



AgVetLink

ISSN 1174 - 3735 ISSUE NO 2V MARCH 2004

SPECIAL ISSUE FOR VETERINARIANS

Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997

Feedback from our first special issue of AgVetLink for veterinarians indicated that you found it an effective, simple means of getting information about the ACVM Act. For this reason, we have decided to repeat the exercise. This time we are looking at aspects of the legislation that crop up regularly in our discussions with veterinarians.

In this issue, we introduce a new column to answer your queries about the ACVM Act. 'Unravelling the ACVM Matrix' has been set up so that you can ask questions anonymously if you prefer.

This month we will hold a series of ten workshops from Whangarei to Invercargill to help clarify the ACVM Act and how it affects you. Topics that will be covered include:

- *withholding periods*
- *discretionary use of registered veterinary medicines*

Contents

- 1 ACVM Act
- 2 Unravelling the ACVM Matrix
- 4 Veterinary discretionary use and compounding activities
- 4 Prescription of Tylan and Zinc Bacitracin
- 5 Default withholding periods
- 6 Withholding periods: FACT or FICTION?
- 8 All veterinary medicine label claims have been approved by the regulator, haven't they?
- 9 Individual veterinary requirements more stringent than ACVM Group requirements
- 10 Restricted veterinary medicines

insert Workshop registration form

- *use of human medicines*
- *compounding*
- *importing products.*

Check the registration form insert for details on topics, dates and venues. Don't miss this opportunity.

*Debbie Morris
Director, ACVM Group*

AgVetLink is provided free of charge. To be added to the mailing list, send your contact details to Gill Wilson (address below). AgVetLink is also available on the ACVM website (www.nzfsa.govt.nz/acvm).

AgVetLink is produced at least six times annually by the New Zealand Food Safety Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of agricultural compounds and veterinary medicines. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

General enquiries: Gill Wilson

ACVM Group, New Zealand Food Safety Authority, PO Box 2835, Wellington, New Zealand

Phone: 04 463 2539, fax: 04 463 2566, email: gill.wilson@nzfsa.govt.nz, website: www.nzfsa.govt.nz/acvm

Disclaimer: This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.

Unravelling the ACVM Matrix

This section will become a permanent feature of the AgVetLink special editions for veterinarians. It will be presented in a 'Question and Answer' format, and should be considered a forum through which veterinarians can ask any general questions relating to the ACVM Act and veterinary medicines anonymously. Chances are, if you don't know, there will be others in the same situation.

All questions should be sent to:

Jennie Moran

ACVM Group, NZFSA

PO Box 2835, Wellington

Email: jennie.moran@nzfsa.govt.nz

Because this is the first appearance of the ACVM Matrix some basic principles of the ACVM Act will be explored and, hopefully, unravelled.

Q What happened to the Animal Remedies Act?

Answer

The Animal Remedies (AR) Act was passed in 1967. There have been many changes since then with respect to how veterinary medicines are manufactured, sold and used. The Agricultural Compounds and Veterinary Medicines (ACVM) Act was passed in 1997 and requires a risk management rather than prescriptive approach to the control of veterinary medicine use. In addition, it manages the manufacture, sale and use of plant compounds.

The ACVM Act came into force in July 2001, at which time the Animal Remedies Act was repealed. However, because all animal remedies could not be immediately updated to fulfil the requirements of the new Act, the ACVM Act included transitional provisions that allowed 'status quo' for licensed animal remedies for a maximum period of three years from the date of the ACVM Act's commencement. This period will expire in July this year.

The ACVM Group is busy updating products to meet the requirements of the ACVM Act. In some cases this has resulted in changes to label content and conditions. **Veterinarians are reminded that this is an intense period of change and that no veterinary products should be prescribed or used unless the label has been read thoroughly.**

Q What are the risks of interest to veterinarians that are managed by the ACVM Act?

Answer

The risks are described in section 4 of the ACVM Act. Of direct interest to veterinarians are the requirements to manage risks to trade in primary produce and prevent breaches to domestic food residue standards (residues) and risks to animal welfare (product safety and efficacy).

In addition, the Act requires the provision of sufficient consumer information about veterinary medicines. The consumer in this case is the user of the veterinary medicine, not the consumer of animal or plant produce. Sufficient information is considered to be enough information to use a product correctly and safely. This means that the ACVM Group will be approving label content related not only to the risk areas mentioned above but also content related to security, safe handling and disposal to protect the health of people and the safety of the environment. Veterinarians have a role to play here.

Q What is a veterinary medicine?

Answer

Products that were identified as animal remedies under the AR Act are now called veterinary medicines under the ACVM Act. Veterinary medicines are themselves a subset of agricultural

compounds. The definition of 'agricultural compound' is included in the Act but, in essence, if a substance or mixture of substances is used in the direct management of an animal, that substance is considered a veterinary medicine. Unlike the AR Act, which excluded 'food for animals', any products fed to animals for the purpose of providing nutrition (oral nutritional compounds) are considered veterinary medicines.

Products that require a veterinary prescription are called prescription animal remedy veterinary medicines or PARs. Products that can be purchased without a prescription are called over-the-counter veterinary medicines or OTCs.

The terms 'PAR' and 'OTC' relate only to access. Other terms are used to describe veterinary medicines according to their intended use. Products that make claims to prevent or treat abnormal or disease conditions are *therapeutic veterinary medicines*. If claims are made to modify physiological functions, the products are called *pharmacological veterinary medicines*. Products that are used to provide nutrition to animals are called *oral nutritional compound veterinary medicines* and include animal feeds and pet foods, feed additives and nutritional supplements.

These product groups are general and are not mutually exclusive. For example, a product may be basically an oral nutritional compound but it may have one or more therapeutic substances added and therapeutic claims are made about the product. That product would be both an oral nutritional compound veterinary medicine and a therapeutic veterinary medicine.

There are substances (e.g. glucosamine and chondroitin) that may be found naturally in some animal feeds that are considered to have some therapeutic effect. If no claims are made about these substances and the concentrations do

not significantly exceed what could be expected in a feed the products would still be considered oral nutritional compounds. However, if therapeutic claims are made in regard to them, then the products become therapeutic veterinary medicines.

Q Do all veterinary medicines need to be registered before being manufactured, sold or used in New Zealand?

Answer

No. Veterinary medicines must all be approved before being manufactured, sold or used in New Zealand. However, the ACVM Regulations 2001 allow certain product groups or use patterns of veterinary medicines to be exempted from the requirement for registration, provided certain conditions are met. These groups include oral nutritional compounds, herbal preparations and some topical preparations. Of course, medicines used in a discretionary manner by veterinarians do not require registration for that use and this specific exemption is also included in the Regulations. The ACVM Act and Regulations are accessible from the ACVM website (www.nzfsa.govt.nz/acvm).

Q How does the ACVM Act control the manufacture, sale and use of veterinary medicines?

Answer

The ACVM Act provides a range of risk management tools including imposing conditions on the registration of products (or on the exemption from registration) that relate to anything from manufacture and labelling to how the product may be used. The label content also forms a condition of use. Codes of practice relating to any aspect of veterinary medicine manufacture, sale or use may be approved.

Veterinarians are reminded that for all products that have been updated to a registration under the ACVM Act, both the label content* and conditions of use are on the ACVM website. All veterinarians are encouraged to familiarise themselves with the conditions that are placed on veterinary medicine registrations, particularly those relating to use.

* Some registrants request that label content publication be deferred for a specified period to avoid market disadvantage.

Q If the Animal Remedies Act is gone, why are there still prescription animal remedies?

Answer

For continuity purposes the term ‘animal remedy’ is still being used by the ACVM Group to indicate the products that require veterinary prescription. As stated above, the complete term to describe the product group is **prescription animal remedy veterinary medicine** but the abbreviation PAR retains a similar meaning under the new Act and it is a term already familiar to all veterinarians.

Q Are there still classes of PAR products and are the definitions of the classes the same?

Answer

Unlike the Animal Remedies Act, the ACVM Act does not specifically mention prescription animal remedies or the classes (except in the transitional provisions which are no longer relevant). Requiring a prescription is just one of the possible conditions that can be applied under section 23 to the registration of a product.

For the immediate future and in a very general way, the ACVM Group will

continue to refer to the three classes of PARs but the class will relate only to the level of veterinary supervision required for a product. Under the ACVM Act the conditions are much more explicit and product specific. The full set of conditions can vary considerably from one product to another. It is no longer appropriate to base a classification solely on the level of veterinary supervision required. The Class I conditions have already changed drastically with the introduction of varying levels of responsibility on veterinarians to manage the potential antibiotic resistance problem. This varying level of obligations on Class I is becoming more relevant for other kinds of products as well.

The simple Class II condition that required the veterinarian to be physically present to achieve the necessary level of control does not provide sufficient flexibility to allow for adequate veterinary control via operational procedures and quality systems. The ACVM Group will review all the products that are presently in Class II to see what flexibility would be acceptable from a risk management perspective.

The Class III condition that required just the veterinarian to administer the product will remain the same. However, the ACVM Group will review the registrations of the few products in Class III to see if that restriction is actually necessary in every case.

Consequently, veterinarians should be familiar with the actual conditions of registration on the products they use. They should not rely on out of date knowledge of the conditions imposed on Class I and II products. Because the conditions are becoming more product specific, even Class III products may have additional conditions that place other obligations on veterinarians. So take the time to find out exactly what conditions are on the products you use or prescribe.

Veterinary discretionary use and compounding activities

As some of you will be aware, the ACVM Group has recently conducted a 'slice of life' audit focusing on the issues of veterinary discretionary use and veterinary compounding activities. The Group has conducted several audits of this nature over the past months in an attempt to assess the 'state of play'.

While gross breaches in current legislation are likely to lead to enforcement action, the primary purpose of the audits is to establish where the Group needs to focus its educational arm. Preliminary indications are that, although veterinarians do not seem to have a high level of understanding of their responsibilities in these two areas, many are still getting it 'mostly right' by applying the principles of good veterinary practice.

This document discusses the current regulatory situation with respect to

veterinary discretionary use.

When is it OK for discretionary use of veterinary medicines in veterinary practice?

One of the most important things for all veterinarians to know is that discretionary or 'off-label' use of veterinary medicines is not the automatic right of registered veterinarians. Only the ACVM Group has the authority to approve veterinary medicines to be used in any way other than those stated on the label. This approval takes the form of a condition placed on the registration of each veterinary medicine for which discretionary use is approved.

The condition reads:

The product may be used at the discretion of a registered veterinarian

- when acting in accordance with any applicable code of practice approved under section 28 of the ACVM Act; and

- on animals under the direct care of that veterinarian unless that use is specifically prohibited in the current registration.

Conditions can be found on the ACVM website (www.nzfsa.govt.nz/acvm).

The use of human medicines and compounded medicines is permitted by a Regulation exempting use by veterinarians subject to an approved code of practice.

At present the applicable code of practice for a veterinarian in general practice is the *Code of Practice for the Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians*. This code may be found in the Veterinary Council of New Zealand handbook and on their website.

Any veterinarian using human medicines, compounded medicines or veterinary medicines in a discretionary manner in the treatment of an animal must do so only with full knowledge of the requirements of the applicable code. Veterinarians should note that the minimum withholding period of 60 days (section C, A4) is out of date. Veterinarians should refer to the default WHPs set by the ACVM Group (see article on page 5).

The ACVM Group recognises that for the vast majority of veterinary medicines, there are many legitimate off-label uses and it is not our intention to prevent a well-established and usually self-regulated behaviour. However, on occasion, to manage the risks prescribed under the ACVM Act it may be necessary for a veterinary medicine to be used only according to label directions.

When is it NOT OK for discretionary use of veterinary medicines in veterinary practice?

Where discretionary use is not

Prescription of Tylan and Zinc Bacitracin

With the changes to PAR I status for these antibiotics, all growth promotion claims were removed. In conjunction with this some dose rates were changed to those supported for therapeutic use. A recent ACVM audit indicated that even though these antibiotics were being prescribed in some cases the dose rates were consistent with use for growth promotion.

Veterinarians should be aware that continued prescribing at levels below label dose rates is off-label and subject to the *Code of Practice for Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians*, which is recognised under the ACVM Act. The veterinary evaluation required would allow these drugs to be used at lower dose rates for treatment of other species or diseases but only when the dose rate and duration can be justified to achieve a therapeutic outcome.

Where prescription products have been used for growth promotion, prescribing veterinarians must re-evaluate the dose and use against the approved claims. If the use is off-label the prescribing must conform with applicable ACVM standards or approved codes of practice.

acceptable, the veterinary medicine label will (usually) have a statement to the effect of 'It is a legal requirement that this product be used only according to label directions' in addition to lacking the discretionary use condition. Where this applies, it is NOT OK for the veterinary medicine to be used off-label. Where possible the discretionary use condition will be preserved; however, specific prohibitions may appear on a label.

Veterinarians must also be aware that certain compounds are restricted and may not be used to treat food-producing animals. Currently, the list only contains substances that have been banned for use in food-producing animals by our major trading partners for reasons other than proven toxicity. (This list has been included in this issue—see page 10.)

When is it OK to compound?

Where possible, veterinarians must use veterinary medicines in preference to human medicines or compounded medicines. If a necessary treatment cannot be acquired in a registered form, veterinarians may compound (or direct a second party to compound for them) a veterinary medicine of their own design.

In general, the ACVM Group interprets 'own design' as being all of the following:

- The veterinarian has personally constructed, or knows exactly what the formulation of the product is (active and excipients) and has verified that it contains no restricted or prohibited substances.
- The veterinarian has sufficient information to expect the product will be efficacious and provide the desired therapeutic outcome.
- The veterinarian has sufficient information to know that the product will be safe to the treated animal.
- Where a food-producing animal is to be treated, the veterinarian has set a withholding period that will manage any residue risks.
- Where using a second party to compound the product, the veterinarian has provided:
 - a) full details regarding the type and quality as well as quantities of all ingredients to be used;
 - b) full details regarding the method of manufacture of the product and any quality control processes required;
 - c) full details regarding the type of packaging to be used; and
 - d) full directions regarding the label text to be included.

When is it NOT OK to compound?

Veterinarians must not compound and provide for general sale any veterinary medicine that requires registration unless they have registered that product. Compounded veterinary medicines may be used only to treat animals in the care of the compounding veterinarian.

It is common practice within certain specialised branches of veterinary medicine for veterinarians to compound veterinary medicines. The nature of the process is such that to be economically viable, larger quantities than are needed by the vet at the time must be produced. Compounding veterinarians MUST NOT advertise (which includes via newsletters) or sell the surplus product to other vets* or the general public. To do so would be in breach of the ACVM Act (i.e. marketing/selling an unregistered veterinary medicine).

* Veterinarians may request that a veterinarian engaged in compounding activities compound a veterinary medicine on their behalf. It must be noted, however, that the rules of 'own design' discussed above apply.

Default withholding periods

The following is a list of default withholding periods applied to the registration of veterinary medicines where no residue data are provided. The figures have been arrived at following consideration of all residue data provided to the Group and can be considered conservative.

These withholding periods do not apply to sustained release formulations because the withholding period must apply to the time after the release period, not after administration.

AVIANS

Meat 63 days
Eggs 10 days

RUMINANTS (including deer)

Meat 91 days
Milk 35 days

CAMELIDS

Meat 63 days

LAGOMORPHA (e.g. rabbits)

Meat 63 days

MONOGASTRICS (e.g. pigs, horses)

Meat 63 days

FISH, CRUSTACEA, MOLLUSCS

Meat 35 days

Withholding periods: FACT or FICTION?

Withholding periods define the ‘treatment to sale-of-produce period’

FACT

The withholding period (WHP) that appears on the label of veterinary medicines is the time for which a specified agricultural product must be withheld before entering the human food chain. It is defined as ‘the minimum permissible time between the last application of that veterinary medicine to an animal and the sale of the animal to slaughter, the sale of farmed fish or the sale of any milk, eggs, or honey from an animal for human consumption’.

Legally enforceable withholding periods can be set only by regulators

FACT

A WHP is the regulatory tool used by the ACVM Group to manage compliance with the residue thresholds as prescribed under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 or the Animal Products (AP) Act 1999. Although notified as part of the label content, any WHP is also considered to be a condition of registration for any veterinary medicine registered with one—it is a legally binding requirement for any user of that veterinary medicine to obey WHPs (with the exception of default WHPs, which will be discussed later).

Manufacturers have in the past and continue to recommend ‘withholding periods’ that are not based on regulatory requirements, e.g. to manage issues of product quality such as wool residues, which are outside the scope of the ACVM or AP Acts. During the update process the ACVM Group will ensure that such label information is grouped away from the regulatory (and therefore

legally binding) WHPs that currently relate only to meat, milk, eggs, farmed fish and honey.

The residue thresholds prescribed in the ACVM Act are those defined in the domestic food residue standards alone

FICTION

Section 4 of the ACVM Act, which describes risks to be managed in association with the use of agricultural compounds, does state that registered uses must not result in breaches of domestic food residue standards. The primary domestic standard is the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2002. This document contains a list of the maximum residue limits (MRLs) that can be present in agricultural produce (meat, milk, eggs, honey and crops) sold in New Zealand.

However, one of the other risks that must be managed under the ACVM Act is ‘risks to trade in primary produce’. In consequence, the approved WHP for any veterinary medicine that is registered for use in animals that produce exportable food for human consumption will take into consideration any MRLs established by our major export markets. These MRLs are expressed through Regulations issued under the AP Act. Currently, only pig and poultry products are not exported to major overseas markets.

There is only one type of approved withholding period

FICTION

It is a requirement for registration that

applicants provide residue data or equivalent information and technical argument to enable the establishment of a WHP. Such WHPs will therefore either be *assessed* (approved following analysis of residue trial data) or *allocated* (based on less data together with other information). These WHPs are the minimum treatment to harvest intervals to be followed by users of the products.

In some circumstances it is not possible for registrants to conduct residue trials to establish WHPs for all the possible food commodities. This is common for horse and sheep products where meat and milk WHPs respectively must be established by law. The horsemeat and sheep milk sectors are considered minor uses globally and the ACVM Group recognises that to require residue trials for affected products (i.e. all horse and sheep products) would probably result in effective products being deregistered for use or new products not gaining registration.

In the past, such insufficient data presentations were managed by including a statement ‘Not for use in animals producing meat/milk for human consumption’. However, under the current risk management regulatory model it is inappropriate to deal with the lack of residue data by way of a blanket ban on use in entire groups of animals and the restriction is no longer supportable. Instead, the ACVM Group has adopted a range of ‘default’ WHPs that will be approved under certain circumstances where residue data have not been provided (see ‘Default withholding periods’ on page 5 for a full list).

Another group of standardised WHPs has also been established. The WHPs are specific to named active ingredients when included in specified formulation types and indicated for the treatment of certain species. This is mostly of benefit for registrants who are seeking

registration of a generic veterinary medicine (as it exempts them from the requirement for producing residue data) but may also be a useful reference for veterinarians. A full list can be found as an annex to the *ACVM Registration Standard and Guideline for Determination of a Residue Withholding Period for Veterinary Medicines*, which is available on the website (www.nzfsa.govt.nz/acvm).

Assessed withholding periods are calculated using the mean data from the residue trials

FICTION

In New Zealand, WHPs are set using the upper confidence levels (UCL) calculated from residue data. The WHP is set at the time that the UCL falls below the applicable MRL. The UCL has the advantage of assessing the likely impact of individual animal variation on the residue levels that may occur in produce when sold, which is not a feature of WHPs based on mean data alone.

When calculating the UCL a constant factor is used to enable the calculation of a one-sided tolerance estimate of conformance with a given threshold with a given conformance level, with population normality assumed. The threshold and conformance levels vary depending on the produce and species (which consider issues such as the likelihood that the entire population will be treated with any particular active ingredient at any one time or immediately before produce is taken).

When setting milk WHPs the UCL is calculated on a whole herd basis with high threshold and conformance parameters applied. This is necessary because overseas market access assurances are issued at the farm gate.

This system enables the WHPs of different products to be assessed equitably while also allowing for the contingency of different trial design and data quality.

The withholding period applied in practice should not be reduced from that stated on the label

IN MOST CASES, FACT

The label does not distinguish whether a WHP is an assessed, allocated or default WHP.

Where the WHP is obviously an assessed or allocated WHP, it will usually be the shortest period possible to manage the residue risk and must not be reduced. Such WHPs are generally, but not exclusively, recognisable by their relatively short duration of days or a few weeks. The milk WHP and prenatal treatment (or treatment-to-calving) intervals (PNTI) approved for intramammary preparations are all assessed or allocated periods, as are the meat WHPs for any long-acting preparations.

Where the WHP is obviously a default period (often the case for sheep milk, horse meat, and cattle milk for many parasiticides) a veterinarian may elect to apply a shorter WHP in practice. Default WHPs are generally, but not exclusively, recognisable by their relatively long duration of several weeks to a few months.

Some default WHPs or even some allocated WHPs are likely to manage the residue risk very conservatively. Nevertheless, in most cases users must comply with the WHP, but specific advice on the effects of non-compliance may be obtained from NZFSA.

One situation where veterinarians may elect to apply a shorter WHP than the approved default for any prescribed PAR or OTC (or equivalent) veterinary medicine is where either the registered veterinary medicine is approved with a discretionary use condition, or where the veterinarian is using a human or specially compounded medicinal preparation in accordance with an approved code of practice. Veterinarians should note that, if the discretionary use condition is not approved for any particular registered veterinary medicine, veterinarians are not legally entitled to use the product off-label in any way. So check the conditions.

Veterinarians should also note that whenever prescribed veterinary medicines are used or managed in any way other than that stated on the label, full responsibility for discretionary use must be accepted for any recommendations made. Furthermore, any recommendation to reduce the WHP should be made only on the basis of sufficient knowledge of the veterinary medicine to provide confidence that the period selected will not result in the sale of produce with residue levels that exceed any applicable MRL.

If I always apply the approved withholding period, residue violations will never occur

FICTION

As previously discussed, WHPs are statistically calculated using a specified threshold and degree of conformance. No regulatory body in the world sets WHPs to actually statistically or practically achieve 100% conformance with the specified MRL, 100% of the time. Because of animal variation etc., to do so would result in impractical and unnecessarily long WHPs (months/years in some cases). However, given New

Zealand husbandry practices, the expected rate of MRL breaches is exceedingly low when label directions are followed.

It is important to note that residue trials are conducted under controlled circumstances. Animals are healthy and monitored throughout. Treatment is applied regularly and precisely and, for lactating cows, milking is regular and complete.

Veterinarians should consider the individual circumstances each and every time any veterinary medicine with a WHP is prescribed for use in food-producing animals and, where considered prudent, recommendations made that WHPs should be increased. Remember that the WHP will usually be set at time of registration to achieve the shortest possible treatment to harvest interval.

Milk withholding periods are expressed as both a number of hours and number of milkings. Milk can go back into the vat once either of these is met, right?

FICTION

Trial data submitted for assessment is gathered under controlled circumstances, which includes twice daily milking to complete evacuation usually at 12 hourly intervals. The milk WHP approved is therefore a function not only of the time that has elapsed, but also the number of milkings that have occurred in the time taken for residues in the milk to comply with the relevant MRL.

Current farm practices are changing and herd management may not revolve around milking twice daily at 12 hourly intervals. Veterinarians must be aware that, where this is not the case, the approved WHP may need adjustment – see box below.

As a general rule, the number of full milkings is the most critical factor for veterinary medicines administered via the *intramammary* route (because the primary route of residue depletion is via the milk). On the other hand, in general, the number of hours is the critical factor for veterinary medicines administered *orally or parenterally* (because the milk acts as only one of the routes of residue excretion).

All veterinary medicine label claims have been approved by the regulator, haven't they?

Although that statement was true under the Animal Remedies (AR) Act 1967, it is no longer necessarily true under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Under the AR Act, the Animal Remedies Board was simply required to 'ensure that animal remedies are efficient and safe for use on animals'. In essence that meant that if a product met the definition of an animal remedy all label information had to be approved by the regulators regardless of the nature of the claim.

As discussed in the Q & A forum on the current regulatory system for veterinary medicines (see pages 2-3), regulators are now required by the ACVM Act to manage specified risks associated with the use of agricultural compounds. In essence, that means if any aspect of the product does not trip the thresholds established for each risk, then the ACVM Group does not have the authority to require, assess or approve any data or label claims relating to that aspect.

In addition, Select Committee, when considering the ACVM Act in its early stages made comment that there was no need for the ACVM Act to consider consumer protection for its own sake as this was already adequately covered by other legislation.

What all of this means is that if veterinary medicine label efficacy claims are such that animal welfare will not suffer as a result of inefficacy, such claims can appear on those labels without the approval of the ACVM Group. This is true for most fertility and productivity enhancement claims. In addition, promotional slogans like 'the best on the market' can be made without the approval of the ACVM Group.

Where claims and advertising that are not regulated by the ACVM Group are found to be untrue, fair trading legislation comes into play. The Commerce Commission enforces this legislation. Although the ACVM Group no longer directly attempts to resolve issues that relate only to breaches of consumer legislation, any complaints received by the Group will be forwarded to the Commerce Commission for assessment.

The ACVM Group continues to require the establishment of efficacy for all veterinary medicines where label claims are such that animal welfare will suffer as a result of inefficacy, as well as the establishment of target animal safety for all veterinary medicines.

Individual veterinary requirements more stringent than ACVM Group requirements

The ACVM Group has received a number of inquiries from the general public in regard to the new requirements for the management of prescription animal remedy veterinary medicines. The inquiries relate to statements made by veterinarians to their clients requiring documentation of the contractual agreement that establishes the veterinary client relationship sufficient to support the prescribing of prescription animal remedy veterinary medicines.

The inquirers reported that veterinarians were demanding written agreements to provide services or documented estimates of drug requirements for the year. Without this documentation the veterinarians were not prepared to prescribe drugs for them. The veterinarians stated or implied that the

documentation was a requirement of the ACVM Group, and that they would be breaking the law if they did not secure the contractual documentation before prescribing or dispensing drugs to them.

It is true that the ACVM Group requires veterinarians to establish a veterinarian/client relationship that confirms that the animals were under the care of the veterinarian at the time the products were prescribed. However, the nature of that relationship is not specified by the ACVM Group, nor does it require the relationship to be permanent or even semi-permanent. The ACVM Group requires the veterinarian to be satisfied that the relationship does exist and s(he) has gathered sufficient information to support the prescribing in any particular event.

It is the prerogative of the veterinarian to stipulate what evidence of the relationship is sufficient and what information is sufficient to support the prescribing. However, from the ACVM Group's understanding of inquiries, some veterinarians seemed to be inappropriately using PAR regulatory controls to secure permanent and binding contracts to supply goods and services.

This documentation is not a requirement of the ACVM Group and any misrepresentation of the regulatory requirements that comes to the attention of the ACVM Group will be reported to the relevant authorities (Veterinary Council of New Zealand and/or the Commerce Commission).

Don't forget to
register for an
ACVM workshop.

Restricted Veterinary Medicines

Our major overseas trading partners have banned the substances listed below. In consequence, these substances may not be used at any time during the life of an animal from which any product may be taken and exported from New Zealand for human consumption.

- All compounds of the nitrofurans class of compound, including but not limited to nitrofurazone, furaltadone, ninhydrone, furazolidone
- All compounds that exert a thyreostatic action:
methyl thiouracil, phenyl thiouracil, propyl thiouracil
- Beta sympathomimetic agents:
cimetarol, salbutamol
- All compounds of the nitroimidazole class of compound,
including but not limited to metronidazole or ronidazole
- Arsenilic acid
- Chloramphenicol
- Chloroform
- Chlorpromazine
- Colchicine
- Dapsone
- Diethylstilbestrol
- Nandrolone
- Phenylbutazone