

*The Ontario
Livestock Medicines Act
and Regulations*

**Standards of Compliance
Manual**

(revised)
July, 2010

The *Ontario Livestock Medicines Act and Regulations* Standards of Compliance Manual

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Introduction

As a licensed livestock medicines outlet operator in Ontario, you are required to ensure your facility develops and implements training, procedures and systems to achieve and maintain compliance with the *Livestock Medicines Act and regulations*. This legislation helps to:

- Provide approved, safe and effective medicines to livestock producers in Ontario at competitive prices and convenient locations.
- Contribute to the health and welfare of livestock.
- Protect the health of farm families and consumers.
- Contribute to a safe food supply system.

The Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA) is responsible for the administration and enforcement of the *Livestock Medicines Act and regulations*. Through a comprehensive inspection system and an enhanced vendor educational initiative, which includes this compliance manual, livestock medicines licence holders will understand their responsibilities and have the tools to assist them in achieving and maintaining compliance. This system will increase accountability and consistency of enforcement and will provide guidelines for infraction management.

The objective inspection scoring system introduced with this compliance manual will provide the Ministry with valuable information, helping us to better utilize resources to ensure the safe and responsible sale of over-the-counter livestock medicines.

Keep this manual close to the medicine storage area as a reference. It is your responsibility, as store manager, to ensure each staff person understands the contents of this manual. Managers should ensure all existing and new staff are familiar with the Act and regulations and the responsibilities of a licensed livestock medicines outlet. File the inspection reports in the back of this Compliance Manual binder to keep track of any deficiencies and suggestions. You, as the manager, can use these inspection reports and compliance references to identify strengths or weaknesses in your facility and implement any necessary changes.

If you have any questions about the Standards of Compliance manual, inspection reports or need advice on permitted medicines or sales practices, please contact the inspector for your area:

Livestock Medicines Inspectors & Contact Numbers

Gerrit Rietveld
Animal Care Specialist
Central/Northern Ontario
OMAFRA - Elora

Craig Richardson
Animal Care Specialist
Eastern Ontario
OMAFRA - Kemptville

Telephone: 519-846-3395

Fax: 519-846-8178

Email: gerrit.rietveld@ontario.ca

Telephone: 613-258-8298

Fax: 613-258-8392

Email: craig.richardson@ontario.ca

Livestock Medicines Act and Regulations

The following URL will access the Act:

http://www.e-laws.gov.on.ca/Download?dDocName=elaws_statutes_90l23_e

Or can be ordered through Publications Ontario:

1-800-668-9938 or 416-326-5300

http://www.e-laws.gov.on.ca/Download?dDocName=elaws_regs_900730_e

Licence Applications

Contact the inspector in your area or the number below for an application for a licence to sell medicines.

Applications for Class 1 (annual) or Class 2 (temporary) licences should be sent to:

Veterinary Services Licensing Coordinator
OMAFRA
1 Stone Rd. W., 5th Floor, NW
Guelph, ON N1G 4Y2

Telephone: 519-826-3571

Inspection System

Licensed Ontario livestock medicines outlets will, generally, be inspected at least once during each licence period. Inspection frequency may vary, dependent on the nature and severity of any deficiencies noted in the initial inspection, or as a result of complaints received by inspection staff.

At the beginning of each inspection visit, a licensed outlet will be awarded 200 points. During the course of the inspection, points will be deducted if any deficiencies or non-compliance with the Act and/or Regulations are found.

For the purposes of inspection scoring, livestock medicines permitted for sale in Ontario outlets have been categorized into 3 groups (Appendix 1) according to their active ingredients, intended use and potential impact on food safety or animal health as a result of improper storage or handling. Failure to comply with these requirements can have a detrimental effect on product potency, efficacy and animal health.

Deficiencies/non-compliance will result in a loss of points depending on which group the product(s) are involved. For example:

Group 1: 30 points for each deficiency involving a Group 1 livestock medicine (anti-microbials, steroids, vaccines).

Group 2: 20 points for each deficiency involving a Group 2 livestock medicine (vitamins/minerals, antiparasitics).

Group 3: 10 points for each deficiency involving a Group 3 livestock medicine (topicals, miscellaneous).

The sale of any drug product not designated under the *Ontario Livestock Medicines Act* will result in a deduction of 100 points.

Deliberate violation of regulations (i.e., products instructed for disposal being re-offered for sale, removal of label expiry dates, etc.) will result in doubling (2X) of penalty points that would be issued in the case of a first infraction.

Example Inspection Scoring

During an inspection, an inspector finds 3 bottles of penicillin that are being sold beyond the expiry date and have not been stored according to the manufacturer's recommendation on the label (i.e., not refrigerated). How many points would be deducted?

Answer:

The inspector would note two deficiencies (expired product and improper storage).

Loss of points:

- **30** points deduction for the expired penicillin, since this is a **Group 1** product, regardless of the fact that there were three bottles involved.
- an additional **30 points** deduction since the penicillin (Group 1) was stored incorrectly.

Total points lost : **60 points**

Final Score: **(200 – 60) = 140/200.**

Inspection Scoring Outcomes

Deficiencies will be discussed with the operator and/or outlet staff and recorded on the inspection report (Appendix 2). A copy of the inspection report will be left with the outlet operator to be filed in the Standards of Compliance binder, as well as in the inspector's file. A score (0 – 200) will be awarded for each inspection. All inspection scores will subsequently be logged into the Livestock Medicines Inspection Database.

A score of less than zero will be documented and appropriate action suggested.

	Score (points)	Outcomes
Initial Inspection	200	Facility is in full compliance.
	140 – 199	Facility is not in full compliance. Deficiencies are discussed and recorded on the inspection form. Suggestions to achieve full compliance are made during the inspection. Follow-up inspection is not required.
	< 140	Facility is in serious non-compliance with the Act and/or Regulations. Deficiencies are noted during the inspection, discussed verbally and recorded on the inspection form. Follow-up actions and timelines are discussed and agreed upon. A repeat unannounced inspection is required within 6 months.
Repeat Inspection	140 – 200	Facility is in compliance or has minor deficiencies. Any deficiencies are discussed verbally and recorded on the inspection form. Follow-up actions and timelines are discussed and agreed upon.
	< 140	Facility continues to be in serious non-compliance with the Act and/or Regulations. Deficiencies and suggested courses of action are discussed verbally and recorded on the inspection form. A further inspection is required within 3 months. A disciplinary letter indicating future actions will be sent to the outlet operator.
	Third score < 140	Recommendation is made to the Director, Animal Health and Welfare Branch to provisionally suspend the licence, pending a hearing.

No person is permitted to sell medicines in the province of Ontario without a licence unless they have permission to do so under the authority of another qualification (i.e., doctor, dentist, pharmacist, veterinarian)

Persons found selling livestock medicines in the province of Ontario without a valid licence under the *Livestock Medicines Act* will be advised of this requirement and provided with an application and a copy of the *Livestock Medicines Act* as well as the Standards of Compliance Manual. They will also be advised to refrain from selling any medicines until a licence signed by the Director is in force. Continued sale of medicines without a livestock medicines licence or other authority to sell medicines will result in appropriate enforcement action.

Note: This includes the requirement of a temporary permit for the sale of medicines at horse shows, agricultural fairs or horse races.

The selling of medicines at these venues without a temporary permit is a violation of the Act and will result in enforcement action.

Deliberate Violation of Regulations

Deliberate violation of the regulations will result in a doubling of penalty points and/or other actions depending on the seriousness of the violation. Examples of deliberate violations include, but are not restricted to, re-shelving and offering for sale expired product previously removed from the display area and initialed by an inspector (marked for disposal), tampering with labels to obscure or remove expiry dates, etc.

Other violations of the *Livestock Medicines Act* (selling without a temporary permit, obstructing an inspector) will be dealt with on a case by case basis. Corrective actions include, but are not limited to, investigations, hearings and/or prosecutions.

Penalties may range from Class 1 licence suspension or revocation to a fine of \$1000.00 and/or imprisonment upon conviction.

Complaints

Irrespective of the inspection system as outlined, complaints will be addressed promptly by the inspectorate.

Licence Renewals and Applications

All operators of licensed livestock medicines outlets automatically receive a Class 1 (annual) licence renewal form prior to July 31 every year. Applications for Class 2 licence can be obtained from the address below and submitted 30 days prior to the event. Applications accompanied by the fee must be mailed to:

Veterinary Services Licensing Coordinator
OMAFRA
1 Stone Road W., 5th Floor
Guelph, ON
N1G 4Y2

New licence requests should also be directed to the above address.

Licensing questions can be sent by mail, fax 519-826-4375 or telephone 519-826-3571.

How to Use This Manual

The Standards of Compliance Manual is designed for use as an educational tool for vendors to ensure they fully understand their responsibilities with respect to the *Livestock Medicines Act and regulations*. By referring to the compliance manual, vendors can be assured that they are operating within the parameters of the act and regulations.

Compliance with the *Livestock Medicines Act* will continue to be monitored through routine, unannounced inspections.

What's in This Manual?

Each page of the manual contains one regulation or section of the *Livestock Medicines Act*. The regulation or section is described using common, easy to understand terminology.

Each page header includes:

- **'Regulation'** which corresponds with the section number in the regulations.
- **'Key Element'** provides a brief indication of the regulation content.
- **'Inspection Form Reference'** provides a link between the compliance manual page and the inspection form.

The main categories on each page include:

- **'Regulation'** or **'Statute'** which quotes the actual regulation or section of the Act directly from the legislation.
- **'Background'** provides insight into the intended purpose of the individual regulation.
- **'To achieve compliance'** and **'Tips'** provides suggestions and recommended management practices to help licensees keep their facilities in compliance with the legislation.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.3.2

Key Element: Established Place of Business

Inspection Form Reference: Sales Practices – Established Place of Business

Regulation:

“A livestock medicine set out in the Schedule is designated as a livestock medicine that may be sold by the holder of a Class 1 licence at the holder’s established place of business.”

Background:

This regulation is intended to prevent the sale of livestock medicines from any location other than the location specified on the Class 1 licence. The Class 1 licence fee is \$75/year and the licence is valid up to and including July 31 after it is issued. There is no fee discount or rebate provision for partial licensing periods (i.e., outlet that opens or closes partway through the licensing period).

An established place of business is defined as a permanent, stationary outlet. i.e., cannot be readily moved from location to location. Each physical location engaged in selling medicines is required to be licensed. i.e., every franchised outlet of a company.

The requirement for a permanent, stationary place of business is intended to discourage the sale of livestock medicines door-to-door.

The term “sale” is not restricted to the common notion of sale i.e., in exchange for money or other goods or services, but includes offering for sale, exposing for sale, having in possession for sale, selling or distributing.

To achieve compliance:

1. Sell only from a permanent, stationary store located at the address stated on the Class 1 licence or a Class 2 temporary permit.

TIPS

- Licences are not transferable from one location to another.
- A separate Class 1 licence is required for each location.
- Apply for you Class 1 licence prior to July 31.

Standards of Compliance - Livestock Medicines Act

Regulation:	730.3.3
Key Element:	Temporary Place of Business
Inspection Form Reference:	Sales Practices – Location/Licence Irregularity

Regulation:

“A Class 2 licence authorizes the holder of a Class 1 licence to sell at a temporary place of business, the livestock medicines that the licensee is authorized to sell at the holder’s established place of business.”

Background:

A Class 2 (temporary) licence allows the holder to sell livestock medicines at a temporary location i.e., a horse show, horse race or agricultural fair. Only a holder of a valid Class 1 licence can apply for a Class 2 (temporary) licence.

This regulation discourages the sale at a temporary location, of any livestock medicines other than those permitted for sale at the permanent outlet location.

An application for a Class 2 licence must be made at least **30 days in advance** of the event. The approved sale location and duration are indicated on the temporary licence. The fee for a Class 2 license is \$50.00.

The term ‘sell’ is not restricted to the common notion of sell, but includes offering for sale, exposing for sale, having in possession for sale, selling or distributing.

To achieve compliance:

1. Livestock medicines must only be sold from the location shown on a Class 1 or Class 2 licence.
2. Only products listed in the Schedule and Addendum are permitted for sale in Ontario (Appendix 1).
3. Application for a Class 2 permit must be made 30 days in advance of the event.

TIPS

- Licences are not transferable from one location to another.
- A Class 2 licence is valid only for the temporary location and time period stated on the licence.
- Apply for a Class 2 licence at least 30 days in advance of the date required.

Standards of Compliance - Livestock Medicines Act

Regulation:	730.6.1(c)
Key Element:	Expiration Date
Inspection Form Reference:	Sales Practices - Expired Products for Sale

Regulation:

“A licence is issued on the terms and conditions that the licensee...shall not keep for sale or sell any livestock medicines after the expiration date indicated by the manufacturer on the label thereof.”

Background:

Livestock medicines cannot be offered for sale after the expiry date printed on the label. The expiry date provides a guarantee from the manufacturer to the purchaser that a properly stored livestock medicine will produce the advertised effect stated on the label or insert up to that time. Product efficacy, dosage required and/or withdrawal information printed on the drug label may no longer be valid beyond six months after the expiry date.

Products purchased up to the date of the expiry printed on the label generally are safe for use as indicated within the next six months, provided they have been stored and administered according to label directions.

Liability for sellers of expired medicines increases significantly, as manufacturers/distributors only guarantee product efficacy, dosage requirements and withdrawal information, warnings or cautions for the period of time up to the expiry date printed on the label.

To achieve compliance:

1. Ensure all staff understand the importance of expiry dates.
2. Do not sell or give away expired products.
3. Remove all outdated livestock medicines from store shelves.
4. Do not sell outdated stock at a discount.
5. Return outdated stock to the manufacturer or dispose as hazardous waste.
6. Selling short dated stock is not a good customer service practice.

TIPS

- Check expiry dates on livestock medicines:
 - When they arrive at the store;
 - Before they are sold;
 - At least every two weeks.
- Rotate stock, placing short-dated inventory in front of longer dated stock.
- Most expiry dates are expressed in month and year:
 - 10/DE means the product expires on December 31, 2010.
 - Unless a day is specified, the last day of the month stated on the label will be the expiry date.
 - Drugs packaged in Canada: the expiry date may be express as day/month/year (03/08/10) refers to August 3, 2010.
 - Drugs packaged in the United States: the expiry date may be express as month/day/year (03/08/10) refers to March 8, 2010.

Standards of Compliance - Livestock Medicines Act

Regulation:	730.6.1(d)
Key Element:	Repackaging/Re-labeling
Inspection Form Reference:	Sales Practices – Repackaged/Relabeled Products: Deliberate Violation

Regulation:

“A licence is issued on the terms and conditions that the licensee...shall not repackage or re-label livestock medicines.”

Background:

Retailers must sell medicines in the original packaging as it was received from the manufacturer or distributor. Medicines cannot be re-packaged or divided into smaller packages. To do so, is a deliberate act and will not be tolerated.

Re-packaging creates many problems, as “homemade” packaging does not contain the original label information including all the essential information for the safe and effective use of the product. The package insert contains valuable information that is too lengthy for the label. It is essential that these inserts are provided with all medicines offered for sale.

Many medicines are assigned lot numbers to assist in trace backs in cases of adverse drug reactions. Repackaging results in the loss of this label information and makes a drug call-back impossible, resulting in a possible food safety or animal welfare risk. The loss of the expiry date could likely result in the inadvertent use of expired medicines.

The manufacturer’s package may also contain items to help maintain product integrity (i.e., desiccants to protect from moisture, opaque boxes to protect medicines from light, cotton fillers to prevent physical damage caused by vibration). Failure to maintain medicines in their original containers can affect product efficacy (effectiveness).

Deliberate tampering with a label (i.e., removal or unauthorized altering of expiry dates or obscuring label cautions, warnings, treatment regimes, expiry dates etc.) is a serious offence and will be penalized accordingly.

To achieve compliance:

1. Do not repackage livestock medicines.
2. Keep package inserts with all livestock medicines.
3. Do not tamper with any labels.

TIPS

- Avoid the temptation to purchase large volumes of medicine (alcohol, furazone, etc.) and repackaging into 500 ml containers.
- Ensure all medicines sold are accompanied by the manufacturers' complete labels and inserts where applicable.

Standards of Compliance - Livestock Medicines Act

Regulation:	730.6.1(e)
Key Element:	Medicine Delivery
Inspection Form Reference:	Sales Practices – No Prior Invoice

Regulation:

“A licence is issued on the terms and conditions that the licensee...shall not deliver a livestock medicine except dairy sanitizers, teat dips and udder washes to a livestock owner without an order from that owner authorizing the delivery evidenced by an invoice prepared by the licensee in advance of delivery.”

Background:

Livestock medicines, other than dairy sanitizers, teat dips and udder washes, may not be transported in a vehicle without an invoice made out prior to the delivery. The invoice must be filled out at the established place of business prior to delivery. This practice further prohibits the sale of medicines door to door.

The invoice must include the name and address of the purchaser, the brand name and quantity of medicines, the lot number of any biologicals (usually stamped as a serial number) and the date of delivery. NOTE: Biologicals, including vaccines, must be transported under refrigeration in a cooler and ice packs to maintain product integrity.

To achieve compliance:

1. An invoice must accompany all livestock medicines to be delivered.
2. Invoices accompanying medicines for delivery must be complete, showing all required information.
3. Adhere to proper storage and transport requirements for all medicines, especially biologicals. (see label).

TIPS

- Establish practice of using store invoices to ensure consistency in complying with this requirement.
- Do not transport any livestock medicines other than dairy sanitizers, teat dips or udder washes without a proper invoice.
- Do not transport any livestock medicines other than dairy sanitizers, teat dips or udder washes without a proper invoice.
- Have a cooler (12 volt) or a cooler with ice packs to transport medicines that require refrigerated storage.
- Make deliveries of temperature – sensitive products promptly.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.6.1(f)

Key Element: Refrigeration

Inspection Form Reference: Storage – Improper Storage Temperature

Regulation:

“A licence is issued on the terms and conditions that the licensee...shall keep refrigerated all livestock medicines that require refrigeration.”

Background:

Products that require refrigeration must be kept in a clean refrigerator, used only for the storage of livestock medicines (no food). Livestock medicines requiring refrigeration will lose efficacy or potency if stored improperly.

To achieve compliance:

1. Make sure all staff read the product labels to know which products require refrigeration.
2. Provide a separate, working refrigerator for the storage of livestock medicines.
3. Clean the refrigerator on a regular basis.
4. Ensure proper temperature conditions for transported medicines, especially biologicals

TIPS

- Install a thermometer in the refrigerator to ensure it is functioning properly. The refrigerator must operate continuously within the range of 2 – 8° C.
- Use a cooler and ice packs for proper transport of medicines requiring refrigeration. Deliver these items first if possible.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.6.1(g)

Key Element: Proper Storage

Inspection Form Reference: Storage – Improper Storage

Regulation:

“A licence is issued on the terms and conditions that the licensee...shall store in a manner prescribed by this Regulation all livestock medicines that do not require refrigeration.”

Background:

All livestock medicines must be stored according to the directions printed on the label.

Information is included under the precautions statement, i.e., avoid direct sunlight.

Medicines particularly sensitive to sunlight are packaged in brown bottles or opaque cardboard containers. Desiccants (chemicals which absorb moisture) in packaging indicates the medicine is sensitive to moisture. These products need to be stored in areas of low humidity.

Improper storage is directly linked to decreased potency and effectiveness of the drug and may even result in an adverse reaction. For improperly stored drugs, the expiry date printed on the label is no longer valid.

To achieve compliance:

1. Store livestock medicines according to label directions.
2. Keep medicines away from direct sunlight.
3. Protect medicines from temperature and humidity extremes.

TIPS

- Medicines in brown glass bottles are particularly sensitive to the effects of light.
- Products sensitive to moisture (high humidity) are packaged with desiccants.
- Do not sell medicines with damaged packaging.
- Do not sell medicines that have been improperly stored.

Standards of Compliance - *Livestock Medicines Act*

Regulation:	730.6.1(i)
Key Element:	Sale to Livestock Owner
Inspection Form Reference:	Sales Practices – Sale to Non-Owner

Regulation:

“A licence is issued on the terms and conditions that the licensee... shall not sell a livestock medicine to any person other than an owner of livestock or for any purpose other than the treatment of livestock.”

Background:

This regulation discourages the use of medicines on any other species than those included in the definition of livestock.

“Livestock” is defined in the regulations as cattle, goats, horses, poultry, rabbits, sheep and swine and animals maintained in captivity for the production of fur.

“Owner” includes a person authorized to act on behalf of an owner.

Any use of a livestock medicine for purposes other than those listed on the product label is considered ‘extra label drug use’. i.e., in species not indicated on the label, altered dosage or treatment regime, route of administration, etc. Veterinarians may use a drug in a manner other than what is prescribed on the label, but they must issue a prescription and assume liability for use of the drug as prescribed. Outlet operators may not provide any advice other than label recommendations.

To achieve compliance:

1. Sell only to owners of livestock.
2. Make reasonable attempts to ascertain that products sold are registered for use in the livestock species the purchaser owns (i.e., do not sell a medicine registered solely for use in turkeys to a cattle producer).
3. Strongly recommend that purchasers contact their veterinarian prior to purchasing product to be used in an extra-label manner (i.e., in a species of livestock not owned by the purchaser).
4. Ultimately, the end user (producer) is responsible for the use of the medicine.

TIP

- As a vendor, you are not permitted to provide advice beyond what is stated on a medicine label.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.7.1

Key Element: Separate Storage

Inspection Form Reference: Storage – In Contact with Food/Human Drugs
Improper Storage

Regulation:

“A licensee who maintains, handles or stores livestock medicines shall keep them in a refrigerator, cabinet or other storage facility that is used solely for that purpose.”

Background:

Human drugs and foods intended for human consumption **must not** be kept in the same refrigerator or storage cabinet as livestock medicines.

Do not store livestock medicines near pesticides or any other type of poisonous material.

A suitable, dedicated storage area for medicines must be available to prevent cross contamination and ensure continued high quality of the product.

To achieve compliance:

1. Store livestock medicines in cabinets or shelves separate from possible contaminants i.e., pesticides and poisons.
2. Do not store food (eggs, cheese, lunches, etc.) or human drugs in the same storage areas as livestock medicines.

TIP

- Invest in a small ‘bar-type’ refrigerator to store staff lunches, eggs, cheese, etc.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.7.2

Key Element: Storage Temperature

Inspection Form Reference: Storage – Improper Storage Temperature
In Contact with Food/Human Drugs

Regulation:

“A licensee shall ensure that livestock medicines, whether they require refrigeration or not, are maintained at the temperatures prescribed for them by the manufacturer and that they do not come in contact with food or medicine for human consumption.”

Background:

Livestock medicines are sensitive to external temperatures; extremes in temperatures can result in loss of efficacy of the active ingredient. Therefore, livestock medicines must be stored according to the directions that are printed on the label to ensure maximum potency and effectiveness. Licensees must have a working refrigerator if selling livestock medicines requiring refrigerated storage.

Foods intended for human consumption **may not** be kept in the same refrigerator or storage cabinet as livestock medicines.

Livestock medicines vendors play an essential role as a link in a chain connecting manufacturers to producers, as end users. It is essential that all medicines are stored according to the recommendations of the manufacturer.

To achieve compliance:

1. Store livestock medicines according to manufacturer’s instructions.
2. Place food and human medicines in storage separate from livestock medicines.

TIPS

- “Refrigerate” means storage at 2 – 8° C.
- “Store in a cool place” means 8 – 15° C.
- “Room temperature means 15 – 25° C.
- “Protect from excessive heat” means storage below 40° C.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.7.3

Key Element: Cleanliness

Inspection Form Reference: Storage – Unsanitary Storage

Regulation:

“The licensee shall maintain every refrigerator, cabinet or other storage facility in a clean and sanitary condition.”

Background:

Livestock medicine storage areas must be kept clean to maintain product integrity.

Product containers and labels that become soiled are difficult to read and can lead to incorrect usage of a product.

To achieve compliance:

1. Keep livestock medicine storage areas clean.
2. Make sure all medicine labels are intact, legible, not dirty or water damaged.
3. Feed mills or other areas that tend to generate excessive dust, should keep medicines in a cabinet to help keep them clean. Ideally, all products should be sold in the same condition they were received in from the distributor/manufacturer.

TIPS

- Discard any medicine containers that are damaged or leaking.
- Assign staff to routinely keep the medicine storage area tidy and perform a check for expired product. i.e., every other Friday afternoon.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.8.1(b)

Key Element: Cautions and Warnings

Inspection Form Reference: Sales Practices – Failure to Point Out Label Cautions

Regulation:

“Every licensee shall...in the case of any livestock medicine bearing a warning or caution on the label, draw the attention of the purchaser to the warning or caution.”

Background:

Sales staff must point out any warnings and cautions that are printed on the product label. Warnings and cautions contain critical information related to the safe and effective use of the medicine.

Examples of warnings (human safety):

- “Avoid contact with skin”
- “In case of contact, wash in running water”
- “Avoid contact with open wounds”
- “If accidentally swallowed, obtain medical attention at once.”

Examples of cautions (animal safety):

- “Do not use in animals other than swine”
- “Intravenous injection in cattle has been fatal”
- “Do not feed to lactating cows.”

To achieve compliance:

1. Become familiar with the medicines in the inventory.
2. Always point out warnings and cautions at the time of sale. Failure to do so may result in some liability in the event of an adverse drug reaction.

TIPS

- Review drug labels and ensure familiarity with label information.
- Keep insert with package/product.

Standards of Compliance - Livestock Medicines Act

Regulation:	730.8.1(c)
Key Element:	Disposal of Expired Product
Inspection Form Reference:	Sales Practices – Expired Products for Sale

Regulation:

“Every licensee shall...immediately after the expiration date indicated by the manufacturer on the label of a livestock medicine, remove the livestock medicine from sale and keep it separate from other livestock medicines until it is disposed of in a manner approved by the Director.”

Background:

Livestock medicines **must not** be offered for sale after the expiry date printed on the label. However, it is legal to purchase a livestock medicine on the last day before the expiration date. Expired products must be disposed of in a safe manner.

The information (i.e., dosage, cautions, withdrawal times) printed on the label will be valid for approximately six months after the expiry date. Misuse of medicines can lead to costly errors (i.e., inappropriate treatment), human and food safety concerns.

Expired products must be removed from any sales area and properly stored until disposal. **Never** dispose of expired livestock medicines as regular household waste, or flush them into municipal sewer drains (i.e., down the toilet)

To achieve compliance:

1. Check expiry dates on products when you receive them.
2. Rotate stock placing older medicines at the front, newer ones at the back.
3. Remove all outdated items from shelves and place in appropriate storage area until disposal.
4. Use an approved method for disposal of expired products:
 - Return to manufacturer/distributor
 - Household/hazardous waste pick up
 - Incineration

TIPS

- “Sell” includes distribute; expired products may not be given away.
- Check with your municipality regarding hazardous waste disposal.
- Establish a system to return expired products to the manufacturer or distributor.

Standards of Compliance - Livestock Medicines Act

Regulation:	730.8.2
Key Element:	Inducements
Inspection Form Reference:	Advertising – Offer Inducement

Regulation:

“No licensee shall engage in any practice by which a livestock medicine is held out as an inducement for the purchase of livestock medicines or other goods, or by which other goods are held out as an inducement for the purchase of livestock medicines.”

Background:

The quantity of livestock medicines purchased by producers should not exceed their actual needs. The purchase of additional medicines, either prompted by promotional offers of material goods or other medicines, could result in the administration of medicines that have expired or are not appropriate. “Any practice” includes, but is not limited to advertising.

Advertisement of a sale price is permitted under this regulation. (i.e., 25% off the regular price of a bottle of penicillin).

Quantity discounts are not permitted (i.e. “buy 3, get 1 free”, “save \$’s when you buy a case”, “the more you buy, the lower the price”. However, advertising a lower price per millilitre or milligram or ounce of product in a larger container as opposed to the price per ml. or mg or oz. in a smaller container is permissible. For example: If a 100 ml bottle of penicillin G costs \$10.00, the per ml. price is .10¢. If a 250 ml. bottle of Penicillin G costs \$23.50, the per ml. cost drops to .094¢.

Volume discounts in the case of the purchaser being required to buy more product than he/she may need in order to realize a saving are not permitted. For example: *Bob goes to the local farm supply store to purchase one bottle of Penicillin that costs \$10.00. He notices a flyer taped to the medicine fridge advertising a case of 12 bottles of penicillin for \$110.00. After a bit of quick math, Bob realizes he could save \$10.00, but he must purchase all 12 bottles in order to realize this saving. This is a tempting offer, but he really only needed one bottle. If he bought the case, this would be more drug product than he had initially intended to buy, possibly leading to a situation where the penicillin may expire before it could all be used, possibly tempting him to use it anyways, perhaps in an extra-label manner. This is basically a ‘buy 11-get one free’ scenario.*

The legal way the store could offer this product at a discount price would be to advertise a 10% off each bottle. Purchasers could then buy as many bottles as they need, rather than the whole case of 12.

Adding 'free goods' such as syringes, pocket-knives, caps, etc., to medicines at the retail outlet is clearly considered to be an inducements and is **not** permitted. Packages received from manufacturer that contain additional items related to their use (i.e., syringes packaged with medicine bottles) will not be removed by inspector, as the retailer is required to sell the product in the container as it was received from the manufacturer.

To achieve compliance:

1. Do not use inducements to promote the purchase of livestock medicines.
2. Price livestock medicines as a single unit. i.e., bottle, jar or pouch

TIPS

- Examples of inducements ***NOT*** permitted
 - Free hat or jack knife with purchase of medicine.
 - Reduce price per bottle if multiple bottles are purchased.
 - Buy two bottles or packages of medicine and get one free.
- Promotional offers requiring purchasers to mail in a coupon are permitted.
- Sales price per bottle or package is permitted.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.8.3

Key Element: Food for Human Consumption

Inspection Form Reference: Storage – Contact with Food/Human Drugs

Regulation:

“No licensee shall store or permit to be stored any food or medicine for human consumption in a refrigerator, cabinet or facility used for the storage of livestock medicines.”

Background:

Foods and medicines intended for human consumption could become contaminated if they come in contact with livestock medicine containers, which may be leaking. Spilled foods or drinks may also contaminate medicines.

To achieve compliance:

1. Store livestock medicines in cabinets or refrigerators used **only** for that purpose.

TIP

- Store cheese, beverages and lunches in a separate refrigerator.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.9.1

Key Element: Invoices

Inspection Form Reference: Records – Incomplete Records

Regulation:

“Every licensee shall keep accurate records of the livestock medicines sold by the licensee, and the records shall include:”

- (a) the date of the sale
- (b) the name and address of the purchaser
- (c) the brand name and quantity; and
- (d) the lot numbers of any biologicals.

Background:

In the event of a product recall due to a problem with a specific lot of medicines, purchasers must be notified in order to take appropriate action.

The lot numbers of biologicals need to be included on the invoice. The lot number is usually stamped as a serial number on biologicals.

To achieve compliance:

1. Maintain proper records of all livestock medicine transactions.
2. Complete all required information on invoices, including certification information, on accompanying products for delivery.
3. Inspectors may review records for accuracy.

TIPS

- All personnel involved in the selling of livestock medicines should be familiar with the record keeping requirements and record system.
- Records are subject to inspection.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.9.2

Key Element: Records Retention

Inspection Form Reference: Records – Failure to Retain Records

Regulation:

“Every record of a sale of livestock medicines shall be kept for a period of at least two years.”

Background:

Records are required in order to notify producers in the event of a product recall due to an adverse reaction or manufacturing irregularity.

To achieve compliance:

1. Maintain accurate and complete records
2. Keep all sales records for at least two years.
3. Records of biological (vaccines, toxoids, etc.) sales must include the lot numbers.

TIPS

- Records must include:
 - Date of sale
 - Name/address of purchaser
 - Brand name and quantity
 - Lot number of vaccines

Standards of Compliance - Livestock Medicines Act

Regulation: 730.10

Key Element: Advertising

Inspection Form Reference: Advertising – Extra Label Advertising

Regulation:

“No advertising in respect of livestock medicines by a licensee shall exceed the claims or information set out on the manufacturer’s label.”

Background:

All advertising with respect to livestock medicines must not exceed the claims or information printed on the label. The product name, quantity of the drug and indications for use may be stated in any advertising. Advertisements may not make false claims about the use or effectiveness of a product.

Offering additional information may include, but is not limited to:

- suggesting treatment for diseases or disorders;
- alternate use, route of administration, dosage, duration of treatment, withdrawal time or product combinations (overlapping). A veterinarian is the only person authorized to use a product in an extra-label manner under the authority of the *Veterinarians Act*.
- Testimonials

To achieve compliance:

1. Advertisements may only include label information. If it is not on the label, it may not appear in an advertisement.
2. Product sales advertisements may not use promotional material or claims supplied by the manufacturer or distributor *unless the information also appears on the product label*. For example, a manufacturer may supply promotional material suggesting a product is efficacious in treating a certain disease but, unless this information also appears on the product label, sales advertising may not use this claim.

TIPS

- This requirement of adherence to label claims is not restricted to print advertising only, but pertains to any verbal interaction with clients as well.

Standards of Compliance - Livestock Medicines Act

Regulation: 730.11.2(a) (b)

Key Element: Detained Product

Inspection Form Reference: Sales Practices - Deliberate Violation

Regulation:

“Where a livestock medicine is detained, no person shall, (a) remove the tag attached to it; or (b) sell, offer to sell, move or allow or cause to be moved such livestock medicine.”

Background:

If, during the course of an inspection, products are found that are:

- Illegal for sale in Ontario Livestock Medicines outlets
- Improperly stored
- Expired

An inspector may detain the product and provide instructions to prevent its sale. Products not permitted for sale will be marked by initializing by the inspector.

If marked or detained products are found offered for sale at the time of a subsequent inspection, this will be regarded as a deliberate infraction and will result in appropriate disciplinary action. Deliberate infractions result in an automatic doubling of the penalty points on the inspection form. Disciplinary action may include but may not be restricted to a hearing before the Director.

To achieve compliance:

1. Dispose of, or otherwise remove from sale, detained products as instructed by the inspector.
2. Do not continue to offer detained or marked products for sale.
3. Do **NOT** interfere with products ordered detained by an inspector.

TIP

- “Sell” includes distribute. Detained products may not be given away.
- Promptly remove and keep separate any medicines removed from the display area by the inspector.
- Ensure all staff are aware these products are not to be offered for sale under any circumstances.

Standards of Compliance - Livestock Medicines Act

Regulation:	730.13
Key Element:	Permitted Livestock Medicines
Inspection Form Reference:	Sales Practices - Non Designated Products

Regulation:

“In addition to the grounds mentioned in section 6 of the Act, the Director may, after a hearing, refuse to renew or may suspend or revoke a licence where the licensee sells any drug other than a livestock medicine.”

Background:

It is a very serious offence to sell other drugs that are not classified as livestock medicines. Remember, ***all livestock medicines are drugs; but not all drugs are livestock medicines*** (as defined in the schedule of the regulations).

Licenses may sell only drugs designated as livestock medicines in Ontario (i.e., listed on the Schedule or Addendum in the Regulations, see Appendix 1). The Director may revoke or suspend the license of anyone who sells a drug not listed on the *Livestock Medicines Schedule* or the *Livestock Medicines Addendum*.

To achieve compliance:

1. Sell only livestock medicines listed in the schedule of the regulations of the *Livestock Medicines Act* and Addendum (Appendix 1). Any drug with a “Pr” designation on the label (prescription) must not be sold by a Livestock Medicines Outlet.
2. Check with your distributor before stocking medicines. The list of products permitted for sale over-the-counter varies from province to province. Note: Distributors are not subject to the provisions of the *Livestock Medicines Act*.
3. Ask for assistance from your inspector if you are unsure if the product is permitted for sale in Ontario.

TIPS

- Drugs approved for sale in Canada have a DIN (Drug Identification Number).
- Drugs with a prescription (Pr), controlled or narcotic drug designation are not allowed for sale in an Ontario Livestock Medicines Outlet.
- Biologicals offered for sale must have a Canadian Food Inspection Agency Registration Number (CFIA No.).
- Biologicals imported from the USA must have a US Veterinary Licence Number (US Vet. Lic. No.).
- Do not purchase inventory based on the word of a pharmaceutical salesperson, as requirements vary greatly from province to province.

Standards of Compliance - *Livestock Medicines Act*

Livestock Medicines Act: RSO 1990, Chapter L23, Section 4.2

Key Element: Offence

Inspection Form Reference: Livestock Medicines Act – Section 4.2

Statute:

“Any person who sells a livestock medicine to an owner of livestock for the treatment of livestock without a licence under this Act is, unless authorized therefor by any other Act, is guilty of an offence under this Act and on conviction is liable for a first offence to a fine of not more than \$1,000 or to imprisonment for a term of not more than three months, or to both, and for a subsequent offence to a fine of not more than \$2,000 or to imprisonment for a term of not more than six months, or to both.”

Background:

Anyone selling livestock medicines in the province of Ontario must have a valid licence issued under the authority of the *Livestock Medicines Act*. This requirement includes temporary permits – regardless if there is a Class 1 licence in force or not. This licence is only valid for the location stated on it.

Veterinarians, pharmacists, physicians and dentists do not require a licence under the *Livestock Medicines Act*.

Penalties outlined in section 4(2) are designed to be a deterrent to reflect the serious nature of selling livestock medicines without an appropriate licence.

To achieve compliance:

1. Establish a permanent place of business.
2. Apply for a licence before July 31 every year.
3. Apply to OMAFRA for a temporary permit (Class 2 licence) at least 30 days prior to selling at a horse show, horse race or agricultural fair.

TIP

Send licence application to:

Livestock Medicines Administrative Assistant
OMAFRA - Veterinary Services Unit
Animal Health and Welfare Branch
1 Stone Rd. W., 5th Floor
Guelph, ON N1G 4Y2

519-826-3571

Appendix 1: List of Approved Medicines by (Active Ingredient) for Sale in Ontario

February, 2000

Group 3 Topicals	Group 2 Vitamin/minerals	Group 1 Antimicrobials	Group 1 Biologicals
Acid Phosphoric	Iron	Bacitracin	Aleutian Diseases Antigen
Benzocaine	Vitamin/mineral combinations	Chlortetracycline	Avian Encephalomyelitis
Chloroform	Ethylene Diamine Dihydroiodide	Tiamulin (denagard)	Bordetella bronchioseptica bacterin
Creosote	Potassium Antimoyltrtrate	Dihydrostreptomycin	Clostridial Bacterins
Copper Salts/compounds or preparations thereof	Arsenic	Erythromycin	Clostridium Botulinum, Type C.Toxoid
Furazolidone	<i>Calcium Borogluconate</i>	Lincomycin	Equine Encephalomyelitis (killed) Vaccine
Iodine (> 2.5%)	<i>Ammonium Carbonate</i>	Neomycin	Equine Influenza (killed) Vaccine
Isopropyl Alcohol	<i>Potassium Bicarbonate</i>	Novobiocin	Erysipelas Bacterin
Lidocaine	<i>Ammonium Alum</i>	Penicillin G. Potassium	E. Coli Bacterin
Mercury		Penicillin G. Procaine	Fowl Cholera Bacterin
Iodoform		Oxytetracycline	Fowl Pox Vaccine
Methyl Salicylate		Polymyxin B	Infectious Bronchitis Vaccine
Nitrofurazone		Scopolamine	IBR-PI3 Intranasal Vaccine
Phenol	Antiparasitics	Spectinomycin	Immunocox Coccidiosis Vaccine
Potassium Permanganate	Albendazole	Sulfabenzamide	Infectious Bursal Disease Vaccine
<i>Chorhexidene Acetate</i>	Amprolium	Sulfadimethoxine	Infectious Laryngotracheitis Vaccine
Sodium Hydroxide	<i>Doramectin</i>	Sulfaethoxyipyridazine	Killed Bacteroides Nodosus Bacterin
<i>Acetylsalicylic Acid</i>	Thiabendazole	Sulfamerazine	Leptospirosis Bacterin
Lead Acetate	Copper Sulfate	Sulfamethazine	Marek's Vaccine
<i>8 - Hydroxyquinoline Sulfate</i>	Ivermectin	Sulfanilamide	Mink Distemper Vaccine
<i>Cetrimide</i>	Levamisole	Sulfapyridine	Mink Enteritis Vaccine
	Mebendazole	Sulfaquinoxaline	Mycoplasma Hyopnuemonia Bacterin
	Oxfendazole	Sulfathiazole	Newcastle Disease Vaccine
	Phenothiazine	Spiramycin	Pasturella Bacterin (with B. Bronchiseptica Bacterin)
	Piperazine	Streptomycin	Porcine Parvovirus Vaccine
	Tyrothricin	Tetracycline	Psuedomonas Bacterin
	Warbex	Tylosin	Tetanus Toxoid
Miscellaneous	Roxarsone	Virginiamycin	Viral Arthritis Vaccine
Nux vomica	<i>Moxidectin</i>	Ronidazole	
Cedar oil	Febendazole	Dimetradizole	Steroids
Belladonna	<i>Pyrantel Pamoate</i>	Carbadox	Estradiol Benzoate
Methenamine	<i>Trichlorfon</i>	Ionophores	Progesterone
<i>Kaolin</i>			Testosterone
			<i>Trenbolone acetate</i>
			<i>Xeranol</i>

NOTE: *Products in italics are not listed on the Livestock Medicines Act Schedule, but are permitted for sale as per Section 2 of the Livestock Medicines Schedule.*

