Province of Alberta

ANIMAL HEALTH ACT

PRODUCTION ANIMAL MEDICINE REGULATION

Alberta Regulation 299/2003

With amendments up to and including Alberta Regulation 164/2012

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Note

All persons making use of this consolidation are reminded that it has no legislative sanction, that amendments have been embodied for convenience of reference only. The official Statutes and Regulations should be consulted for all purposes of interpreting and applying the law.

(Consolidated up to 164/2012)

ALBERTA REGULATION 299/2003

Animal Health Act

PRODUCTION ANIMAL MEDICINE REGULATION

Table of Contents

Definitions

1 In this Regulation,

(a) "Act" means the *Animal Health Act*;

(b) "active pharmaceutical ingredients" means bulk pharmaceutically active substances used in the formulation of medicines in dosage forms;

(c) "Committee" means the Advisory Committee established by the Minister under section 7 of the *Government Organization Act* for the purposes of this Regulation;

(d) "Department" means the Department of Agriculture and Rural Development;

(e) "end user" means a person who administers medicine to a production animal;

(f) "licence" means a licence issued under this Regulation to sell medicine to the public;

(g) "licensee" means a person who holds a licence issued under this Regulation;

(h) "medicine" means

(i) a biological,

(ii) a product that has been assigned a Drug Identification Number (DIN) under the *Food and Drugs Act* (Canada), or

(iii) a product that contains a Pest Control Product number that is intended for direct application to a production animal, including, without limitation, insecticide impregnated ear tags;

(i) "permanent place of retail business" means a business operated in a building or a part of a building that

(i) is accessible to the public during regular business hours of not less than 40 hours per week, and

(ii) has signs or other markings that identify the building or a part of the building as a place of retail business,

but does not include a business operated in a private dwelling or in a building used to permanently house production animals;

(j) "production animal" means

(i) a species of animal that may be used for human consumption or whose products may be used for human consumption,

(ii) a fur-bearing animal referred to in section 1 of the *Fur Farms Regulation* (AR 299/96), or

(iii) a species of animal used for crop pollination;

(k) "sell" includes offer for sale, expose for sale and have in possession for sale and distribution, whether or not the distribution is made for consideration;

(l) "wholesaler" means a person who sells medicine to persons other than end users.

AR 299/2003 s1;35/2007;68/2008;288/2009

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, or

(b) the sale of medicine by a manufacturer or wholesaler of medicine to

(i) a registered veterinarian or a pharmacist,

(ii) another manufacturer or wholesaler of medicine, or

(iii) a licensee.

Licence required

3 No person shall sell medicine to the public except under the authority of a licence issued under this Regulation.

Application for licence

4(1) A person wishing to apply for a licence must submit a completed application in the form provided by the Director, accompanied with

(a) a copy of the applicant's retail business licence acceptable to the Director or, in a case where the local authority does not issue retail business licences, a letter or a copy of a development permit from the local authority indicating that the applicant has authority to operate a retail business,

(b) such other information as required by the Director,

(c) an application fee in an amount set by the Director, and

(d) a licence fee in an amount set by the Director, payable on approval of the application.

(2) The Director may refer to the Committee, for its review and recommendations, any application for a licence that, in the opinion of the Director, is unusual.

Renewal of licence

5 A person wishing to apply for a renewal of licence must submit a completed application in the form provided by the Director, accompanied with a licence renewal fee in an amount set by the Director.

Refusal to issue or renew licence

6(1) The Director may refuse to issue or renew a licence if the Director is of the opinion that the applicant

(a) does not have a permanent place of retail business or otherwise lacks the equipment and facilities required to properly sell medicine to the public, or

(b) has contravened

(i) the Act or this Regulation,

(ii) the *Pharmaceutical Profession Act*,

(iii) the *Veterinary Profession Act*, or

(iv) any Act of the Parliament of Canada relating to the sale or distribution of medicine.

(2) If the Director refuses to issue or renew a licence, the Director shall notify the applicant in writing of that fact.

Term of licence

7 A licence expires on December 31 of the year for which it is issued.

Licence non-transferable

8 A licence is not assignable or in any other manner transferable.

Change in ownership

9(1) On a change of ownership of a licensee's business, the licensee shall notify the Director forthwith and return the unexpired licence to the Director.

(2) For the purposes of 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;

(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.

Notices

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

Fee not refundable

11(1) Subject to subsection (2), any fee paid under this Regulation is not refundable.

(2) Where the Director refuses to issue or renew a licence under section 6, the Director shall return the licence fee or licence renewal fee, as the case may be, to the applicant.

Qualification certificate required

12(1) No licensee shall sell medicine unless the licensee has on duty during regular business hours at least one staff member who holds a qualification certificate.

(2) A person may apply to the Director for a qualification certificate.

(3) The Director shall issue a qualification certificate to an applicant who has

(a) successfully completed any course of instruction or training regarding the proper handling of medicine that is required by the Director,

(b) passed an examination set by the Committee, and

(c) paid a fee for making the application in an amount set by the Director.

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

(5) A licensee shall notify the Director forthwith of

(a) ceasing to have a staff member who holds a qualification certificate as required by subsection (1), or

(b) the name and qualification certificate number of any new staff member on the applicant's premises who holds a qualification certificate.

Permitted medicine

13(1) Subject to subsections (2) and (3), a licence issued under this Regulation authorizes the licensee to sell any of the following medicine:

(a) injectable biologicals for the prevention or treatment of disease in production animals, including antiserums, bacterins, toxoids, antitoxins, products containing concentrated or purified antibodies and vaccines, except Brucella, Rabies, Anthrax, modified-live virus and live virus vaccines for mammals;

(b) antibiotics for administration to production animals and sulfonamides and their salts and derivatives listed or described in Part II, Schedule F of the *Food and Drug Regulations* (C.R.C., 1978 c.870) made under the *Food and Drugs Act* (Canada), including drug preparations listed in the *Compendium of Medicating Ingredients Brochure* (MIB) published by the Canadian Food Inspection Agency;

(c) preparations for the control of external and internal parasites and insect pests of production animals, including those registered under the *Pest Control Products Act* (Canada);

(d) 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;

(e) preparations labelled by the manufacturer for the treatment of surface wounds and lacerations, wire cuts and burns in production animals;

(f) preparations labelled by the manufacturer for the treatment of skin diseases in production animals, including topical hoof care products;

(g) 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;

(h) 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;

(i) growth promotants in the form of implants and feed additives labelled by the manufacturer for use in production animals;

(j) injectable epinephrine for treatment of anaphylactic reactions in production animals;

(k) 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;

(l) anti-cannibalism compounds for poultry;

(m) topical preparations labelled by the manufacturer as liniments, counter-irritants or poultices for the treatment of joint pain, swollen ligaments, tendons or muscles;

(n) oral or topical preparations labelled by the manufacturer as antitussives, decongestants, brochodilators or expectorants;

(o) acetylsalicylic acid boluses for horses and cattle;

(p) disinfectants, udder washes and teat dips and sanitizers.

(2) No licensee shall

(a) purchase or sell a medicine not listed in subsection (1),

(b) sell a medicine listed in subsection (1) that is listed or described as a drug in Part I, Schedule F of the *Food and Drug Regulations* (C.R.C., 1978 c.870) made under the *Food and Drugs Act* (Canada), or

(c) permit a medicine, including active pharmaceutical ingredients, not listed in subsection (1) to be stored at the licensee's permanent place of retail business.

(3) No licensee shall sell a medicine listed in subsection (1) that has been imported from a jurisdiction outside Canada unless the medicine has first been approved by the Veterinary Drug Directorate of Health Canada.

Suspension or cancellation of licence

14(1) Where a licensee has made a false statement in the application for a licence or renewal of a licence, or has contravened the Act or this Regulation, the *Pharmaceutical Profession Act*, the *Veterinary Profession Act* or any Act of the Parliament of Canada relating to the sale or distribution of medicine, the Minister may

(a) request the licensee to provide a written undertaking, in a form acceptable to the Minister, that the licensee will refrain from engaging in the act or practice that gave rise to the contravention,

(b) suspend the licensee's licence for a period that the Minister considers appropriate, or

(c) cancel the licensee's licence.

(2) Where the Minister has suspended or cancelled a licensee's licence, the Minister shall notify the licensee in writing of that fact.

(3) Where the Minister has suspended or cancelled a licensee's licence, the licensee shall

(a) remove all medicine from public display,

(b) provide the Director with a description and inventory of all medicine in the licensee's possession,

(c) cease to carry on business until the licence is reinstated, and

(d) cease to purchase any further medicine.

(4) Where the Minister has suspended or cancelled a licensee's licence, the Minister may cause an inspector

(a) to seal the cabinet or storage space where the licensee's medicine is kept, and

(b) to erect a placard within the licensee's business premises that reads "Medicine for Diseases of Production Animals Not For Sale by order of the Minister of Agriculture and Rural Development".

(5) No person other than an inspector shall remove a seal or placard referred to in subsection (4).

AR 299/2003 s14;35/2007;68/2008

Records and reports

15(1) A licensee shall keep an accurate record for each medicine purchased and sold by the licensee, including

(a) the date, name and address of the purchaser,

(b) the type and quantity of the medicine purchased, and

(c) such other records as the Director may require.

(2) A licensee shall keep copies of all purchase receipts and records of sales for a period of 2 years.

(3) 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.

(4) The Director may at any time require a written report from a licensee, in a form satisfactory to the Director, containing information required by Director.

Inspection of records

16(1) On the request of an inspector, a licensee shall

(a) make available for inspection by the inspector any record described in section 15, and

(b) provide copies of the records acceptable to the inspector or permit the inspector to remove the records for the purpose of making copies of them.

(2) Where an inspector removes any records under subsection (1)(b), the inspector shall

(a) leave a statement with the licensee specifying which records have been removed for copying, and

(b) as soon as possible, make the required copies and return the records to the licensee.

Inspection of medicines and premises

17(1) A licensee shall permit an inspector to inspect during ordinary business hours

(a) the medicine the licensee has in stock, and

(b) the premises where the medicine is stored and sold.

(2) If an inspector during an inspection finds any medicine that is not listed in section 13(1), the inspector shall

(a) direct the licensee to forthwith return the medicine to the supplier of the medicine, or

(b) with the consent of the licensee take possession of the medicine and dispose of it on the direction of the Director.

Manner of sale

18(1) No licensee shall sell medicine in any manner other than over the counter at the licensee's permanent place of retail business.

(2) Without restricting the generality of subsection (1), no licensee shall solicit the sale of medicine by mail order, Internet communication or at a place other than the licensee's permanent place of retail business.

(3) Subsection (1) does not apply to the sale of disinfectants, udder washes and teat dips and sanitizers.

Advertising

19 A licensee, when advertising the sale of medicine, may

(a) use only the words "Medicine for Diseases of Production Animals", and

(b) refer only to the factual information from the medicine label or package insert of the medicine.

Storage of medicine

20(1) A licensee shall store medicine for sale in a manner recommended by the manufacturer of the medicine.

(2) Without restricting the generality of subsection (1),

(a) a licensee shall store or display medicine for sale that does not require refrigeration in a place that

(i) prevents the medicine from coming in contact with any food or other medicine designated for human use, and

(ii) is clean and sanitary at all times,

and

(b) a licensee shall

(i) keep medicine for sale that requires refrigeration in a refrigerator at the temperature recommended by the manufacturer of the medicine, and

(ii) ensure that the refrigerator

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

(B) is clean and sanitary at all times.

(3) A licensee shall ensure that all medicine for sale is stored and handled in a manner that protects animals and their feed from being contaminated with the medicine.

Other duties of licensee

21(1) A licensee shall

(a) sell medicine only in containers labelled by the manufacturer,

(b) draw to the attention of a purchaser of medicine any precautions to be taken with respect to the minimum amount of time that must elapse

(i) between the administration of the medicine to a production animal and the slaughter of the animal, and

(ii) between the administration of the medicine to a production animal and the time at which the products from the animal may be used for human consumption,

(c) draw to the attention of a purchaser of medicine any toxicity warnings or other precautions on the label,

(d) display a sign, in a form determined by the Director, in a prominent location within the licensee's permanent place of retail business that

(i) emphasizes the importance of proper use of medicine, and

(ii) refers customers to a staff person who holds a qualification certificate for clarification of any

questions regarding the safe and proper use of medicine,

and

(e) immediately after the expiration date of any medicine, remove the medicine and keep it separate from other stock until it is destroyed or returned to the supplier.

(2) No licensee shall

(a) repackage or alter the contents of any medicine,

(b) give away, barter or sell any medicine as an inducement to purchase other merchandise,

(c) sell medicine after the expiry date of the medicine,

(d) refuse a request to provide a receipt to any person who purchases medicine, or

(e) diagnose, prescribe or otherwise contravene the *Veterinary Profession Act*.

(3) Despite subsection (1)(a), a licensee may sell individual boluses of medicine if

(a) copies of the package inserts and suitable containers are provided to the purchaser at the point of sale, and

(b) the containers are inscribed with the DIN, lot number and expiry date of the medicine sold.

Restricting sale of other products

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

Businesses must be kept separate

23 A licensee who is also licensed under another enactment to sell medicine shall not carry on both businesses in the same permanent place of retail 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 and other products.

Form of notice of appeal

24 The form of the notice of appeal required for the purposes of section 46(2) of the Act is as set out in the Schedule.

AR 299/2003 s24;288/2009

Repeal

25 The *Production Animal Medicine Regulation* (AR 31/98) is repealed.

Expiry

26 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 October 31, 2015.

AR 299/2003 s26;239/2007;231/2009;151/2010;164/2012

Schedule

Notice of Appeal

TO: Minister of Agriculture and Rural Development
408 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 (indicate either the Director or Minister) to (indicate whether the decision was to refuse a licence, to suspend a licence or to cancel a licence), dated the (day) of (month), (year).

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 (month), (year).

(Signature)

FOR INFORMATION ONLY:

1. In accordance with section 10 of the *Animal Health Act*, a person who has been refused a licence, or whose licence has

been suspended or cancelled may appeal the refusal, cancellation or suspension by serving a notice of appeal on the Minister within 30 days of being notified in writing of the refusal, cancellation or suspension.

AR 299/2003 Sched.;35/2007;68/2008;288/2009

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