



AgVetLink

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From the Director

This issue of AgVetLink provides some clarifications about registrant obligations and 'old' product. It also details policy changes regarding:

- *labelling requirements for multiple individually packaged units*
- *advertising veterinary medicines.*

The ACVM compliance process is outlined (page 4), and the recent conviction handed down in the Auckland District Court as a result of a lengthy compliance investigation is reported on page 5.

We have had several staff changes as a result of NZFA's restructuring. See page 6.

In October we will hold workshops for registrants in Australia. Details are provided on page 4 and a registration form is enclosed.



Debbie Morris
Director
ACVM Group

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.

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

GENERAL INTEREST

Registrants must provide information

On a number of occasions recently it has been necessary to remind registrants of the condition on registrations providing for ongoing obligations which states:

The registrant must provide an annual summary of adverse events to the ACVM Group. Adverse events that have serious implications for the continued use of the product must be notified immediately.

The registrant must also advise the ACVM Group of any new studies or data that contradict information previously supplied.

New information

New information includes research or trial results or even field observations

that:

- contradict the information provided during registration or
- would prompt a reassessment from an altered perspective of the information provided during registration.

The intent of this condition is to ensure that registrations continue to be based on current relevant information. This includes not only information that supports the existing approval but also any information that apparently contradicts the information that was initially provided, whether or not it is believed the risks are still managed or there is opposing information.

Post-registration trials

A number of trials are carried out post-

registration for ongoing stability, marketing, new claims and other regulatory requirements. These results must be supplied not only if they detract from the established efficacy, safety, residues and shelf life but also if they change the rationale on which the approval was based. The ACVM Group will consider the post-registration information as new for the purposes of a reassessment under section 29, if necessary.

Application declaration

Applicants are also reminded that an application for registration must contain any information or studies that are contradictory in order for them to sign the declaration *truthfully*.

Antibiotic Resistance Expert Panel Report

The Antibiotic Resistance Expert Panel met for the last time on 20 July. The Panel discussed the submissions on the draft report from Steering Group members and finalised the report's recommendations. The report is now undergoing a final edit and will be presented to the Steering Group who will consult and make their own set of recommendations to the ACVM Group. We hope to release the report publicly at the NZFSA conference in October.

We have been fortunate in securing the agreement of both animal and human health experts to peer review the report – Professor Mary Barton from the University of South Australia and Professor John Turnidge of Women's and Children's Hospital, Adelaide.

Containers of multiple individually packaged units

The ACVM Group has reviewed its policy relating to the regulatory management of agricultural compounds that are marketed in containers with multiple numbers of individually packaged veterinary medicine, vertebrate toxic agent or plant compound products. The Group is aware that inconsistent advice may have been provided regarding requirements in this area.

It is common practice for veterinary medicine products to be packaged in foils, blisters, pouches and vials and sold as multiple lots in containers. Although it is less common for vertebrate toxic agent and plant compound products, smaller individually packaged bottles of product may be sold in bulk lots in a similar fashion.

Policy

The current policy is that where units are individually packaged (e.g. tablets in foils or blisters, vaccine vials, bottles of product) and then included in multiple numbers in containers, the actual number of individual units included per container does not need to be stated on the label approved by the ACVM Group provided the container does not contribute to the stability profile of the product.

In consequence, where changes are made to the number of individual units included per container, no formal ACVM approval is required provided there are no changes to the individual unit or ACVM-relevant approved label text. Where the container contributes to the stability profile of the product, the usual policy regarding approved pack sizes (which must be identified on approved label text and for which C3 applications are required prior to changes being made) is likely to apply. The labelling/advertising guides have been altered to reflect this change in policy.

GENERAL INTEREST

Sale or use of old product

The ACVM Group has had a number of enquiries about the legal status of old product.

Some products, like most veterinary medicines, have specific expiry dates. Other products, like most plant compounds and vertebrate toxic agents, have a 'best used by' date. In either case, the simple answer is that neither sale nor use of old product is a breach of the conditions of registration or the ACVM Act, but this answer needs some explanation.

Product stability

The ACVM Group assesses trade name products for registration on the basis of the chemistry and manufacturing information provided, including the stability of the product over time. The risks are assessed for the product before it deteriorates. Over time products can change in composition or concentration.

The ACVM Group imposes a limited time in which a person can use the product with confidence. This limited time is based on the stability data provided when the product was registered. Consequently, the assessments may not be relevant after that time.

Use of old product

While it is not illegal to use old product, nothing should be assumed about the efficacy, safety or prudent withholding period for product that has not been used before the expiry of that period. In effect, the ACVM Group assessment of the product may not be relevant any longer and it should not be used to support use beyond that time.

Prudent action would be to either not use the product or to check with the registrant to see if it would still be appropriate to use it. Registrants are usually helpful in this regard but sometimes they may be reluctant to give advice because it may create liabilities for themselves that they are not prepared to accept.

The ACVM Group would advise that, if product has not been used before the expiry date or the 'best used by' date, then the product should not be used.

If it is inappropriate to use the product, then it should be disposed of carefully and in a way that is consistent with obligations under other legislation such as the Hazardous Substances and New Organisms and Resource Management Acts and local authority requirements. **It should not be kept if it should not be used.**

Sale of product after the expiry date or use by period

Sale of old product is not a breach under the ACVM Act. However, the ACVM assessment may not be relevant and the seller would be offering for sale a product that has no supporting information or assurances in regard to

safety, potential residues or effectiveness. While this is not an offence under the ACVM Act, it may be one under the Fair Trading Act, especially if anything goes wrong.

Use or sale after registration is cancelled or expired

It is illegal to use or sell product after the product's *registration* has expired or has been cancelled. Such products are unregistered. Registrants are advised that they must not supply any more product from their stores.

As for product that is already in the marketplace or has already been purchased, the ACVM Group provides a 12-month grace period in which that product may be sold and used to clear stock-in-trade. After that time further sale or use would be illegal.

MRL update

NZFSA has gazetted the second amendment for the year to the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005 (the MRL standards).

Amendment 2 comes into force on **28 August 2005**. As mentioned in the last issue of *AgVetLink*, it was considerably larger than previous amendments and contained several changes to the MRL standards such as:

- a reformatting of the MRL table, including adding a CAS number and residue definition column and altering terms to be consistent;
- a proposal to include MRLs below the 0.1 mg/kg default MRL for 40 plant compound active ingredients that have been reassessed; and
- removal of three obsolete plant compounds and their MRLs.

In addition to the above changes, Amendment 2 set three MRLs and one MRL exemption. NZFSA is planning a consolidation of the entire standard to bring it up to date with the formatting changes made in Amendment 2.

NZFSA will be consulting on a third round of amendments for the year in the near future. This third round will propose:

- removing several obsolete MRLs;
- setting MRLs below the default MRLs for approximately 30 more reassessed plant compounds; and
- setting several MRL exemptions.

GENERAL INTEREST

Compliance process

We are often asked about the process used to ensure compliance with ACVM legislation. This is a summary of the 2005 ACVM Group programme.

The ACVM Group compliance monitoring programme has been revised and extended to include regulatory controls implemented since the start up of the ACVM Act. The compliance monitoring programme includes audits, reviews and investigations.

Audits

Audits are the regular, planned and targeted assessments of compliance with regulatory standards (some of which are internationally agreed) and usually include site inspections.

About one hundred inspections are carried out annually for regular reassessment of manufacturers of veterinary medicines, distributors of hormonal growth promotants, and traders in prescription animal remedy (PAR) and/or vertebrate toxic agent (VTA) products. New applicants in these categories are also audited. There is a well-established and generally very knowledgeable stakeholder base with a good level of compliance.

Reviews

Reviews are undertaken to provide the ACVM Group with better knowledge of the sectors it must regulate and to determine the effects of its regulatory actions. Reviews are a relatively new concept introduced two years ago, and the ACVM Group is developing this aspect of compliance monitoring to improve its own competence and contribution as the regulator in the veterinary medicine and agricultural compound sectors.

Reviews may be either targeted to a specific product or have a broad scope to provide a general understanding of an industry segment. They are usually carried out by specialists within the Compliance and Investigation Group (CIG) of NZFSA.

Proposed reviews include the following topics:

- Import clearance processes at the border
- Levels of compliance with conditions placed on approvals for research
- Levels of compliance with conditions placed on products exempt from registration under the Act
- Levels of compliance with conditions placed on provisional registrations
- Levels of compliance of oral nutritional compounds and fertilisers in Schedules 4 and 5 respectively of Regulations under the ACVM Act
- Levels of compliance of homeopathic and herbal products with the Regulations
- Levels of compliance of activities or procedures carried out under codes

of practice approved under the ACVM Act.

The ACVM Group will need to use a priority ranking for conducting reviews because of the time required and complexity of the task. With current resources, two reviews can be carried out in a year.

Investigations

Investigations concern allegations or suspicions that non compliance or illegal activities under the Act are occurring. Such allegations or suspicions are always followed up by the Group. While most investigations are able to be resolved through the provision of guidance and/or warnings by the ACVM Group, some require further action. In the last year six such cases have been referred to the CIG who lead any prosecutions taken (see page 5).

Registrant Workshops – Australia

The ACVM Group will hold our biennial Australian workshops on 26 and 27 October 2005. This year we will cover topics such as:

- Documentation (Chemistry and Manufacturing)
- Data Assessment Service (DAS)
- MRL process
- Labelling
- NZFSA restructure
- ACVM Act Amendments
- Fees and charges
- GLP – Trial work

Other topics will be added as interest builds.

Sydney

Wednesday, 26 October, at the Novotel (Sydney Olympic Park)

Melbourne

Thursday, 27 October, at Melbourne Zoo

The cost will be \$50.AUD per person. This will cover morning/afternoon teas and lunch. A registration form is enclosed.

GENERAL INTEREST

NZFSA 'comfortable' with fines

The New Zealand Food Safety Authority (NZFSA) is comfortable that the sentence handed down recently in the Auckland District Court reflects the severity of the offences committed by VetPharm (NZ) Ltd. and Phoenix Pharm Distributors Ltd. and their company directors Graeme John Webb, Gary William Gibson, Wallace Bruce Neiderer and Robert Sadler.

Conviction

Justice Field convicted and fined the companies and their directors a total of \$70,000 plus costs on all charges relating to the importation and sale of two unregistered veterinary drugs over several years.

The investigation around these illegal activities began in mid 2003 after audits of the companies detected inventory and procedural discrepancies.

CIG comment

"I'm pleased that a lot of hard work by NZFSA investigators has resulted in such a clear message," says NZFSA Director (Compliance and Investigation) Geoff Allen.

"The message is that the importation and sale of unregistered veterinary drugs seriously risks food safety and trade and will result in significant fines.

This proves that the systems that NZFSA has in place are effective, and that any illegal behaviour in this area will be detected and the appropriate action taken. All those dealing with agricultural compounds and veterinary medicines need to ensure that they are doing everything that they should.

Our approach is one of education to ensure knowledgeable compliance.

However, if intentional breaches are detected, we will pursue investigations and prosecute where necessary and appropriate."

Unregistered products

The two drugs at the centre of the case, Ulcerguard and Pentosan Equine, are intended for use in the protection and treatment for stomach ulcers, and treatment for arthritis respectively. They had not gone through the risk assessment and management process, which is part of New Zealand registration to ensure that drug residue, animal welfare and trade risks are appropriately managed.

The use in New Zealand of any unregistered veterinary medicine or agricultural compound is an offence under the Agricultural Compounds and Veterinary Medicines Act 1997.

Animal feed commodities – 'fit for purpose'

Recently the ACVM Regulations 2001 were amended to make it clear that feed commodities to be sold for use in animal feeds or as animal feeds in their own right are subject to the condition to be 'fit for purpose' as listed in Schedule 4 of those Regulations. This means that these commodities must not:

- result in violative residues in produce from animals exposed
- cause toxic reactions
- cause physical harm to animals exposed
- result in malnutrition
- be a source of pathogenic organisms or pests.

Concerns have been expressed that some imported feed commodities, such as grain or palm kernel expeller meal, may not meet the above criteria. The ACVM Group wishes to remind people that it is a statutory obligation to take due care to be confident that the commodities they are selling are actually fit for purpose as animal feeds. This includes persons who trade in imported feed commodities. They must be confident that the commodities are fit for purpose if they are going to sell them as animal feeds.

The ACVM Group considers that the seller has a moral obligation to advise the purchasing feed manufacturer of any hazards they may suspect if they are going to sell the commodities as ingredients to be used in the manufacture of animal feeds. However, the statutory obligations fall on the feed manufacturers to ensure that their products are fit for purpose as an animal feed. They must take due care in procuring ingredients that are appropriate for their manufacturing operation so the final products will comply with the Regulations.

GENERAL INTEREST

Staff update

As a result of NZFSA restructuring, some ACVM Group staff members have shifted position within the organisation.

NZFSA's Science Group, which provides the Executive Director with scientific inputs into standards for food and food-related products, including risk assessments, has gained two ACVM Group members as principal advisers who are recognised as experts in their fields:

- **John Reeve** is now Principal Adviser Toxicology. Although his new position is more a reflection of the work he has been doing than a real change, he is no longer directly linked to the ACVM Group.
- **Paul Dansted** is now Principal Adviser Chemicals. This position is designed to provide an overview of food safety and suitability in terms of chemical hazards that may be present in food or that may be introduced throughout the food chain.

There have also been changes within the ACVM Group itself. Additional responsibilities have been added to the

positions of the following staff members as the ACVM and Approvals Group merges with the Animal Products and Domestic and Imported Food Approvals teams respectively:

- **Chris Boland** is now Senior Programme Manager (Approvals and ACVM Standards). His work has been expanded to include Approvals across the NZFSA spectrum, from animal products to wine.
- **Warren Hughes** is acting in the position of Programme Manager (ACVM and Non-food Assessment).
- **Maree Zinzley** has the new title of Programme Manager (ACVM and Non-food Products).

More changes

Gill Wilson, who was Debbie Morris's Executive Assistant, has moved across into the Communications and Infrastructure team under the same title but working mainly as executive support for Andrew McKenzie, NZFSA's Executive Director.

Laurence Clear, who worked as an Advisor (Web Development) supporting

the ACVM Group, is now working under the same title within the Communications and Infrastructure Group and doing projects across a number of business groups.

Sheryl Robertson has also moved to the Communications and Infrastructure Group, and will have administration duties across all NZFSA groups. Sheryl has been an employee of the ACVM Group for 35 years and we are glad that she is still part of the organisation. However, as we keep a long-serving member, we farewell one of our advisers, **Claire Truscott**. Many of you will remember Claire from her stint with the ACVM Group before she ventured on her OE. Claire returned to us in 2004 and has just accepted a new role within the New Zealand Police Department. Her jovial and enthusiastic nature will be missed. We wish her well in her new endeavour.

After reading the above, you may realise that this leaves us in a difficult position in regards to advisers. Please bear with us as we go through interviewing, training and rebuilding the team.

VETERINARY MEDICINES

Antibiotic products review

The ACVM Group is instigating reassessments of all antibiotic products that are prescription animal remedy (PAR) veterinary medicines. After considerable dialogue between the Group, the Ministry of Health, Medsafe, the veterinary pharmaceutical industry, the veterinary profession and other technical experts it has been grudgingly accepted that the risk management role of veterinarians is made more difficult by advertising PAR antibiotic products directly to end users.

The ACVM Group has publicly announced its intention to impose a

prohibition on such advertising via a new condition of registration (see page 8). However, limitations in the ACVM Act cause logistical difficulties in doing this.

The only mechanism provided in the ACVM Act is a reassessment under section 29. This requires a process that is focused on individual products (or at best on products that are very much alike). Each registrant must be individually contacted and advised that a reassessment is being considered. The reassessment itself must be conducted like a registration, requiring gazette notices and consultation.

The ACVM Group has combined products according to antibiotic active ingredients and formulation type and sent letters to registrants notifying them of the reassessments. Because there are 67 groups, there will have to be 67 reassessments. The expected outcome is exactly the same for all the groups, so the ACVM Group is trying to rationalise the time and process to facilitate the application of the new condition. In the meantime, the registrants are well aware of what is going to happen and are being advised to adjust their advertising programmes accordingly.

‘Breaking down’ registered products

Two of the considerations in the assessment and registration of an agricultural compound or veterinary medicine trade name product are the container or packaging in which the product will be offered for sale and the labelling of the product. Breaching the original container/packaging and removing a portion could result in significant changes in the product. It could also separate that portion from the information that must be provided with the product. Consequently, both the container/package and label are tools used to manage risks and are integral components of the ACVM approval for the product.

To avoid confusion about the possible terms such as decanting, separating, dispensing etc. that could be used to describe breaching a container and removing a portion, the ACVM Group will use the general term ‘breaking down’ regardless of the physical state or formulation type.

This policy relates to breaking down product into volumes or quantities that are different from those specified in the ACVM approval for the product and for which the container or packaging approved for general sale is breached. It does not refer to breaking down shipments or pallets of products when the integrity of packages approved for general sale is not breached.

While there may be circumstances in which breaking down of products may be appropriate, doing so may nullify the relevance of the registration approval.

The following are the rules of acceptable practice governing the breaking down of registered agricultural compound and veterinary medicine trade name products.

Operational policy

General

It is a breach of the ACVM Act (section 8) to offer for sale any product that is not registered or exempt from

registration. Breaking down proprietary products alters characteristics of a registered product and, consequently, may nullify the relevance of the registration.

Acceptable practices after purchase

Once the purchaser of a registered trade name product takes possession of the product the purchaser is responsible for the appropriate care and use of that product, including any subsequent breaking down of the product. Breaking down the product by the owner of the product in any manner is not an offence under the ACVM Act as long as the result is not offered for sale. If a product is purchased by a group of persons, each person in the group is considered by the ACVM Group to be an owner of the product and they can manage the care and use of that product as they see fit. (NOTE: The activities of the person or group may be subject to requirements under other legislation such as the HSNO Act.)

Agricultural contractors (including chemical application contractors or dipping/tailing/shearing contractors, farm management services, pest control contractors etc.) may break down registered trade name products in the course of providing their services. This should be done in a manner that is consistent with Standards New Zealand Standard P8409 *Management of Agricultural Chemicals*. Contractors must not sell broken down quantities of trade name products separately from their services (i.e. sell portions of the products they are using to any other person, including the person who contracted them). These rules apply in a contractor/sub-contractor arrangement as well as in the supply of pest control services.

Acceptable sales practices

Where breaking down of a product and subsequent sale was anticipated and provided for in the registration of a product, such activities must be carried out in accordance with the approved instructions for them. The registration

will specify what the minimum requirements are for the product.

If breaking down was not provided for in the registration, then those activities must not be carried out and the results offered for sale. Traders in registered products should stock products in appropriate container/packaging sizes to meet their customers’ needs. Traders should recommend appropriate alternatives if certain products are not marketed in convenient sizes. Product must not be broken down and offered for sale if those activities were not provided for in the registration.

Approved traders in prescription animal remedy veterinary medicines must always follow the instructions of the prescribing veterinarian exactly. If some aspect is uncertain or might require variation from those instructions, this must be discussed with and endorsed by the prescribing veterinarian.

A veterinarian who determines that, for the welfare of the animals concerned, a specific quantity (less than the total quantity in an approved package size) of a registered veterinary medicine is required, that veterinarian may break down a registered trade name product and sell/supply the required amount.

If this is done, the veterinarian must take full responsibility for the appropriate repackaging and relabelling of the product dispensed to ensure that:

- the quality or the product is not jeopardised;
- the container packaging is safe and appropriate;
- sufficient information is provided to allow the product to be used according to the veterinarian’s instructions; and
- the veterinarian and/or veterinary practice and contact information are included.

Veterinarians must not offer altered product (including repackaged/relabelled product) for general sale.

Advertising veterinary medicines

No advertising PAR antibiotic products to end users

The ACVM Group is in the process of changing the conditions of registration for certain prescription animal remedy veterinary medicines (PARs) to prohibit advertising and promotion directly to end users. At this stage, only PAR antibiotic products will have the prohibition applied.

The Group considers that such advertising jeopardises the risk management role of the prescribing veterinarian due to the pressure to supply products that the veterinarian considers inappropriate under the circumstances.

End users are considered to be those persons who own or are responsible for the animals to be treated and are likely to administer (or arrange for the administration) the product to the animals. It does not include veterinarians or approved traders of PAR products. Advertising to veterinarians and approved traders will not be restricted by the new conditions.

Registrants of antibiotic products have been advised that the registrations of their products are to be reviewed and the conditions on registration changed to include the prohibition on advertising or promotion to end users.

What constitutes advertising?

Some registrants have asked for clarification about the distinction between advertising and information transfer (editorials) about disease conditions and treatment alternatives, particularly when the articles are not commissioned by the registrant or trader.

The ACVM Group uses a simple definition for advertising – it is any kind of communication that is intended to promote the sale of a particular trade name product. It recognises that any communication about disease conditions

or treatment alternatives may result in increased sales for a particular product. This means that the intent, content and context are all important in distinguishing between advertising and information transfer. While the boundary is not (and will never be) black and white, most readers in the majority of cases can tell the difference.

Nevertheless, individuals and companies constantly test the boundary and a large portion of the ACVM Group's compliance activity is taken up with arguments about whether or not a particular communication has overstepped the boundary.

The ACVM Group uses the following rule in making judgements:

If, because of the context, content (text and or graphics), layout, association with other material, or any other factor, the reader would interpret the communication as a prompt to choose or buy a particular trade name product, then the communication is an advertisement or promotion.

Whether or not the communication was directly paid for by the registrant or trader is not particularly relevant because other kinds of arrangements, agreements or considerations could be involved, none of which would be known to the ACVM Group. So the Group makes its judgement on the basis of what it sees and how the communication is likely to be seen by others.

Industry code of good advertising practice

While the ACVM Group tries to be consistent, sometimes it is difficult to judge whether or not a particular communication is advertising, given the endless ways in which the material can be presented. To assist the Group in this difficult area, the veterinary pharmaceutical industry and the veterinary profession have joined forces to develop a code of practice for

advertising veterinary medicines. In addition, they are developing a forum in which appointed representatives of the industry as a group will be able to examine a particular communication and advise whether or not it complies with the code of practice.

The ACVM Group applauds this industry initiative and is looking forward to a time in the near future when its judgement on individual cases that are borderline will have the benefit of an industry-wide perspective on whether it is or is not acceptable advertising practice.

Closantel

The ACVM Group has been advised that a letter was sent to veterinary practices by a third party alleging the closantel base in Q Drench (A9291) was largely ineffective. It is implied in the letter that this product will not treat *Haemonchus contortus*. The assumption is made that reduced absorption from the gut of closantel demonstrates that the closantel in Q drench is not effective and its use would promote anthelmintic resistance.

This is disputed and contradicted by data supplied to the ACVM Group in support of the registration. The assertion and the additional information provided with the letter to veterinary practices has been taken seriously by the ACVM Group and examined against the information held by the Group for the product.

Q Drench remains registered with claims for treatment of *Haemonchus* properly supported by clinical efficacy data.

NZFSA ACVM Group Australian Workshop Registration Form

Complete one form per person attending and return to Gill Wilson,
NZFSA facsimile: +64 4 463 2501 by Monday, 3 October 2005.

Tuesday 18th October 2005

Mecure Sydney , 818-820 George St,
Sydney

Wednesday, 19th October 2005

Bong Su Room, Melbourne Zoo, Elliot Ave,
Melbourne

Name:

Organisation:

Fax number and e-mail address:

City:

Date of session:

Workshop charge of \$50.00 AUD (per person) covers morning tea, lunch and afternoon tea.

Method of Payment

Cheque – please make out to NZFSA - Post to Gill Wilson, NZFSA
PO Box 2835
Wellington, NZ

Credit Card Mastercard Visa Diners Club Amex

Card Number exp.date

Cardholders name

Receipts will be issued with all payments.