Classification of veterinary medicines

ACVM Operational Interpretation 182

October 2009

IMPORTANT DISCLAIMER

Every effort has been made to ensure the information in this document is accurate.

NZFSA does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

WEBSITE

This document may be altered at any time. It was current as at the date in the footer of each page. We recommend that anyone intending to use this document should contact the Approvals and ACVM Group of NZFSA or check our website (http://www.nzfsa.govt.nz/acvm/) to confirm that it is the current version.

Classification of veterinary medicines

1 Purpose

The purpose of this operational interpretation is to state the rules to be used when classifying veterinary medicines in regard to:

- who can authorise them for purchase and use
- who can sell them
- who can use them.

This operational interpretation should be read in conjunction with *Operational Interpretation 183: Classification of veterinary medicines in regard to sale, purchase and use.*

2 Classification is to manage risks

2.1 Relevant risk areas to consider

The primary reason for imposing restrictions on access for certain veterinary medicines is to manage the following risks relevant to the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) (section 4):

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

The risk thresholds that prompt restricted access conditions on product registrations all relate to the risk areas listed above. Restrictions on sale, purchase and use are based on potential impacts in these risk areas.

In addition to the following guiding principles, the actual classification may be influenced by extenuating circumstances such as:

- product characteristics that minimise risks
- existing controls that are likely to achieve the necessary risk reduction without imposing additional restriction on access
- common practices that result in a sufficient level of expertise and competency in the likely user groups.

The decision on classification is done on the best information available at the time. New information may prompt reconsideration of any decision and consequential change in conditions of registration.

In all cases, a product must be given the classification of 'restricted veterinary medicine' (RVM) if conditions are imposed to limit sale, purchase and use.

2.2 Unrestricted access unless restriction can be justified

A veterinary medicine must be categorised as unrestricted unless there is sound justification to restrict access.

The following criteria support classification of a product as unrestricted:

- in normal circumstances, the likely user of the product can obtain sufficient information from the material provided with the product (i.e., label content) to use the product effectively, appropriately and safely, and
- there are no relevant international or domestic obligations or requirements to impose restricted access, and
- unrestricted access will not significantly jeopardise public health, trade in primary produce, agricultural security, or animal welfare outcomes.

2.3 Restricted access

2.3.1 Active ingredients which are prescription medicines for humans under the Medicines Act or controlled substances under the Misuse of Drugs Act

As a starting principle, all veterinary medicines with active ingredients that would attract classification as prescription medicines under the Medicines Act or controlled substances under the Misuse of Drugs Act should be classified as restricted veterinary medicines and, in most cases, a condition requiring veterinary authorisation should be imposed.

NZFSA recognises that it could be a temptation for people to use readily available veterinary medicines that would be equivalent to prescription human medicines. This could prompt an illegal trade in veterinary medicines for use on humans. This is even more likely for the few veterinary medicines that contain substances that are regulated under the Misuse of Drugs Act. There is sufficient evidence of this diversion happening and the temptation is sufficiently real to impose restrictions on sale, purchase and use.

However, if the Ministry of Health has no concerns about classifying a particular veterinary medicine that contains ingredients that are prescription medicines, and there is no other reason to restrict its sale or use, then it should be classified as unrestricted.

Veterinary authorisation is the primary type of authorisation for products containing ingredients that are prescription medicines/controlled substances. There are also alternative authorisations that could achieve equivalent risk reduction for certain uses, including authorisation under the approved operating plans of research, testing and training organisations (RTTOs).

It is also possible that a prescription medicine active ingredient may be needed under an approved operating plan that provides controlled authorisation other than a veterinary authorisation. In such cases the relevant product must be classified as RVM but the alternative authorisation must be linked to the conditions of registration. If acceptable use is limited to only what has been approved in the operating plans then veterinary authorisation as an alternative must be prohibited.

If there is uncertainty about the most appropriate classification and conditions of registration relative to the control imposed on similar human medicines and controlled substances, NZFSA will ask the Ministry of Health for guidance.

2.3.2 Exposure brings serious risks to people

Restricted veterinary medicine classification is not imposed under the ACVM Act to minimise the risk of harm to people unless:

- the risk is not relevant to the hazard characteristics for which HSNO controls have been imposed, and
- there is technically sound evidence to support the view that restriction on access will actually reduce the level of risk down to an acceptable level, or
- there is a direction from the Minster to do so (ref: section 38, ACVM Act).

Controls are imposed on veterinary medicines under the Hazardous Substances and New Organisms Act 1996 (HSNO Act) when they have hazard characteristics that exceed the HSNO critical thresholds. Restrictions under the ACVM Act should not be imposed when they would be redundant to HSNO controls. However, sometimes there are risks (such as the transfer of disease or pharmacological or physiological effects resulting from exposure) to humans that are not related to hazard characteristics managed under the HSNO Act and ACVM conditions are needed.

NZFSA will consider the impact of exposure to veterinary medicines on the health and safety of people exposed when the risks are associated with matters not relevant to the HSNO Act. In these cases NZFSA will apply its risk management framework when considering whether or not restrictions on access should be imposed. For example there are animal vaccines that if inadvertently injected, can result in human infections. NZFSA will assess the level of risk and evaluate the likely impact that restricting access would have on reducing these risks. It will impose restrictions on purchase and use if considered necessary.

2.3.3 Maintaining market access and meeting specific market access requirements

Restriction on access for particular veterinary medicines should be imposed when there is evidence that failure to do so will jeopardise access of animal (or plant) products into one of New Zealand's major market areas. The actual classification depends on the nature of the market access requirement.

While NZFSA can try to influence market access requirements to encourage authorities to base their requirements on technically sound risk assessment information, the specific market requirements are beyond NZFSA's control. Therefore, if there is an actual requirement that must and can be met by classifying particular products as restricted, then NZFSA will do so.

2.3.4 Expert judgement, oversight or advice required

The restricted classification will be imposed on any veterinary medicine for which diagnosis, choice of product, determination of treatment regime, overview of effects and intervention to address adverse effects requires veterinary involvement to ensure the product is used appropriately, safely and effectively while avoiding consequential negative effects. If such a product has a particular use for which veterinary involvement is not needed, alternative authorisation may be allowed under an approved operating plan for that use only. Otherwise, veterinary authorisation would be required.

Authorisation under an approved operating plan of an RTTO will be an acceptable option for all restricted veterinary medicines to meet particular research, testing or training protocols. This does not include use of RVMs for purposes that require veterinary judgement, oversight or advice (e.g., managing the health of laboratory animal colonies).

2.3.5 Insufficient label content to use a product appropriately and safely

Restricted veterinary medicine classification should be imposed on any veterinary medicine if the instructions for use are too complicated to be understood and followed without expert guidance from a veterinarian. For products that allow authorisation via an approved operating plan, the plan must state how the complexity of use instructions will be addressed before the plan is approved.

2.3.6 Insufficient training to administer a product safely

Restricted veterinary medicine classification should be imposed on any veterinary medicine if the likely users would not normally have the training, experience and practice to administer the product safely. For products that allow authorisation via an approved operating plan, the plan must state how the training to administer the product will be addressed before the plan is approved.

2.3.7 Protecting biosecurity, agricultural security, public health or other specialist outcomes

NZFSA will impose restricted veterinary medicine classification on any product when its biosecurity, agricultural security or public health purposes are more likely to be achieved if the sale and use of the product is controlled via proper authorisation. The uses are most likely to be governed by a particular programme with a specified distribution and administration infrastructure. Very occasionally there may be particular products used in closed systems that may also be managed only via an approved operating plan. In such cases the authorisation must be linked to the operating plan and, if alternative uses are unacceptable, veterinary authorisation should be prohibited.

2.3.8 Unanticipated justifications for imposing restrictions on sale, purchase and use

Sections 2.3.1-2.3.7 address the most likely reasons why NZFSA would impose restrictions on sale, purchase and use of veterinary medicines. There may be other reasons in particular cases why NZFSA would consider imposing restrictions. However, whatever the reason, the decisions must be sound from a technical/risk management perspective and control must be no more onerous or invasive than is necessary to reduce the ACVM-related risk down to an acceptable level bearing in mind the requirements of the Act for cost effectiveness (least cost to the public) of any intervention.