILITIES OF AUTHORIZED MEDICINE SALES OUTLET LICENSEES AND QUALIFICATION CERTIFICATE HOLDERS

I. ROLES AND RESONSIBILITIES

Every person who holds

- an authorized medicine sales wholesale licence
- an authorized medicine sales outlet license, or
- a Qualification Certificate (QC)

is expected to:

- have a thorough knowledge and understanding of the *Authorized Medicine Sales Regulation* (AMSR), and
- abide by all of its sections.

The responsibilities of persons who hold both authorized medicine licenses and Qualification Certificates may overlap.

A. Key Players in the Sale of Authorized Medicine

1. Wholesale licensees

- Wholesale licensees may only sell authorized medicine to outlet licensees but NOT to the public.

2. Outlet licensees

- Only outlet licensees may sell authorized medicine to the public.
 - ◆ If a medicine is not authorized under the AMSR, then an outlet licensee is prohibited from purchasing, storing, or selling it.
- Authorized Medicine Sales Outlet (AMSO) licensees must ensure that there is at least one QC holder on duty or available during all regular hours of business operation for consultation or clarification of any questions that purchasers of authorized medicine may have concerning its safe and proper use.
- AMSO licensees must ensure that all employees, including QC holders, perform their duties in accordance with the requirements of the AMSR.

- ◆ They are directly responsible for any contravention or contraventions by themselves or any of AMSO employees of the :
 - *Authorized Medicine Sales Regulation,*
 - *Pharmacy and Drug Act,*
 - *Veterinary Profession Act,*
 - *Food and Drugs Act (Canada)* or
 - Any Act of the Parliament of Canada relating to the sale or distribution of medicines.

3. *QC Holders*

- QC holders work at authorized medicine outlets (AMSOs).
- There must be at least one QC holder on duty or available for consultation during regular business hours at an AMSO.
- QCs holder provide clarification in response to any questions that customers may have regarding the safe and proper use of authorized medicine.
- QC Holders are prohibited from
 - ◆ Recommending the use of authorized medicine for purposes, or at a dosage level, or for a species not prescribed on the label.
 - ◆ Diagnosing a disease, disorder, or condition of an animal, or prescribing medicine, or otherwise practicing veterinary medicine without a licence.

B. Licenses and Certificates

1. *Wholesale or Outlet Licenses*

Prerequisites

- In order to sell authorized medicine, a wholesaler or outlet must possess a valid license.
- The licensee must apply for a licence and pay a fee.
 - ◆ In order to obtain an authorized medicine sale licence, an applicant is responsible for possessing a valid business licence and must have the following :
 - In the case of wholesale licensees: a permit to operate a wholesale business
 - Additionally, if a wholesale licensee is also selling products regulated under the Food and Drugs Act (Canada), a valid Health Canada establishment licence is also required.
 - In the case of outlet licensees: a permit to operate a retail business
 - ◆ The applicant must conduct wholesale or retail operations in a permanent place of business.
 - A permanent place of business means:
 - A fixed location in a building or part of building
 - There are signs to identify the building or part of building as a place of business that is open to the public
 - It is not a private dwelling
 - It is not used for permanent housing of production animals

- Business premises must be inspected and approved of before the licence is issued.

An outlet licence is only valid for the premises which have been inspected and approved.

This means that outlet licensees cannot sell medicines in venues such as trade fairs, agricultural fairs, livestock sales or shows, other community events, etc.

Changes in Business Ownership

- Licenses are not transferable.
- If there is a change in the ownership that results from the sale, transfer, or assignment of more than 50% of the ownership, then the licensee must
 - ◆ Notify the Minister of the change in ownership and
 - ◆ Return the unexpired license.

2. *Qualification Certificates*

- A person who successfully takes and completes, by way of examination, training or a course on the proper handling or authorized medicine and pays the required fee may obtain a Qualification Certificate.

3. *Expiry of Licenses and Certificates*

AMSO licences and qualification certificates expire on December 31 of the fifth year following the year in which they are issued.

- In order to carry on the lawful sale of authorized medicines, licenses and Qualification Certificates must be kept current.
- Wholesale and AMSO licensees are prohibited from selling production animal medicines if their license has expired.
- The onus is on the licensee and QC holder to renew the license or certificate.
- It is an offence to make any false statements in an application for a new license, or renewal of a license.

No person shall sell authorized medicine to the public except under the authority of an outlet (AMSO) licence.

[Section 22(4)(c)]

No AMSO licensee shall purchase, store, or sell medicine to the public that is not authorized medicine.

No AMSO licensee shall sell authorized medicine unless at one qualification certificate holder is on duty or is available for consultation during regular business hours.

II. BUSINESS OPERATING PRACTICES AND RESPONSIBILITIES OF AMSO LICENSEES

The AMSR requires that the business practices described below must be followed.

A. Maintenance of Business Premises

- AMSO licensees must maintain a permanent place of retail business that
 - ◆ is accessible to the public for a minimum of 40 hours per week
 - ◆ is clearly identified as a place of retail business
 - ◆ is not located in a private residence and
 - ◆ is not used for permanent housing of production animals

In practice, there may be occasions where production animals, may be housed in AMSOs on a seasonal basis. This commonly occurs in the bee and hatchery industries.

B. Operation of Two or More Authorized Medicine Sales Businesses

- If an AMSO licensee also holds a wholesale licence or a licence under other legislation to sell medicine, then the businesses must be kept separate from each other.
- This means that each business must operate under its own unique name that must be easily distinguishable from each other.
- Specifically, each business must
 - ◆ Have its own entrance and exit
 - ◆ Have its own receiving and storage area
 - ◆ Use separate invoices for the sale of medicine or sale of authorized medicine and other products

C. Manner of Selling Authorized Medicine

- Authorized Medicine may only be sold by the following means:
 - ◆ in person at the outlet licensee's permanent place of business
 - ◆ by telephone sales, or
 - ◆ online or by other electronic means

- ◆ antibiotics may only be sold in person at the outlet licensee's permanent place of business

D. Safe Storage and Handling of Authorized Medicine

- All authorized medicine must be stored in the manner recommended by the manufacturer.
- All storage and display areas for authorized medicines must be kept clean.
- Authorized medicine that is stored must be kept separate from any human foods or drugs that may be stored or sold at an AMSO.
- Authorized medicine must be stored and handled in a manner that protects animals and their feed from being contaminated.

E. Product Safety Assurance

1. Always Follow Best Practices

AMSOs must be pro-active in their approach to selling authorized medicine. Licensees must:

- Ensure that at least one Qualification Certificate Holder is available, at all times, during regular business hours to clarify any questions that customers may have regarding the safe and proper use of authorized medicine
- Display a sign that draws attention to
 - ◆ safe and proper drug use, and
 - ◆ provides the contact information for a staff QC holder.
 - Signs that have been approved of by the Minister and are be provided by the Department of Agriculture and Rural Development.
- AMSO licensees and QC holders should also always draw the purchaser's attention to all information on the label of authorized medicine with respect to:
 - ◆ its recommended dosage, frequency, and duration of treatment,
 - ◆ the species for which its use is approved,
 - ◆ withdrawal times,
 - ◆ method of administration,
 - ◆ the expiry date,
 - ◆ toxicity warnings, and
 - ◆ any other precautions on the label.
- AMSO licensees must ensure that no expired authorized medicines are offered for sale.
 - ◆ If any drugs have expired, then the product must promptly be removed from the shelf and stored until it is either returned to the supplier or destroyed.

2. Product Claims and Advertising

- Care should be taken to avoid all false or misleading claims about an authorized medicine product.
 - ◆ Instead, reference should be made only to factual information from the drug label or package insert in all advertisements.

- It is prohibited for an AMSO licensee to advertise drug prices anywhere other than in the AMSO or on its website.

3. *Offences Relating to Product Safety*

Product safety is of utmost importance in the sale of authorized medicine.

Contraventions of the AMSR are offences.

- **It is prohibited to sell any product that poses a health risk to humans or production animals.**
- In order to protect the safety of production animals and humans,
 - ◆ repackaging, altering the label of, or
 - ◆ altering the contents of any authorized medicine is strictly prohibited.
- It is prohibited to sell authorized medicine after the expiry date of the authorized medicine.
- It is an offence to give away, barter, or sell any authorized medicine in order to encourage or persuade customers to purchase other merchandise that may be sold at an AMSO.

F. Documenting Sales

- Each purchaser of an authorized medicine must be provided with a receipt that shows
 - the name of medicine purchased,
 - its lot number,
 - the quantity of medicine purchased,
 - expiry date of the authorized medicine, and
 - the premise identification number of the animal owner or operator who purchased the authorized medicine.

An AMSO licensee that sells an authorized medicine to a purchaser must record and retain for their records the

- ◆ name and telephone number of the purchaser,
- ◆ date of sale, and
- ◆ information that appears on the purchasers receipt.

G. Keeping Proper Records

- Copies of all purchase receipts and records of sales **must be kept for a minimum of 10 years.**

H. Inspection of Business Premises

- Regular inspections are made to ensure that an AMSO is in compliance with the legislation.
- Inspectors may conduct inspections during regular business hours in order to determine whether the AMSR is being complied with.
- AMSO licensees must permit an inspector to enter, during business hours, to inspect the premises, medicine in stock and the records of medicines purchased and sold.
- An AMSO licensee may be suspended or cancelled if the holder has contravened the
 - ◆ Authorized Medicine Sales Regulation
 - ◆ Pharmacy and Drug Act
 - ◆ Veterinary Profession Act or
 - ◆ Food and Drugs Act (Canada)
 - ◆ Or any Act of the Parliament of Canada relating to the sale or distribution of medicines
- If an AMSO licence is suspended or cancelled because the AMSR or any of the above noted legislation has been contravened
 - ◆ An inspector will make a list of every medicine found at the AMSO licensee's permanent place of business or premises.
 - ◆ The inspector may also
 - seal any cabinet or storage space where authorized medicine is kept, and
 - place a placard in the AMSO that reads "Authorized Medicine for Production Animals Not For Sale by Order of the Minister of Agriculture and Rural Development.
- It is an offence to remove any seal or placard placed in the business by an inspector.

Review Questions Chapter 8

1. What are the two important responsibilities of all AMSO Licensees and Qualification Certificate Holders?

2. Section 1(i) of the AMS Regulation defines a “permanent place of retail business”. What are the requirements of this definition?

3. When do AMSO licences expire?

4. What general responsibilities does an AMSO licensee have regarding Qualification Certificate holders at his/her other place of business?

5. What are the responsibilities of an Authorized Medicine Sales Outlet licensee if there is a change in partners, or if more than 50% of the shares of a corporation are sold, assigned, or transferred?

6. For how long must drug sales and purchase invoices be kept?

7. When can an AMSO Inspector perform his or her duties and what can they inspect?

8. Storing restricted drugs at an AMSO is prohibited. If restricted drugs are found during an inspection, what options can be given for disposal of these products?

9. What information can be included in advertisements by an AMS outlet?

10. In general terms, what medicines can be sold at an AMS Outlet?

11. What information must be recorded on sales receipts?

12. What information must an AMSO licensee record and retain for his or her own records?

13. What general requirements must be observed when storing drugs at an AMS Outlet?

14. What label items must be brought to the attention of a purchaser of authorized medicine?

15. How should expired medicines be handled?

16. Your employer is going to set up a booth at a Trade Fair. Is it legal for him to sell authorized medicines at this fair? Why or why not?

17. Your employer has livestock of his own. He purchases some prescription drugs from his veterinarian. Can these drugs be stored at his AMS outlet?

18. What five activities are outlet licensees or Qualification Certificate holder specifically prohibited from undertaking in respect of the handling, selling, and providing of information about authorized medicines at licensed outlets?

APPENDIX A

Answers to Review Questions

Introduction and Chapter 1

Legislation Relevant to the Sale of Authorized Medicines for Production Animals

1. Name two objectives that the *Authorized Medicine Sales Regulation (AMSR)* supports.

It supports Animal Health and Food Safety by regulating the wholesale distribution, sales to promote access to livestock medicines and promote their safe and proper use by non-veterinary professionals.

2. Can an AMS Outlet sell medicines containing generic drugs included on the Prescription Drug List – Products for Veterinary Use? Why or why not?

No. Any medicine containing a generic drug on the prescription drug list cannot be sold by an AMSO. Further, an AMSO cannot have these drugs in their place of business. Drugs listed on the prescription drug list can only be dispensed by a registered veterinarian or a pharmacist.

3. Who can legally sell drugs in the Province of Alberta and what qualification must they possess?

- Pharmacists (druggists) – must possess the qualifications in the Pharmacy and Drug Act
- Registered veterinarians – must possess the qualifications listed in the Veterinary Profession Act
- Outlet licensees as per the qualifications in the Authorized Medicines Sales Regulation.

4. What is an OTC drug?

An OTC drug is one that can be bought at a licensed outlet and which can be used without veterinary supervision.

5. In what manner are Outlets only permitted to sell authorized medicine? What is the exception?

Outlets are permitted to sell at the outlet's permanent place of business, by telephone sales or on line or by other electronic means.

The exception is antibiotics which can only be sold in person at the permanent place of business.

Chapter 2

General Disease Information

1. Define “disease”.

Disease is any departure from the normal state of health which results in a disturbance of normal body functions of the animal.

2. What is the difference between an infectious and non-infectious disease?

Infectious diseases are caused by organisms, such as bacteria, viruses, fungi or parasites.
Non-infectious diseases are caused by non-living agents.

3. What is the difference between contagious and non-contagious diseases?

Contagious diseases pass easily from one animal to another. Non-contagious diseases do not spread from animal to animal.

4. What are the differences between viruses and bacteria?

- Viruses are smaller than bacteria
- Viruses cannot reproduce outside the body of the host
- Viruses do not produce toxins
- Antibiotics have no effect on viruses

5. List five common parasites of livestock (any 5 of the 6).

- Worms (lung or intestinal)
- Lice
- Mange mites
- Warbles
- Bots
- Coccidia

Chapter 3

General Drug Information

1. Name three physical agents that may damage drugs (any 3 of the 5).

- Light
- Moisture
- Vibration
- Freezing
- Excessive Heat

2. What measures do drug manufacturers take to protect their product from damage?

- Light protection through the use of dark brown bottles or outer opaque packages (i.e. cardboard).
- Moisture protection through the use of desiccants.
- Physical damage protection through the use of cotton or other fillers.

3. What is the generic name of a drug?

The generic name of a drug is the chemical name of the active ingredient.

4. What do these symbols mean?



Prescription Drug as per the Prescription Drug List – Products for Veterinay Use

Controlled Substance as per the Controlled Substances Act

Narcotic under the Narcotics Control Regulations

5. Can an Outlet handle or store a drug that has any of the symbols listed in Question 4?

No

6. What is the DIN and what is its significance?

The DIN is the “Drug Identification Number” which is given to all pharmaceuticals. The DIN is a method of identification of pharmaceuticals in Canada and is listed in the Health Canada Drugs Product Database, which provides easy reference to the ingredients and manufacturer. The DIN will provide specific product information to physicians, through the “Poison Control Centers”, which will ensure proper treatment procedures in the case of accidental human exposure. For the purposes of the AMS regulation, the DIN is also used to determine whether a product is a drug or not.

7. Do all livestock medicines handled in Outlets have a DIN? If not, which products do not have one and what do they have instead?

No. Biologicals do not have a DIN. They have an “Agriculture Canada Establishment License Number” instead.

8. a) What do the following terms stand for: mg; g; ml; cc; kg?

mg – milligram
g – gram
ml - millilitre
cc - cubic centimetre
kg – kilogram

b) Which of the measures are the same?

ml and cc.

9. a) A producer has a calf which he claims weighs 770 pounds. He purchases a product from you and wants to know how many cc’s he should give to his animal. The label states that this product has 500 mg of product per ml. The dosage is expressed as 50 mg per kg. There are 2.2 pounds in a kg.

How many cc’s would you tell the producer to give this calf?

The calf weighs 350 kg (770 pounds divided by 2.2)

The dose calls for 50 mg per kg.

Because there are 500 mg of drug per ml, this calf would require 1 ml (cc) per 10 kilograms of body weight; therefore, the total dose would be 35 cc’s.

b) What would the dose be if the concentration of this drug was 250 mg rather than 500 mg?

It would be double or 70 cc’s.

10. What does the indication section of a drug label tell you?

It tells you what the drug is intended to be used for and for what species

11. What are the four main components of a dosage regime?

- Amount to be given
- Frequency of administration
- Length of time to be given (duration of treatment)
- Route of administration

12. What is the major difference in dosage rates for a vaccine compared to other drugs?

A vaccine has the same dose regardless of the size of the animal. With other drugs the total dose is based on the size of the animal.

13. What is the withdrawal time and where would you find this time on a drug label?

The withdrawal time is the length of time that must elapse from the last treatment before an animal or any of its products can be used for human consumption.

Usually withdrawal times can be found in the “Warning” section of a drug label.

14. What activities could affect the withdrawal time as stated on the label?

The withdrawal time is invalid if the drug is used in any manner other than as stated on the label. The most common situations where the withdrawal times would be invalid are:

- Giving the drug to a different species of animal
- Giving too much drug at one time
- Giving a drug too often
- Giving a drug for too long a period of time
- Using a different route of administration than is stated on the label.

15. Why are lot numbers and expiry dates important?

Lot numbers provide the ability to recall a particular batch of drugs.

Expiry dates guarantee the potency and effectiveness of a drug up to that date, providing it has been stored properly and has not been opened.

16. What is meant by the term “contraindication”?

Contraindications are particular reasons, or circumstances, under which a drug should not be used.

17. What is meant by the term “Extra Label Use” and under what conditions is it legal?

Extra label use means using a drug in any way other than as recommended on the label. “Extra Label Use” can only be recommended by a registered veterinarian, who in turn assumes all liabilities for any adverse reactions.

18. What is the withdrawal time for “Extra Label Use”?

Extra label use in any way other than recommended on the label does not have an approved withdrawal time.

Chapter 4

Drug Formulations

1. List the three basic types of drug formulations.

- Liquid
- Semi-solid
- Solid

2. Name the only type of drug formulation that may be given by the intravenous route.

Liquid formulation

3. What special properties are necessary if a solution is to be injected into an animal or placed in its eye?

They should be sterile (free of any living organisms) and free from particulate material.

4. What is the difference between a solution and a suspension?

Solutions are clear (solutes completely dissolved in a solvent), while suspensions are cloudy (solute is suspended in the solvent, not dissolved). When the drug is left to sit the particles, in a suspension, will settle out unless an emulsifying agent has been added.

5. What is the advantage of using a cream rather than an ointment for weeping or wet wounds?

Creams mix well with body fluids (due to higher water content), thus they will stay on a wet wound. Ointments, because of their oily base, will not stick to a wet wound and tend to float off.

6. Name the types of solid drug preparations that are most likely to be handled by an Outlet.

- Boluses or bollettes
- Implants
- Resins
- Powders
- Granules

Chapter 5

Drug Administration Routes

1. What is meant by oral administration?

Giving a drug by mouth.

2. What are the advantages of oral administration?

- Relative ease of administration
- Relative safety (less likely to cause a serious adverse reaction such as anaphylaxis)

3. What are the disadvantages of oral administration?

- Slower onset of action
- Less predictable absorption
- Drug could be inactivated by stomach acids
- Sick animals may not get enough drug if they are not eating or drinking
- Special skills and equipment may be required
- Inadequate dosing/overdosing when given via feed/water due to inconsistent feed/water intake between individual animals

- 4. What is the best method to give the following types of medication by mouth? a) large volumes of fluid? b) small volumes of fluid? c) boluses? d) powder or granules?**
- Large volumes of fluid by stomach tube
 - Small volumes of fluid by drench bottle or dose syringe
 - Boluses by balling gun
 - Powders or granules by mixing in feed or water
- 5. What are the most commonly used routes for the parenteral administration of drugs?**
- Subcutaneous
 - Intramuscular
 - Intravenous
- 6. List some common locations on the body where subcutaneous injections may be given.**
- Side of neck
 - Side of chest
 - Behind the elbow
 - Base of the ear for implants
- 7. Explain two ways to give a subcutaneous injection.**
- Pick up a loose fold of skin and run the needle parallel to the skin after insertion.
 - Inject straight through the hide with a short needle (1.25 cm).
- 8. When giving an intramuscular injection, how can you determine that the needle is actually in the muscle rather than in a blood vessel?**
- Put the needle in and observe for blood before attaching the syringe, or
 - Draw back on the plunger to observe for blood before making the injection.
- 9. Where should intramuscular injections be given and why?**
- They should be given in the neck to avoid damaging the more expensive meat cuts in the ham and rump.
- 10. What general guidelines should be considered when administering any type of injection?**
- Use recommended routes
 - Avoid injections in high value cuts
 - Use clean or sterile techniques
 - Select a proper sized needle
 - Restrain the animal
 - Do not inject too much at any one site
 - Choose different injection sites for repeat treatment
- 11. What is the difference between a 14 gauge and an 18 gauge needle?**
- The 14 gauge needle is much thicker and has a larger opening
- 12. What special precautions should be taken when injecting a drug into the udder?**
- Clean and disinfect the teat end
 - Use only individual treatment syringes
 - Only insert the cannula a short distance
 - Use a disinfectant teat dip following treatment

13. What precautions should be taken when placing boluses into the uterus?

- Thoroughly wash the entrance to the reproductive tract
- Use clean plastic sleeves

14. What precautions should the handler take when using a pour-on treatment?

- Avoid human skin contact
- Wash thoroughly after use

Chapter 6

Drugs Licensed for Sale through Authorized Medicine Sale Outlets

1. What are biologicals and what are they used for?

They are drugs derived from living organisms (e.g. vaccines) which are used to stimulate an active or passive immunity.

2. What is the difference between active and passive immunity?

Active immunity occurs when an animal has developed its own antibodies. Passive immunity can be gained from antiserums or from drinking colostrum

3. What is a vaccine?

A vaccine is a biological product which contains one or more antigens, from one or more disease causing organisms, which will stimulate the development of an active immunity against a particular disease.

4. What is a “booster” vaccination?

A “booster” vaccination is a second or third injection of the same vaccine that was given the first time. It is not a different vaccine from the first.

5. What is an antiserum or immunoglobulin preparation?

These are biological products which contain antibodies against a particular disease causing agent.

6. What types of vaccines are not allowed to be sold through AMS Outlets?

“Live” or “Modified Live” vaccines for mammals. “Live” or “Modified Live” vaccines for poultry can only be sold by hatcheries that are licensed as AMSOs.

7. Why are vaccines and toxoids recommended for the prevention of disease rather than for treatment?

Because it takes time for immunity to develop.

8. Live vaccines must be reconstituted. What does this mean?

Reconstitution refers to the mixing of a diluent (liquid) with the lyophilized (freeze dried) portion of a live vaccine.

9. What could happen, to a “live” vaccine, if a chemical sterilizing, or cleaning, agent such as alcohol was used on the syringes or needles that were going to be used to inject the vaccine?

The chemical agent could inhibit or kill the virus or bacterium in the vaccine which in turn would reduce the effectiveness of the vaccine.

10. What is an antibiotic and what is its primary use?

Antibiotics are drugs which are primarily used for the treatment of diseases caused by bacterial infections.

- 11. Antibiotics, antibacterial agents and parasitacides are said to have a spectrum of activity. What does this mean?**
The spectrum of activity refers to the number of different types of organisms the drug is effective against. Broad-spectrum drugs affect a large number of different types of organisms while narrow spectrum drugs affect fewer types of organisms.
- 12. What does the term “antibiotic resistance” mean and how can it be prevented?**
Antibiotic resistance refers to the ability of bacteria to develop resistance to the killing effects of an antibiotic. Resistance can be prevented by using the recommended dose, frequency, duration and route for a given drug.
- 13. Name the three general types of parasitacides that are licensed for sale at an Outlet.**
- Anthelmintics
 - Insecticides
 - Anti-coccidial agents
- 14. What type of wound and skin medication would be prohibited from sale in an Outlet?**
Any wound/skin medication product containing antibiotics.
- 15. Name the two injectable minerals that can be sold at an AMS outlet?**
Selenium and Iron.
- 16. Name the only injectable hormone (other than growth implants) that is allowed to be sold at an Outlet.**
Epinephrine (Adrenaline).

Chapter 7

Drug Interactions and Adverse Reactions

- 1. Producers may wish to mix two or more drugs together, for convenience, prior to injecting them. What could go wrong if they do this? Can a QC holder advise a producer on mixing medications?**
Incompatibilities may occur when two drugs are mixed together. For example, an acidic drug may neutralize a basic drug. Water and oil based solutions do not mix. Solutes could precipitate. All of these could render the drug(s) ineffective. If asked about mixing drugs, the QC holder should direct the producer to speak to their registered veterinarian.
- 2. What are the main types of adverse reactions?**
- Allergic Reaction
 - Swellings at the injection site.
 - Sudden death of the animal
 - Failure of the drug to perform as stated on the label
- 3. What is the responsibility of a Qualification Certificate holder when they are told about an adverse drug reaction?**
The QC holder should advise the producer to report the adverse reaction to the drug manufacturer, the appropriate federal government department, or their registered veterinarian, who will in turn report the reaction. For veterinary drugs, the report goes to the Veterinary Drugs Directorate of Health Canada. For veterinary biologics, the report goes to the CFIA. For pesticides, the report goes to the Pest Management Regulatory Agency. If asked, the QC holder should be able to provide the producer with the contact information for any one of these departments.

Chapter 8

Responsibilities of Qualification Certificate Holders and AMS Outlet Licensees

1. What are the two important responsibilities of all AMSO Licensees and Qualification Certificate Holders?

- To have a thorough knowledge of the AMS Regulation.
- To abide by all sections of the AMS Regulation.

2. Section 1(i) of the AMS Regulation defines a “permanent place of retail business”. What are the requirements of this definition?

- The business is in a fixed location in a building or part of a building
- The business is clearly identified to the public.
- The business is not in a private residence.
- Production animals are not permanently housed on the premises.
- Establish and maintain business hours of not less than 40 hrs. per week.

3. When do AMSO licences expire?

On December 31 of the fifth year following the year it was issued.

4. What general responsibilities of an AMSO licensee have regarding Qualification Certificate holders at his/her place of business?

Ensure that a QC holder is on duty or is available for consultation throughout regular business hours.

5. What are the responsibilities of an AMSO licensee if there is a change in partners, or if more than 50% of the shares of a corporation are sold, assigned or transferred?

The Minister should be notified of the change and the unexpired license should be returned to the Minister.

6. For how long must drug sales and purchase invoices be kept?

Minimum of 10 years.

7. When can an AMSO Inspector perform his or her duties and what can they inspect?

Inspections can be done any time during regular business hours.

The following items can be inspected:

- The physical premises
- All stock (on display and in storage)
- Purchase invoices
- Sales invoices

8. Storing restricted drugs at an AMSO is prohibited. If restricted drugs are found during an inspection, what options can be given for disposal of these products?

- The licensee must immediately remove the restricted drugs from the outlet.
- The licensee can contact the supplier to see if they can be returned.
- The licensee can make arrangements for the safe disposal of these drugs.

9. What information can be included in an advertisement?

They can include a picture of the product and factual information from the drug label or package insert.

Only advertisements made in the store, online or by other electronic means may include the price of the authorized medicine.

10. In general terms, what medicines can be sold at an AMS Outlet?

Only those that fit into one of the categories of section 14(2) of the AMS Regulation.

11. What information must be recorded on sales receipts?

- Name of the authorized medicine purchased
- Lot number of the authorized medicine purchased
- Quantity of the authorized medicine purchased
- Expiry date of the authorized medicine purchased
- Premise identification number of the owner of the animal or the commingling site operator who purchased the authorized medicine

12. What information must an AMSO licensee record and retain for his or her own records?

- A) name and telephone number of the purchaser,
- B) date of sale, and
- C) information that appears on the purchasers receipt.

13. What general requirements must be observed when storing drugs at an AMS Outlet?

General requirements pertaining to the storage of drugs are:

- All display and storage areas must be clean
- Drugs must be kept separate from human foods
- Drugs must be stored according to the recommendations of the manufacturer, including refrigeration and protection from light and moisture.

14. What label items must be brought to the attention of a purchaser of authorized medicine?

The purchaser must be made aware of:

- Dosage
- Approved species
- Withdrawal time
- Method of administration
- Expiry date
- Toxicity warnings
- Precautions on the label

15. How should expired medicines be handled?

They should be promptly removed from the shelf and stored separate from all other drugs until they are returned to the supplier or are destroyed.

16. Your employer is going to set up a booth at a Trade Fair. Is it legal for him to sell authorized medicines for production animals at this fair? Why or why not?

No. An Outlet license is only valid in the premises that were inspected.

17. Your employer has livestock of his own. He purchases some prescription drugs from his veterinarian. Can these drugs be stored at his outlet?

No. Section 13, not only prohibits the sale of restricted or prohibited products; it also prohibits the storage of these products at the licensed outlet.

18. What five activities are outlet licensees or Qualification Certificate holders specifically prohibited from undertaking in respect of handling, selling, and providing of information about authorized medicines at licensed outlets?

Prohibited methods of sale under the AMS Regulations are:

- Advertising prices in the newspaper or on radio advertisements.
- Repackaging or altering the label or contents of any authorized medicine with the exception of individual boluses
- Give away, barter or sell any authorized medicine as an inducement to purchase other merchandise.
- Recommending the use of an authorized medicine for purposes, or at a dosage level, or for animals not prescribed on the manufacture's label.
- Diagnosing a disease, disorder or condition of an animal, prescribing medicine or otherwise contravening the *Veterinary Profession Act*.

APPENDIX B
ALBERTA REGULATION 131/2014
ANIMAL HEALTH ACT
AUTHORIZED MEDICINE SALES REGULATION

Table of Contents

| | |
|-----------|--|
| 1 | Definitions |
| 2 | Application of Regulation |
| 3 | Application for licence |
| 4 | Suspension or cancellation of licence |
| 5 | Expiry of licence |
| 6 | Licence must be displayed |
| 7 | Change respecting licence |
| 8 | Change in ownership |
| 9 | Surrender of licence |
| 10 | Effect of surrender, suspension, cancellation or expiry of licence |
| 11 | Qualification certificate |
| 12 | Fee not refundable |
| 13 | Notices |
| 14 | Authorized medicine |
| 15 | Prohibitions, exception |
| 16 | Duties of inspector |
| 17 | Return of medicine |
| 18 | Records, receipts and reports |
| 19 | Manner of sale |
| 20 | Advertising |
| 21 | Storage of authorized medicine |
| 22 | Other duties of licensee |
| 23 | Qualification certificate holder prohibition |
| 24 | Restricting sale of other products |
| 25 | Businesses must be kept separate |
| 26 | Appeal |
| 27 | Fees |
| 28 | Offences |
| 29 | Penalties |
| 30 | Repeal |
| 31 | Expiry |
| 32 | Coming into force |

Schedules

Definitions

- 1** In this Regulation,
- (a) “Act” means the *Animal Health Act*;
 - (b) “commingling site operator” means an operator of a commingling site as defined in the *Premises Identification Regulation* (AR 200/2008);
 - (c) “licence” means an outlet licence or a wholesale licence issued under the Act;
 - (d) “licensee” means a person who holds a licence under this Regulation;
 - (e) “municipal authority” means a municipal authority as defined in the *Municipal Government Act*;
 - (f) “permanent place of business” means a fixed location in a building or a part of a building where a business is operated that has signs or other markings that identify the building or a part of the building as a place of business open to the public, but does not include a business operated in a private dwelling or in a building used to permanently house production animals;
 - (g) “premises identification number” means a premises identification number as defined in the *Premises Identification Regulation* (AR 200/2008);
 - (h) “production animal” means
 - (i) a species of animal whose animal products or animal by-products may be used for human ingestion, including horses, or
 - (ii) a species of animal used for crop pollination, but does not include dogs or cats;
 - (i) “sell” includes to offer for sale, expose for sale and have in possession for sale or distribution, whether or not the distribution is made for consideration.
- 1(1)** For the purposes of the Act and this Regulation, “authorized medicine” means a medicine described in section 14.

Application of Regulation

- 2** This Regulation does not apply to
- (a) the sale of medicated feeds prepared either in accordance with the *Feeds Act* (Canada) or pursuant to a prescription issued by a registered veterinarian,
 - (b) the sale of medicine by
 - (i) any person authorized by the *Veterinary Profession Act* to sell medicine, when acting under authority of that act, or
 - (ii) any person authorized by the *Pharmacy and Drug Act* to sell medicine, when acting under authority of that Act,
 - (c) the sale of medicine by a manufacturer of medicine or a person who sells medicine on a wholesale basis to
 - (i) any person referred to in subsection (b),
 - (ii) another manufacturer of medicine, or
 - (iii) a person who sells medicine on a wholesale basis.

Application for licence

- 3(1)** An applicant for a wholesale licence must, in respect of each permanent place of business for which a wholesale licence is required,
- (a) submit an application in Form 1 set out in Schedule 1 to this Regulation,
 - (b) have
 - (i) a valid business licence issued by a municipal authority that authorizes the holder to operate a wholesale business, or
 - (ii) where the municipal authority does not issue business licences, a letter or copy of a development permit that is acceptable to the Minister indicating that the applicant is authorized to operate a wholesale business,
 - (c) have a valid Health Canada drug establishment licence, if such a licence is required under the *Food and Drugs Act* (Canada), and
 - (d) submit payment in full of the wholesale licence fee set out in section 27(b).
- 3(2)** An applicant for an outlet licence must, in respect of each permanent place of business for which an outlet licence is required,
- (a) submit an application in Form 2 set out in Schedule 1 to this Regulation,
 - (b) have
 - (i) a valid business licence issued by a municipal authority that authorizes the holder to operate a retail business, or
 - (ii) where the municipal authority does not issue business licences, a letter or copy of a development permit that is acceptable to the Minister indicating that the applicant is authorized to operate a retail business,
 - and
 - (c) submit payment in full of the outlet licence fee set out in section 27(a).

Suspension or cancellation of licence

- 4(1)** Where a licensee has intentionally made a false statement in the application for a licence, or has contravened the *Pharmacy and Drug Act*, the *Veterinary Profession Act*, the *Food and Drugs Act* (Canada) or any Act of the Parliament of Canada relating to the sale or distribution of medicine, the Minister may
- (a) suspend the licensee's licence for a period of time that the Minister considers appropriate, or
 - (b) cancel the licensee's licence.
- 4(2)** Where the Minister has suspended or cancelled a licensee's licence under subsection (1), the Minister shall notify the licensee in writing of that fact.
- 4(3)** Where the Minister has suspended or cancelled an outlet licence, the outlet licensee shall
- (a) immediately remove all medicine from public display,
 - (b) provide the Minister with a description and inventory of all medicine in the outlet licensee's possession within 5 working days,

- (c) immediately cease the carrying on of business, including advertising, related to the sale of medicine, and
 - (d) immediately cease the purchase of any further medicine.
- 4(4)** Where the Minister has suspended or cancelled a wholesale licence, the wholesale licensee shall not sell authorized medicine to an outlet licensee.

Expiry of licence

- 5** A licence expires on December 31 of the 5th year following the year in which it was issued.

Licence must be displayed

- 6(1)** Subject to subsection (2), a licensee must display the licensee's licence at all times in a prominent location within the licensee's permanent place of business.
- 6(2)** A licensee must remove a licence from display if the Minister has suspended or cancelled the licence.

Change respecting licence

- 7(1)** A licensee shall notify the Minister forthwith of a change in any of the information provided on the application for the licence, or the expiry, suspension or cancellation of any of the following documents required under section 3 in respect of the licensee's licence:
- (a) business licence;
 - (b) development permit or authorization letter;
 - (c) drug establishment licence.
- 7(2)** A licensee's licence is deemed to have been suspended by the Minister on the expiry, suspension or cancellation of any of the documents referred to in subsection (1)(a) to (c).

Change in ownership

- 8(1)** On a change of ownership of a licensee's business, the licensee shall notify the Minister forthwith and return the unexpired licence to the Minister.
- 8(2)** Without limiting subsection (1),
- (a) in the case of a licence issued to a partnership, a change in ownership is deemed to have occurred if there is a change in the partners of the partnership, and
 - (b) in the case of a licence issued to a corporation, a change in ownership is deemed to have occurred if 50% or more of the beneficial ownership of the shares in the corporation is sold, assigned or transferred.

Surrender of licence

- 9** A licensee who intends to cease selling authorized medicine shall
- (a) notify the Minister at least 14 days prior to the cessation of the sale of authorized medicine at each permanent place of business, and
 - (b) upon ceasing to sell authorized medicine, return the licensee's licence to the Minister.

Effect of surrender, suspension, cancellation or expiry of licence

- 10(1)** Sections 18(7), (8) and (9) and 22(1)(b) continue to apply to a person whose licence has been suspended, cancelled or surrendered or has expired.
- 10(2)** Section 17 applies to a person whose outlet licence has been suspended or surrendered or has expired as if the person's outlet licence had been cancelled by the Minister.
- 10(3)** Section 4(3) and (4) apply to a person whose licence has been surrendered or has expired as if the person's licence had been cancelled or suspended by the Minister.
- 10(4)** A person whose licence has been surrendered or cancelled or has expired shall for 10 years following the date of the surrender, cancellation or expiry notify the Minister within 14 days of any change of address.
- 10(5)** A person whose licence has been suspended shall, during the period of the suspension specified by the Minister under section 4(1)(a), notify the Minister within 14 days of any change of address.
- 10(6)** A person whose licence has been suspended or cancelled or has expired shall on request surrender the licence to an inspector.

Qualification certificate

- 11(1)** The Minister may issue a qualification certificate to an applicant who has
- (a) successfully completed any course of instruction or training regarding the proper handling of authorized medicine that is required by the Minister,
 - (b) passed an examination set by the Minister, and
 - (c) paid the fee for making the application as set out in section 27(c).
- 11(2)** A qualification certificate expires on December 31 of the 5th year following the year in which the certificate was issued.
- 11(3)** An application for a qualification certificate must be made in Form 3 set out in Schedule 1 to this Regulation.

Fee not refundable

- 12(1)** Subject to subsection (2), any fee paid under this Regulation is not refundable.
- 12(2)** Where the Minister refuses to issue a licence under section 43.4 of the Act, the Minister shall return the licence fee to the applicant.

Notices

- 13** A notice to be given to a licensee by the Minister under this Regulation may be given by personal service or by registered mail addressed to the licensee's last known address for service.

Authorized medicine

- 14(1)** A medicine listed in subsection (2) is an authorized medicine if the medicine
- (a) is a veterinary biologic that, under the *Health of Animals Act* (Canada), has been authorized for manufacture in, or import into, Canada and is approved for sale in Canada,

- (b) has been assigned a Drug Identification Number (DIN) under the *Food and Drugs Act* (Canada) for use in production animals in Canada, or
- (c) is a product that is registered under the *Pest Control Products Act* (Canada) as a product for direct application to a production animal, including, without limitation, insecticide impregnated ear tags.

14(2) The following are the medicines listed for the purposes of subsection (1):

- (a) veterinary biologics for use in production animals, including antiserums, bacterins, toxoids, antitoxins and products containing concentrated or purified antibodies and vaccines, except
 - (i) Anthrax vaccine,
 - (ii) Brucella vaccine,
 - (iii) rabies vaccine, or
 - (iv) modified-live virus and live virus vaccines for use in mammals;
- (b) modified-live virus and live virus vaccines for use in poultry;
- (c) antibiotics and sulfonamides, including their salts and derivatives, labelled by the manufacturer for administration to production animals that do not require a prescription as defined in the *Pharmacy and Drug Act*;
- (d) preparations for the control of external and internal parasites and insect pests of production animals;
- (e) oral preparations labelled by the manufacturer for the prevention or treatment of diseases of the digestive system in production animals, including bloat, colic, indigestion, diarrhea, constipation and impaction;
- (f) preparations labelled by the manufacturer for the treatment of surface wounds and lacerations, wire cuts and burns in production animals;
- (g) preparations labelled by the manufacturer for the treatment of skin diseases in production animals, including topical hoof care products;
- (h) vitamins for injection or oral administration to production animals, injectable vitamin A, not to exceed 500 000 I.U. per millilitre, and injectable vitamin D, not to exceed 75 000 I.U. per millilitre;
- (i) preparations containing minerals for oral administration and selenium and iron for injection into production animals for the prevention or treatment of deficiencies, including hematinics for horses, containing not more than 1 milligram of copper gluconate or cobalt gluconate, or both;
- (j) growth promotants in the form of implants and feed additives labelled by the manufacturer for use in production animals;
- (k) injectable epinephrine for treatment of anaphylactic reactions in production animals;
- (l) dextrose, calcium, phosphorus and magnesium preparations and propylene glycol labelled by the manufacturer for treatment and prevention of acetonemia and hypocalcemia in production animals and preparations intended as an aid in the supportive treatment of nutritional deficiencies in debilitated production animals;
- (m) anti-cannibalism compounds for poultry;

- (n) topical preparations labelled by the manufacturer as liniments, counterirritants or poultices for the treatment of joint pain, swollen ligaments, tendons or muscles;
- (o) oral or topical preparations labelled by the manufacturer as antitussives, decongestants, bronchodilators or expectorants;
- (p) acetylsalicylic acid boluses for horses and cattle;
- (q) disinfectants, udder washes, teat dips and sanitizers;
- (r) any other medicine authorized by the Chief Provincial Veterinarian.

Prohibitions, exception

- 15(1)** Only an outlet licensee or a wholesale licensee may sell authorized medicine.
- 15(2)** Despite subsection (1), only an outlet licensee who operates a hatchery under a permit pursuant to the *Health of Animals Regulations* (Canada) may sell modified-live virus and live virus vaccines for use in poultry.
- 15(3)** A person referred to in subsection (2) whose permit to operate a hatchery has expired or been suspended or cancelled under the *Health of Animals Regulations* (Canada) shall immediately
- (a) notify the Minister of the expiry, suspension or cancellation, and
 - (b) cease to sell modified-live virus and live virus vaccines.
- 15(4)** No outlet licensee shall
- (a) purchase or sell a medicine that is not an authorized medicine,
 - (b) purchase or sell a medicine that requires a prescription as defined in the *Pharmacy and Drug Act*, or
 - (c) permit a medicine that is not an authorized medicine to be stored at the licensee's permanent place of business or other premises.
- 15(5)** No wholesale licensee shall sell a medicine that is not an authorized medicine to an outlet licensee.

Duties of inspector

- 16(1)** Where the Minister has suspended or cancelled an outlet licence, the Minister may require an inspector to
- (a) make a list of every medicine found at the outlet licensee's permanent place of business or other premises,
 - (b) seal the cabinet or storage space where the outlet licensee's medicine is kept, and
 - (c) erect a placard within the outlet licensee's permanent place of business that reads "Authorized Medicine for Production Animals Not For Sale by Order of the Minister of Agriculture and Rural Development".
- 16(2)** No person other than an inspector shall remove a seal or placard referred to in subsection (1)(b) and (c).
- 16(3)** If the Minister reinstates an outlet licence, the inspector shall remove the seal or placard referred to in subsection (1)(b) and (c).

Return of medicine

- 17(1)** Where the Minister has cancelled an outlet licence, the outlet licensee shall return any returnable medicine to the person from whom it was purchased and shall provide proof to the Minister that the medicine has been returned.
- 17(2)** Any medicine that has not been returned under subsection (1) shall be disposed of by the outlet licensee as directed by the Chief Provincial Veterinarian or turned over to an inspector for disposal.

Records, receipts and reports

- 18(1)** A licensee shall keep an accurate record for each authorized medicine purchased and sold by the licensee in accordance with this section.
- 18(2)** An outlet licensee and a wholesale licensee, when purchasing an authorized medicine, shall record
- (a) the source from which the authorized medicine was purchased,
 - (b) the date of purchase,
 - (c) the name of the authorized medicine,
 - (d) the quantity of the authorized medicine, and
 - (e) the lot number of the authorized medicine.
- 18(3)** An outlet licensee, when selling an authorized medicine to a purchaser, shall record
- (a) the name and telephone number of the purchaser,
 - (b) the date of sale, and
 - (c) the information that appears on the purchaser's receipt as set out in subsection (4).
- 18(4)** An outlet licensee shall provide to each purchaser of an authorized medicine a receipt that shows
- (a) the name of the authorized medicine,
 - (b) the lot number of the authorized medicine,
 - (c) the quantity of authorized medicine purchased,
 - (d) the expiry date of the authorized medicine, and
 - (e) a premises identification number of the owner of the animal or the commingling site operator who purchased the authorized medicine.
- 18(5)** A wholesale licensee, when selling an authorized medicine to an outlet licensee, shall record
- (a) the name and address of the outlet licensee,
 - (b) the date of sale, and
 - (c) the information that appears on the outlet licensee's receipt as set out in subsection (6).
- 18(6)** A wholesale licensee shall provide to each outlet licensee who purchases an authorized medicine a receipt that shows

- (a) the name of the authorized medicine,
 - (b) the lot number of the authorized medicine, and
 - (c) the quantity of authorized medicine purchased.
- 18(7)** A licensee shall keep copies of all purchase receipts and records of sales required under this section for a period of 10 years.
- 18(8)** A licensee shall ensure that all records required to be kept by the licensee under this section are readily available for inspection by an inspector.
- 18(9)** The Minister may at any time require a written report from a licensee, in a form satisfactory to the Minister, containing information required by the Minister.

Manner of sale

- 19(1)** Subject to subsection (2), an outlet licensee may sell authorized medicine only
- (a) in person at the outlet licensee's permanent place of business,
 - (b) by telephone sales, or
 - (c) online or by other electronic means.
- 19(2)** An outlet licensee may sell antibiotics only in person at the outlet licensee's permanent place of business.
- 19(3)** No outlet licensee shall solicit the sale of authorized medicine by telephone, fax or other electronic means.
- 19(4)** This section does not apply to the sale of disinfectants, udder washes, teat dips and sanitizers.

Advertising

- 20** An outlet licensee, when advertising the sale of authorized medicine, shall not
- (a) make a claim about the use, application or effectiveness of the authorized medicine other than the factual information from the label or package insert of the authorized medicine, or
 - (b) advertise the price of an authorized medicine, other than on the outlet licensee's website or within the outlet licensee's permanent place of business.

Storage of authorized medicine

- 21(1)** A licensee shall store authorized medicine in a manner recommended by the manufacturer of the authorized medicine.
- 21(2)** Without restricting the generality of subsection (1),
- (a) a licensee shall store or display authorized medicine that does not require refrigeration in a place that
 - (i) prevents the authorized medicine from coming in contact with any food or medicine designated for human use, and
 - (ii) is clean and sanitary at all times,
- and

- (b) a licensee shall
 - (i) keep authorized medicine that requires refrigeration in a refrigerator at the temperature recommended by the manufacturer of the authorized medicine, and
 - (ii) ensure that the refrigerator
 - ◆ does not contain any food or medicine designated for human use, and
 - ◆ is clean and sanitary at all times.
- 21(3)** A licensee shall ensure that all authorized medicine is stored and handled in a manner that protects animals and their feed from being contaminated with the authorized medicine.
- 21(4)** A licensee shall, immediately after the expiration date of any authorized medicine, remove the authorized medicine from public view and keep it separate from other stock until it is destroyed or returned to the supplier.

Other duties of licensee

- 22(1)** A licensee shall
 - (a) sell authorized medicine only in containers labelled by the manufacturer, and
 - (b) package and ship or transport authorized medicine in accordance with the manufacturer's specifications.
- 22(2)** An outlet licensee shall establish and maintain business hours of not fewer than 40 hours per week at the permanent place of business to which the outlet licence applies.
- 22(3)** An outlet licensee shall
 - (a) draw to the attention of a purchaser of authorized medicine any precautions to be taken with respect to the minimum amount of time that must elapse
 - (i) between the administration of the authorized medicine to a production animal and the slaughter of the animal, and
 - (ii) between the administration of the authorized medicine to a production animal and the time at which the animal products and animal by-products may be used for human ingestion,
 - (b) draw to the attention of a purchaser of authorized medicine all information on the label with respect to
 - (i) dosage,
 - (ii) approved species,
 - (iii) method of administration,
 - (iv) expiry date,
 - (v) toxicity warnings, and
 - (vi) precautions,

and
 - (c) with regard to sales in person, display a sign, in a form determined by the Minister, in a prominent location within the licensee's permanent place of business, and, with

regard to telephone or online or other sales by electronic means, provide written notice that emphasizes and draws the purchaser's attention to

- (i) the importance of proper use of authorized medicine, and
- (ii) the contact information of a staff person who holds a qualification certificate for clarification of any questions regarding the safe and proper use of authorized medicine.

22(4) No licensee shall

- (a) repackage, alter the label of or alter the contents of any authorized medicine,
- (b) give away, barter or sell any authorized medicine as an inducement to purchase other merchandise, or
- (c) sell authorized medicine after the expiry date of the authorized medicine.

22(5) No licensee shall

- (a) recommend the use of an authorized medicine for purposes, or at a dosage level, or for animals not prescribed on the manufacturer's label, or
- (b) diagnose a disease, disorder or condition of an animal, prescribe medicine or otherwise contravene section 2(1) of the *Veterinary Profession Act*.

22(6) Despite subsections (1) and (4), an outlet licensee may sell individual boluses of authorized medicine if

- (a) copies of the package inserts and suitable containers are provided to the purchaser, and
- (b) the containers are inscribed with the Drug Identification Number, lot number and expiry date of the authorized medicine sold.

Qualification certificate holder prohibition

23 No holder of a qualification certificate shall

- (a) recommend the use of authorized medicine for purposes, or at a dosage level, or for animals not prescribed on the label, or
- (b) diagnose a disease, disorder or condition of an animal, prescribe medicine or otherwise contravene section 2(1) of the *Veterinary Profession Act*.

Restricting sale of other products

24 No licensee shall sell a product that, in the opinion of the Minister, poses a health risk to humans or production animals.

Businesses must be kept separate

25(1) A licensee who also holds another licence under the Act to sell authorized medicine, or a licence under another enactment to sell medicine, shall not carry on both businesses in the same permanent place of business unless each business

- (a) has its own entrance and exit separate from the entrance and exit for the other business,
- (b) operates under a unique name or a name that is distinct from the name of the other business,

- (c) has its own receiving and storage area separate from the receiving and storage area for the other business, and
- (d) uses separate invoices for the sale of its medicine or authorized medicine and other products.

25(2) In addition to the requirements of subsection (1), where a licensee carries on two businesses in the same permanent place of business, the business premises must be separated by a partition that does not permit customers to pass from one to the other.

Appeal

26 An application for an appeal for the purposes of section 46(1)(c), (d) or (e) of the Act must be made in the form set out in Schedule 2 to this Regulation.

Fees

27 The fees for licences and qualification certificates are as follows:

- (a) an outlet licence \$100;
- (b) a wholesale licence \$100;
- (c) a qualification certificate \$100.

Offences

28 A person who contravenes or fails to comply with this Regulation is guilty of an offence.

Penalties

29(1) A person who is guilty of an offence under section 28 is liable

- (a) for a first offence, to a fine of not more than \$15,000 and, in the case of a continuing offence, to a further fine of not more than \$1000 for each day or part of a day during which the offence continues after the first day, and
- (b) for a 2nd or subsequent offence,
 - (i) to a fine of not more than \$30 000 and, in the case of a continuing offence, to a further fine of not more than \$2000 for each day or part of a day during which the offence continues after the first day, or
 - (ii) to imprisonment for a term not exceeding one year,
 - (iii) or to both fines and imprisonment.

29(2) A prosecution under subsection (1) may be commenced within 2 years of the commission of the alleged offence but not afterwards.

Repeal

30 The *Production Animal Medicine Regulation* (AR 299/2003) is repealed.

Expiry

31 For the purpose of ensuring that this Regulation is reviewed for ongoing relevancy and necessity, with the option that it may be repassed in its present or an amended form following a review, this Regulation expires on September 30, 2023.

Coming into force

- 32** This Regulation comes into force on the coming into force of section 19 of the *Animal Health Amendment Act, 2009*.

Schedule 1

Form 1

APPLICATION FOR WHOLESALE LICENCE

Applicant Information

- (a) Individual
- (b) Partnership
- (c) Corporation (attach copy of incorporation certificate)
- (d) Other

Incorporation number/corporate access number: _____

Trade name(s), if applicable: _____

Mailing address: _____

Town/city: _____ Postal code: _____

Key Contact Information

Name and telephone numbers of:

| OWNER | MANAGER |
|---------------|---------------|
| Name: | Name: |
| Telephone: | Telephone: |
| Mobile phone: | Mobile phone: |
| E-mail: | E-mail: |

Permanent Place of Business

Address of the permanent place of business: _____

Business Licence or Development Permit

Attach a copy of the current business licence or, in the case of municipal authorities that do not issue business licences, a letter or a copy of a development permit from the municipal authority that indicates you have authority to operate a wholesale business.

Other Licences

Health Canada Drug Establishment Licence number and expiry date: .

Attach a copy of the Health Canada Drug Establishment Licence to this application.

Certification

I am an authorized representative of the applicant.

OR

I am the applicant.

I certify that the information given on this form is, to the best of my knowledge, true and complete.

Dated at: _____, Alberta

this _____ day of _____, 20__

First and last name (print)

Position/title

Signature and/or corporate seal

Form 2

APPLICATION FOR OUTLET LICENCE

Applicant Information

- (a) Individual
- (b) Partnership
- (c) Corporation (attach copy of incorporation certificate)
- (d) Other

Incorporation number/corporate access number: _____

Trade name(s), if applicable: _____

Mailing address: _____

Town/city: _____ Postal code: _____

Key Contact Information

Name and telephone numbers of:

| OWNER | MANAGER |
|---------------------|---------------------|
| Name: _____ | Name: _____ |
| Telephone: _____ | Telephone: _____ |
| Mobile phone: _____ | Mobile phone: _____ |
| E-mail: _____ | E-mail: _____ |

Permanent Place of Business

Municipal address of the permanent place of business: _____

Addresses of any premises where authorized medicine is stored:

Business Operation Details

My retail business sells the following products or services:

Proposed business hours are: _____

Business Licence or Development Permit

Attach a copy of the current business licence or, in the case of municipal authorities that do not issue business licences, a letter or a copy of a development permit from the municipal authority that indicates you have authority to operate a retail business.

Qualification Certificates

The following individual(s) hold or will be applying for a qualification certificate in accordance with the *Authorized Medicine Sales Regulation*:

Name: _____ Qualification Certificate #: _____ Expiry Year: _____

Certification

I am an authorized representative of the applicant.

OR

I am the applicant.

Form 3

APPLICATION FOR QUALIFICATION CERTIFICATE

Name: _____

Address: _____

Town/city: _____ Postal code: _____

Telephone: _____ Fax: _____

I am applying for a qualification certificate.

I wish to write the qualification certificate examination on _____ in _____.

Schedule of examinations:

Examinations are scheduled for ____ (a.m./p.m.) at the assigned locations.

The qualification certificate fee of \$100.00 is due at the time of writing the examination.

Applicant's signature

Dated _____, 20____.

Appendix C

UNITS OF MEASURE

DEFINITIONS

Milli means 1 one thousandth (1/1,000) of a part

Kilo means one thousand (1,000) parts

MEASURES OF VOLUME

Used for liquids

1 ml (millilitre) = 1/1,000 of a litre (L)

NOTE: 1 cubic centimeter (cc) is identical to 1 ml.

1,000 ml = 1L

Conversion to Imperial Measure

| | | |
|----------|---|----------|
| 1 ounce | = | 28.41 ml |
| 1 pint | = | 0.568 L |
| 1 quart | = | 1.137 L |
| 1 gallon | = | 4.546 L |

| | | |
|---------|---|--------------|
| 1 ml | = | 0.03 ounces |
| 1 litre | = | 0.88 quarts |
| 1 litre | = | 0.22 gallons |

MEASURES OF WEIGHT

Used for solids or semi solids

| | | |
|-----------------------|---|-----------------|
| 1,000 mg (milligrams) | = | 1 g (gram) |
| 1,000 g | = | 1 kg (kilogram) |

Conversion to Imperial Measure

| | | |
|---------|---|---------------------|
| 1 kg | = | 2.2 pounds |
| 1 pound | = | 0.454 kg or 454 gms |