FALKLAND ISLANDS

Livestock and Meat Products (Veterinary Medicinal Products) Regulations 2015

(S.R. & O. No. 30 OF 2015)

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PART 1
Introduction

1 Title and commencement

(1) These regulations are the Livestock and Meat Products (Veterinary Medicinal Products) Regulations 2015.

(2) These regulations come into force on publication in the *Gazette*.

2 Interpretation

In these regulations-

"competent authority" means the Senior Veterinary Officer or any other authorised official of the Department of Agriculture;

"controlled drugs" has the same meaning under the Misuse of Drugs Ordinance 1987;

[Revision w.e.f. 31/07/2017]

"feed" or "feedingstuff" means any substance or product, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

"feed additive" means any substance or product that contains a medicinal product that is added to the feed or feedingstuff of animals;

"import permit" means a permit issued by the competent authority under regulation 14;

"livestock" …

"medicated feed or feedingstuff" means any substance or product, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals to which a medicinal product or feed additive has been added;

"non-food producing animals" means any animal that is not kept, fattened or bred with the intention of it, or products produced from it, being used for human consumption;

"official veterinarian" means an official of the Department of Agriculture appointed under section 7(1)(b) of the Ordinance;

"prescribing cascade" means a recognised practice or provision in the United Kingdom to allow a veterinary surgeon to prescribe a medicine to an animal that is unauthorised if there is no suitable authorised preparation for the condition from which the animal is suffering;

"recognised veterinary practice" means any veterinary practice recognised as such under regulation 12;

"registered pharmacist" means a person registered to work as a pharmacist by virtue of completing a degree in Pharmacy and being registered with the United Kingdom General Pharmaceutical Council or the equivalent body in the country in which they qualified;

"suitably qualified person (SQP)" means a person approved as such under regulation 10;

"the Small Animal Exemption Scheme (SAES)" means the United Kingdom scheme for medicines marketed for use in certain pet species that are declared by the Secretary of State as not requiring veterinary control;

"qualified veterinarian" means a person who has completed a degree in veterinary medicine and surgery and who has not had this qualification removed by a regulatory authority;

"veterinary medicinal product" means any substance or combination of substances-

(a) presented as having properties for treating or preventing disease in animals; or

(b) that may be used in, or administered to, animals with a view to-

(i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(ii) making a medical diagnosis;

"Veterinary Medicines Directorate" means the United Kingdom based executive agency of the Department of Environment, Food and Rural Affairs (DEFRA); and

"withdrawal period" in relation to an authorised veterinary medicinal product administered to animals or batch of animals, means the period specified for that product (either in the marketing authorisation relating to that product or as prescribed by the official veterinarian) which is required to be observed from the time the product is administered to the animal and the time the animal can be placed on the market for slaughter for human consumption.

3 Application

(1) These regulations do not apply to veterinary medicinal products-

(a) referred to as "authorised veterinary medicine - general sales list (AVM-GSL)" which can be imported and sold by any person without restrictions; and

(b) indicated as medicines which are not subject to veterinary control which are used for certain pet species in accordance with the Small Animal Exemption Scheme (SAES) as described under paragraph E of the Schedule.

(2) These regulations apply to veterinary medicinal products for use in the treatment of livestock and include veterinary medicinal products imported from countries other than the United Kingdom.

(3) Veterinary medicinal products imported from countries other than the United Kingdom are to be treated, in relation to the equivalent active ingredients, to have the same categorisation as veterinary medicinal products from the United Kingdom regardless of the categorisation the products are given in the country of providence.

PART 2
GENERAL PROHIBITIONS

4 General prohibition on sale and import of veterinary medicinal products

(1) Subject to the provisions of these regulations, a person commits an offence who, without an import permit or authorisation from the competent authority-

(a) imports into the Falkland Islands any veterinary medicinal product; or

(b) sells or places on the market for sale any veterinary medicinal product.

(2) A qualified veterinarian or a registered pharmacist may sell or import any veterinary medicinal products without authorisation or an import permit from the competent authority subject to the requirements of these regulations.

(3) Subject to Part D of the Schedule any person may sell, place on the market for sale or import veterinary medicinal products referred to under regulation 3(1) without authorisation or an import permit from the competent authority.

(4) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 6 months or to a fine not exceeding level 6 on the standard scale, or to both.

5 Administration of controlled drugs to livestock

Qualified veterinary surgeons, pharmacists and suitably qualified persons must adhere to the Veterinary Medicines Directorate guidelines in relation to the prescribing, storage and destruction of controlled drugs.

6 Prohibition on sale and import of feed additives for livestock

(1) Subject to subregulation (2), a person who imports into the Falkland Islands, or places on the market for sale or sells any medicated feedstuffs without an import permit or authorisation from the competent authority commits an offence.

(2) A recognised veterinary practice, pharmacist or a suitably qualified person may sell or import feed additives without an authorisation or an import permit from the competent authority.

(3) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 6 months or to a fine not exceeding level 6 on the standard scale, or to both.

7 Prescription only medicines (POM-V)

(1) Veterinary medicinal products which are referred to as "prescription only medicines (POM-V)" must be provided or dispensed on prescription by a qualified veterinarian.

(2) It is an offence for a person who is not a qualified veterinarian to provide or dispense veterinary medicinal products which are referred to as "prescription only medicines (POM-V)".

(3) It is an offence for a person to administer veterinary medicinal products which are referred to as "prescription only medicines (POM-V)" to livestock where the medicine was not provided or dispensed by a qualified veterinarian.

(4) A qualified veterinarian must make a prescription referred to under this regulation orally or in writing following a clinical assessment of the animal in the qualified veterinarian's care and subject to the additional requirements under Part A of the Schedule to these regulations.

(5) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 12 months or to a fine not exceeding level 8 on the standard scale, or to both.

8 Prescription only medicines (POM-VPS)

(1) Veterinary medicinal products which are referred to as "prescription only medicines (POM-VPS)" must be provided or dispensed on prescription by a qualified veterinarian, a registered pharmacist or a suitably qualified person.

(2) It is an offence for a person who is not a qualified veterinarian, a registered pharmacist or a suitably qualified person to provide or dispense veterinary medicinal products which are referred to as "prescription only medicines (POM-VPS)".

(3) It is an offence for a person to administer veterinary medicinal products which are referred to as "prescription only medicines (POM-VPS)" to livestock where the medicine was not provided or dispensed by a qualified veterinarian, a registered pharmacist or a suitably qualified person.

(4) A prescription referred to under this regulation may be given orally or in writing.

(5) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 6 months or to a fine not exceeding level 8 on the standard scale, or to both.

9 Non-food animal medicine (NFA-VPS)

(1) Veterinary medicinal products which are referred to as "non-food animal medicines (NFA-VPS)" must be provided or dispensed on prescription by a qualified veterinarian, a registered pharmacist or a suitably qualified person.

(2) It is an offence for a person who is not a qualified veterinarian, a registered pharmacist or a suitably qualified person to provide or dispense veterinary medicinal products which are referred to as "non-food animal medicines (NFA-VPS)".

(3) It is an offence for a person to administer veterinary medicinal products which are referred to as "non-food animal medicines (NFA-VPS)" to livestock where the medicine was not provided or dispensed by a qualified veterinarian, a registered pharmacist or a suitably qualified person.

(4) A person convicted of an offence under this regulation is liable to a term of imprisonment not exceeding 6 months or to a fine not exceeding level 6 on the standard scale, or to both.

PART 3
APPROVALS, RECOGNITIONS AND LICENCES

10 Suitably qualified persons - approval and recognition

(1) The competent authority must train, approve and recognise certain persons as suitably qualified persons for purposes of dispensing and providing certain veterinary medicinal products.

(2) The competent authority must keep a list of suitably qualified persons.

11 Suitably qualified persons - responsibilities

A suitably qualified person must, before dispensing or providing any veterinary medicines referred to under regulations 8 and 9-

(a) be satisfied that the person requiring the medicine is competent to administer it safely;

(b) give the person information about the medicine including information on warnings and contraindications as detailed in the product leaflet or label; and

(c) give the person advice on the administration of the medicine.

12 Recognised veterinary practice

(1) Any independent or private veterinary practice from which veterinary medicinal products are sold or placed on the market for sale must be recognised by the competent authority.

(2) In order to be recognised by the competent authority the owner of a veterinary practice must submit to the competent authority trading licences, qualification certificates and any other information as may be required by the competent authority.

(3) The competent authority must keep a list of all recognised veterinary practices.

13 Authorisation to sell or place on the market for sale

(1) Any person who wishes to sell or place on the market for sale any veterinary medicinal products or medicated feedingstuff referred to under regulation 6 must apply for an authorisation from the competent authority.

(2) The competent authority may require any information as may be necessary from an applicant including any information about training, approval or recognition of the applicant as a suitably qualified person or as a recognised veterinary practice.

(3) An application for an authorisation under subregulation (1) must be made in writing to the Senior Veterinary Officer.

(4) Where the applicant meets the requirements of this regulation the competent authority may issue an authorisation

(a) subject to any conditions as may be necessary;

(b) for such a period as it may specify; and

(c) in any form as it may specify.

14 Import permit

(1) Any person who wishes to import into the Falkland Islands any veterinary medicinal products or any medicated feedingstuff must apply for an import permit from the competent authority.

(2) The competent authority may require any information as may be necessary from an applicant including information about-

(a) any training, approval or recognition of the applicant as a suitably qualified person or as a recognised veterinary practice;

(b) the quantities and names of the veterinary medicinal products to be imported; and

(c) the purpose of importing the veterinary medicinal products.

(3) An application for an import permit under subregulation (1) must be made in writing to the Senior Veterinary Officer.

(4) Where the applicant meets the requirement of this regulation the competent authority may issue an import permit-

(a) subject to any conditions as may be necessary;

(b) for such a period as it may specify; and

(c) in any form as it may specify.

15 Record keeping

(1) There must be kept on a farm a register on which the following is recorded-

(a) information relating to any veterinary medicinal products or medicated feedingstuffs administered or given to livestock;

(b) the date when the products or medicated feedingstuffs were acquired and the establishment from where they were acquired;

(c) the date when the products or medicated feedstuffs were administered or given to the livestock;

(d) the withdrawal periods to be observed for those products (including information indicating when those periods elapsed);

(e) the identification of the livestock receiving the product; and

(f) any other relevant information that the competent authority may require.

(2) A suitably qualified person, recognised veterinary practice or any other person who imports, sells or places on the market any veterinary medicinal products must keep records of the following-

(a) all veterinary medicinal products imported or sold, including invoices;

(b) in the case of a suitably qualified person, any information and advice given in accordance with regulation 11;

(c) any training undertaken in relation to the use of veterinary medicinal products; and

(d) any other relevant information that the competent authority may require.

(3) A qualified veterinarian and a registered pharmacist must keep a record of all prescriptions issued in relation to veterinary medicinal products that require prescriptions as well as a record of all products provided or dispensed.

(4) A copy of the records to be kept under this regulation must be made available to the competent authority when requested.

16 Competent authority to give guidance - codes of practice

(1) The competent authority must publish guidance in relation to the prescribing, storage and destruction of controlled drugs in terms of regulation 5.

(2) The competent authority may prepare and issue codes of practice regarding the prescribing of veterinary medicinal products other than controlled drugs.

(3) A guidance or code of practice must be-

(a) published in the *Gazette;* and

(b) kept under review.

SCHEDULE
CATEGORIES OF MEDICINES

Part A
POM-V medicines

(regulation 7)

1. A veterinary medicinal product that has been classified as a POM-V may only be supplied to the client where it has been prescribed by a qualified veterinarian who has carried out a clinical assessment of an animal, or group of animals, under the qualified veterinary's care.

2. Qualified veterinarians are expected to use their professional judgement in deciding how 'clinical assessment' should be interpreted in their particular circumstances and when an animal is 'under their care'.

(The Royal College of Veterinary Surgeons (RCVS) has interpreted "clinical assessment" as meaning an assessment of relevant clinical information, which may include an examination of the animal, and "under their care" as meaning-

(a) the qualified veterinary must have been given the responsibility for the health of the animal or herd by the owner or the owner's agent;

(b) that responsibility must be real and not nominal;

(c) the animal or herd must have been seen immediately before prescription or recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe; and

(d) the veterinary surgeon must maintain clinical records of that herd/flock/individual.

What amounts to 'recent enough' must be a matter for the professional judgement of the qualified veterinarian in each individual case.)

3. The client may request a written prescription from the qualified veterinarian if they wish to obtain the product from a supplier other than the prescribing qualified veterinarian. In all cases, the prescribing qualified veterinarian must accept clinical responsibility for the treatment.

4. Any registered qualified veterinarian or registered pharmacist may supply POM-V products or products to be used under the Veterinary Medicines Directorate Prescribing Cascade in accordance with a written prescription from a qualified veterinarian.

5. The supplying qualified veterinarian or pharmacist should use their specialist knowledge to check that the prescription accords with their own understanding of the product. If they have concerns about the prescription they should raise them with the prescribing qualified veterinarian before dispensing the medicine. It is open to any supplier to refuse to supply against a prescription.

6. A product will generally be included in the POM-V category when --

(a) it requires a strict limitation on its use for specific safety reasons;

(b) it requires the specialised knowledge of a veterinary surgeon for its use or application;

(c) it has a narrow safety margin requiring above average care in its use;

(d) Government policy demands professional control of it at a high level. For example, products containing controlled drugs (CDs) are classified as POM-V and will be clearly identified on their labels with "CD" and the relevant class to which they fall under in the Schedule of the Misuse of Drugs Ordinance 1987.

7. Products containing new active substances will usually be categorised as POM-V, although in very rare cases the nature of the substance, indications, supporting data and other data may enable a product to be categorised as POM-VPS. A product for a food-producing species will usually be classified as either POM-V or POM-VPS.

Part B
POM-VPS medicines

(regulation 8)

1. A veterinary medicine classified as POM-VPS may be prescribed by a qualified veterinarian, a registered pharmacist or an appropriately qualified SQP (collectively known as Registered Qualified Persons - RQPs)).

2. A clinical assessment of the animal(s) is not required when prescribing this category of veterinary medicine and the animal does not have to be seen by the prescriber. However sufficient information about the animal and the way it is kept must be known to the prescriber in order to prescribe and supply appropriately.

3. The customer may request a written prescription from the prescribing RQP if they wish to obtain the product from a supplier other than the prescribing RQP.

4. An RQP may supply POM-VPS medicines in accordance with a written prescription from another RQP.

5. Registered pharmacists and SQPs may supply a POM-VPS medicine for use under the cascade if prescribed by a veterinary surgeon and, in the case of SQPs, if they hold the relevant qualification to supply that medicine.

6. A veterinary medicine will generally be included in the POM-VPS category when-

(a) it is used to reduce or prevent the effects of endemic disease in herds, flocks or in individual animals (such as treatment for worms and other parasites);

(b) its use implies risks for the user, the animal, consumer safety or the environment but users can be made aware of suitable countermeasures through simple, oral or written, advice;

(c) a professional user can be given adequate training in its regular use.

Part C
NFA-VPS medicines

(regulation 9)

1. A veterinary medicine classified as NFA-VPS may be supplied by any RQP provided the requirements for supply under paragraph 2 are met.

2. The requirements referred to under paragraph 1 are-

(a) that the supplier is satisfied that the person who will use the product is competent to do so safely; and

(b) that the person intends to use the product for the purpose for which it is authorised.

3. These medicines do not require a prescription.

4. A medicine will generally be included in the NFA-VPS category when-

(a) it is indicated for use only in non-food animals;

(b) it is used routinely to prevent or limit the effects of endemic disease in non-food animals;

(c) its use implies risks for the user, the animal, for consumer safety or for the environment but users can be made aware of suitable countermeasures through simple, oral or written advice;

(d) the animal keeper can be given sufficient practical advice to permit effective or safe usage.