Classification of veterinary medicines in regard to sale, purchase and use

ACVM Operational Interpretation No 183

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1 Introduction

This document describes the classification of veterinary medicines in regard to:

- sale, purchase and use
- appropriate authorisation of purchase and use.

This interpretation does not cover the circumstance in which a veterinary medicine is exempt from registration but has a prescribed condition that limits who can sell or use it. For example, veterinarians are allowed to use or supply human medicines to be used as veterinary medicines. Such products are not registered under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) and do not attract the restricted category of registered veterinary medicines described in this document. Their use is regulated via the ACVM Regulations 2001 rather than via conditions of registration.

For the decision criteria and rules to be applied when placing individual veterinary medicine trade name products (TNP) into the restricted category and choosing the most appropriate conditions of registration, see *Operational Interpretation 182: Classification of veterinary medicines*.

1.1 Statutory basis for conditions of registration that support classification of registered veterinary medicines

Section 23 of the ACVM Act provides the power to impose conditions on the registration of TNPs for the purpose of managing:

- risks to trade
- risks to agricultural security
- risks to animal welfare
- risks to public health.

At the same time, conditions can be imposed to ensure compliance with relevant residue standards or to ensure adequate consumer information is provided with the product.

Access can be controlled by:

- a condition on the use of the trade name product
- a condition on labelling, advertising, or other information requirements for the trade name product
- a condition specifying standards of competence for manufacturers, sellers, purchasers or users of the trade name product
- a condition requiring that persons who import, manufacture, sell or use a trade name product must do so under the authority of and in compliance with a recognised person or any class or description of recognised persons
- a condition requiring that persons who authorise the use of a trade name product must do so in compliance with any requirement specified by the Director-General
- a condition requiring information and records to be kept and reported, or made available on request, to the Director-General or an ACVM Officer
- such other conditions as the Director-General considers necessary to achieve the purposes of the ACVM Act.

These conditions allow NZFSA to limit sale, purchase and use of certain products and to require appropriate authorisation, if necessary, for purchase and use. Section 23 also allows NZFSA to require records of authorisations and, if necessary, sales to be kept to monitor compliance to the conditions of registration.

1.2 Definitions and abbreviations

Administer: To physically apply or give a veterinary medicine to an animal.

Authorisation: An instruction, in an appropriate form, from the appropriate person/organisation authorising:

- the use of a RVM by the specified person in accordance with the authorisation
- the holding of a relevant RVM in accordance with the authorisation
- the sale by a person with the authority to sell RVMs to a person specified in the authorisation.

Holding veterinary medicines: To have a veterinary medicine in your possession in anticipation of a need. It includes maintaining stocks for wholesale/retail or keeping in a dispensary in anticipation of a use.

Approved operating plan: A plan approved under section 28 of the ACVM Act. The plan describes how a person (or an organisation) intends to meet a particular statutory obligation such as the conditions of registration of a restricted veterinary medicine (RVM).

Over-the-counter (OTC) registered veterinary medicine: An unrestricted veterinary medicine that, at the discretion of the registrant, is available for sale from any party selling veterinary medicines.

Recognised person: A person (or organisation) for the time being having recognition from NZFSA under section 62 of the ACVM Act to carry out specific functions for the purpose of that Act. In the context of this interpretation, recognising a person under section 62 is used as the mechanism to identify persons who can issue a valid veterinary authorisation to purchase and/or use a RVM.

Recognised authoriser: A person recognised under section 62 to authorise the sale (to a specified person), holding and/or using a RVM.

Restricted veterinary medicine (RVM): A restricted veterinary medicine is always a registered trade name product with conditions of registration that restrict sale, purchase and use, and require an authorisation to purchase and use it.

Trade name product (TNP): An agricultural compound identified and packaged under a trade name for a specified use or uses. All registered veterinary medicines are trade name products.

Veterinarian: A person who holds a current practising certificate issued by the Veterinary Council of New Zealand (VCNZ).

Veterinary authorisation: An instruction, in an appropriate documented form, from a veterinarian authorising:

- the purchase of an RVM by a person specified in the veterinary authorisation
- the holding by a person specified in the veterinary authorisation of an RVM in anticipation of a use under the instructions of the authorising veterinarian
- the use of an RVM by a person specified in the veterinary authorisation in accordance with the instructions of the authorising veterinarian.

Unrestricted veterinary medicine: A veterinary medicine product that has no access restrictions on the sale/supply or use, allowing any person to hold it in stock, sell it or use it in a manner that is consistent with any other conditions of registration on that veterinary medicine.

2 Categories of registered veterinary medicines

There are two categories of registered veterinary medicines:

- unrestricted veterinary medicines – there is no official abbreviation for unrestricted veterinary medicines. They are often referred to as over-the-counter (OTC) products, but the terms are not identical (see 2.1.1 below).
- restricted veterinary medicines – officially abbreviated as RVM.

Restricted or *unrestricted* refers only to the ACVM registration conditions controlling sale, purchase and use of certain veterinary medicines. In addition there are always other conditions of registration not related to sale, purchase and use that must be complied with.

ACVM classification does not in any way alter statutory controls under other legislation such as the Hazardous Substances and New Organisms Act 1996 (HSNO Act), Medicines Act 1981 or Misuse of Drugs Act 1975 (MODA).

2.1 Unrestricted veterinary medicines

There are no conditions of registration restricting sale, purchase and use other than ensuring that the product is represented to potential buyers in a manner consistent with its registration. No ACVM Act-relevant authorisation is needed to purchase and use unrestricted veterinary medicines.

There is no sub-classification of unrestricted veterinary medicines related to sale, purchase and use because there is no need for authorisation of purchase and use. Sale of unrestricted veterinary medicines may be controlled (ie, as hazardous substances), but not by NZFSA.

Unrestricted and over-the-counter (OTC) do not mean the same thing. Unrestricted is the official regulatory category and means the conditions of registration that allow veterinary medicines to be sold by any person to any person without authorisation. Over-the-counter implies the product can be purchased in any wholesale or retail outlet that trades in veterinary medicines.

NZFSA does not specifically regulate wholesalers and retailers of unrestricted veterinary medicines. A registrant may choose a particular marketing pathway that does not allow their unrestricted veterinary medicine to be sold by everyone. This would be a commercial decision that is not regulated by NZFSA.

Label content does not have to state that a veterinary medicine has been classified as unrestricted. It can be assumed by anyone that, if there is no specific statement on the label that the veterinary

medicine is restricted, then it is unrestricted and does not require authorisation for ACVM purposes for purchase or use.

2.2 Restricted veterinary medicines (RVMs)

Only specified persons who have an operating plan governing the sale of RVMs approved under section 28 of the ACVM Act have the authority to sell such products. Sales must be controlled and always require appropriate authorisation for purchase and use. The kind of authorisation required varies according to the conditions of registration for each product, but the most common is veterinary authorisation.

Restricted veterinary medicines must have a statement on the label making the restricted status of the veterinary medicine clear.

Although NZFSA regulates who can sell RVMs, it is not an ACVM regulated matter if a registrant chooses not to supply product to any one of these persons, or if a person who has the authority to sell RVMs chooses to stock only certain ones.

2.2.1 RVMs requiring veterinary authorisation

Authorisation

For most veterinary medicines a veterinary authorisation is the primary form of authorisation to purchase and use. It is also the primary form of authorisation issued to a person who does not have the authority to sell RVMs to allow that person to hold them in anticipation of use. This means that, unless otherwise qualified in the conditions of registration, the purchase and use of RVM requires a veterinary authorisation.

However, the conditions of registration that impose the requirement for an authorisation for purchase and use includes an alternative via an operating plan approved under section 28. This will include operating plans of a research, testing or training organisation (RTTO) and for an approved operating plan of an organisation other than an RTTO.

Sale

Unless otherwise specified in the conditions of registration, RVMs requiring veterinary authorisation may be sold or supplied only to:

- another person with the authority to sell RVMs
- a veterinarian
- a person who has a relevant veterinary authorisation. or

- a person with an appropriate alternative authorisation under an approved operating plan.

Inappropriate supply of an RVM requiring veterinary authorisation could result in the revocation of the approval of the operating plan and a loss of the authority to sell RVMs, preventing any further sales of any RVM. If in doubt about supplying a particular RVM, the seller should contact the Approvals and ACVM Group of NZFSA. Selling such a product by any person who does not have the authority to do so is likely to be a breach of the conditions of registration and an offence under section 55 of the ACVM Act.

Use

The commonly applied use condition on RVMs requiring veterinary authorisation are, in effect, the following:

- may be used by a veterinarian according to his/her professional judgment for any approved use
- may be used by a veterinarian according to his/her professional judgment for an unapproved use, unless that use is prohibited in the conditions of registration
- may be used by a non-veterinarian only:
  - in accordance with a veterinary authorisation in circumstances that relate to that authorisation or
  - in accordance with an authorisation issued under an approved operating plan.

2.2.2 RVMs requiring administration only by a veterinarian

There may be veterinary medicines that, for risk management reasons, must only be administered by a veterinarian. The conditions of registration for such a product will include one that precludes its use by non-veterinarians, with consequential limitations on who the product can be sold to.

Prohibition on veterinary authorisation

Only veterinarians may administer an RVM with a condition specifying veterinary administration. Veterinary authorisation of such products will be prohibited.

Sale of RVMs requiring veterinary administration

RVMs requiring veterinary administration may be held in stock only by a veterinarian or a person with the authority to sell RVMs. The approved operating plan of the seller must specify how the product will be held in a secure manner to ensure that no other party has access to them.

Veterinary medicines requiring veterinary administration may be sold only by a person specified in and in accordance with the seller's approved operating plan.

They may be sold only to:

- another person with the authority to sell RVMs or
- a veterinarian.

Inappropriate sale or supply of RVMs requiring veterinary administration could result in the revocation of the approval of the operating plan and a loss of the authority to sell RVMs, preventing any further sales of any RVM.

Use of RVMs requiring veterinary administration

There would be no circumstance in which this kind of product should be allowed to be in the possession of any person other than a person with the authority to sell it or a veterinarian. These products can not be administered by veterinary technicians, nurses or veterinary students, even in the presence of a veterinarian.

2.2.3 RVMs that can be authorised only via an approved operating plan

Where the conditions of registration specify that authorisation to purchase and use a particular product must be via an approved operating plan for all the approved uses of that product, veterinary authorisation will not be an acceptable alternative and will be prohibited. In addition, any use other than an approved use will be prohibited.

Purchase and use of veterinary medicines with the exclusive approved operating plan condition of registration are subject to the rules of the approved operating plan and appropriate authorisation from the organisation responsible for administering the approved operating plan.

Sale

Restricted veterinary medicines restricted for use only under an approved operating plan may be sold only by a person with the authority to do so.

They may be sold only to:

- another person with the authority to sell it or
- a person authorised by the organisation responsible for administering the approved operating plan for that veterinary medicine.

Inappropriate sale or supply of veterinary medicines that must be authorised via an approved operating plan could result in the revocation of the approval of the seller's operating plan and a loss of the authority to sell RVMs, preventing any further sales of any RVM. This will not jeopardise the status

of the operating plan that governs the use of the product, unless sale or supply and use are governed by the same approved operating plan.

Use of veterinary medicines requiring authorisation only via an approved operating plan

RVMs requiring authorisation only via an approved operating plan must be used only in accordance with that operating plan. Off-label use of such veterinary medicines by any other person will be prohibited.