Province of Alberta

ANIMAL HEALTH ACT

AUTHORIZED MEDICINE SALES REGULATION

Alberta Regulation 131/2014

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ALBERTA REGULATION 131/2014

Animal Health Act

AUTHORIZED MEDICINE SALES REGULATION

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Definitions

1(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.

(2) 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).

(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.

(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.

(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) 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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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).

(2) A qualification certificate expires on December 31 of the 5th year following the year in which the certificate was issued.

(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.

(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.

(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.

(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.

(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.

(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.

(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".

(2) No person other than an inspector shall remove a seal or placard referred to in subsection (1)(b) and (c).

(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.

(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.

(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.

(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).

(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.

(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).

(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.

(7) A licensee shall keep copies of all purchase receipts and records of sales required under this section for a period of 10 years.

(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.

(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.

(2) An outlet licensee may sell antibiotics only in person at the outlet licensee's permanent place of business.

(3) No outlet licensee shall solicit the sale of authorized medicine by telephone, fax or other electronic means.

(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.

(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

(A) does not contain any food or medicine designated for human use, and

(B) is clean and sanitary at all times.

(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.

(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.

(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.

(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.

(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.

(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*.

(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.

(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,

or to both fines and imprisonment.

(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.

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 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___.

Schedule 2

Notice of Appeal

Animal Health Act (Section 46(1)(c), (d) and (e))

TO: Minister of Agriculture and Rural Development
Legislature Building
10800 - 97 Avenue
Edmonton, Alberta
T5K 2B6

TAKE NOTICE THAT (name of appellant) of (address of appellant) wishes to appeal the decision of the Minister, dated the (day) of (month), (year), to:

_____ refuse to issue a licence or qualification certificate

_____ suspend a licence or qualification certificate

_____ cancel a licence or qualification certificate

_____ impose terms and conditions on or vary the terms and conditions of a licence

A copy of that decision is attached and forms part of this appeal.

The grounds for the appeal are as follows:

(attach additional sheet if necessary)

DATED at _____, Alberta, this _____ day of _____, 20___.

_____(Signature)_____

Printed on Recycled Paper