



AgVetLink

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SPECIAL ISSUE FOR REGISTRANTS

Agricultural Compounds and Veterinary Medicines (ACVM) Act: policy changes affecting registrants

During the past few months, responses to proposed changes in areas such as prescription animal remedy (PAR) operational policy, results of 'slice of life' audits, and compliance incidents have indicated significant misunderstanding of the way the ACVM Act operates.

This special issue of AgVetLink focuses on areas of concern to registrants – manufacturing, importing, PAR policy, and compliance. We hope it helps to answer your questions and clarifies your responsibilities under the ACVM Act.

*Debbie Morris
Director, ACVM Group*

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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.

Important notice to all registrants – *IVS*

During the investigation of a possible residue violation, the ACVM Group has found that the publication *IVS*, published by Havas MediMedia (NZ) Ltd, is not providing the most up to date information regarding the use conditions for a product. This means that registrants may be ‘advertising’ incorrect information to prescribing veterinarians in possible breach of the ACVM Act. This is of serious concern to the New Zealand Food Safety Authority (NZFSA) because we are aware that many prescribing veterinarians rely heavily on this publication for advice.

The situation that we were investigating involved a product that was not for use in food producing animals likely to be exported to the European Union. Use was limited to

pigs and poultry, but there was a comment in *IVS* about use on calves that we consider is misleading.

In addition, products requiring registration in New Zealand have been ‘advertised’ in *IVS* in possible breach of the ACVM Act.

The ACVM Group understands that registrants provide the information to *IVS*. Registrants are advised that any incorrect information is likely to constitute an offence under section 55 of the ACVM Act. It is an offence to knowingly sell any agricultural compound in contravention of the ACVM Act.

Veterinarians following such advice would also be in contravention of the ACVM Act as would farmers using the

product. Where there are violative residues found in product, both the prescribing veterinarian and the farmer concerned may have recourse against the registrant for the advice provided.

We would urge all registrants to check the information shown in *IVS* regarding your products and the conditions of registration, and provide advice to both veterinarians and to *IVS* so that the opportunity for error is minimised.

If similar information is provided by registrants to other publications or if the information is shown on websites, then information should be checked and updated as needed.

The ACVM Group has advised the editors of *IVS* of our concerns.

Border controls

There are now several hundred MAF Quarantine Services (MQS) staff trained and warranted as ACVM Act inspectors at the border. Under the ACVM Act only product cleared by an inspector may be imported into New Zealand.

MQS uses the ACVM list of registered products (and the approved label where it exists) from the website (<http://www.nzfsa.govt.nz/acvm/registers-lists/acvm-register/index.htm>) to confirm the registration status of a product. This list is updated every fortnight and is searchable by registrant, trade name, registration number or active ingredient (or any part thereof).

If the product does not appear on the list of registered products, the importer is required to present an original copy of an ACVM ‘class determination’ letter showing that the product is exempt from

registration requirements under the ACVM Act. A class determination is valid for two years from the date of issue.

The NZFSA Compliance and Investigation Group (CIG) is soon to undertake a ‘slice of life’ audit of the border process on behalf of the ACVM Group to help determine what is working well and what is not. Recommendations from an earlier audit have suggested that there should be a level of physical checking implemented at the border in the future. The outcome of the current audit and recent investigations will be used to develop an audit programme.

A recent non-compliance investigation has revealed that there may have been illegal importations of unregistered products into New Zealand in breach of

the ACVM Act. As an interim measure, all shipments to and from the companies identified in the investigation are being stopped and physical checks made of the contents. This activity is cost recovered on a time and materials basis under the ACVM Act at \$121.50 per hour inclusive of GST. The costs are payable by the importer.

The ACVM Group is also considering the application of the Regulation making powers in the ACVM Act to develop a list of prohibited substances that will be applied at the border. This list will be in Regulation and will go through the usual consultation process. At this stage we expect that substances such as DDT and Lindane, both of which have had no registered ‘ACVM’ uses for some time, will appear on the list.

Draft operational policy for PAR products – impact on registrants

The ACVM Group is required to identify the risks and benefits for **each application**, and apply conditions to manage the risks in a cost effective manner. In an effort to be consistent and transparent, we have written down the ‘rules’ that are applied when considering if a product should have a PAR status, and the standard conditions that will be applied to manage a range of risks.

There has been extensive consultation and several revisions of this draft operational policy for PAR products. The draft policy does not negate the need for the ACVM Group to consider each product application on its merits, but it is intended to provide a framework for decisions in the future.

Many concerns expressed over earlier drafts of the policy (see the *Summary of Submissions* document at <http://www.nzfsa.govt.nz/acvm/archive/draft/policies/index.htm>) are addressed in later versions. Some of these were concerns over risks that might exist if there were a proliferation of traders and over ‘any person’ being able to trade in PAR products.

The ACVM Group has addressed this by developing a draft standard for traders (currently on the website for public discussion) that will be used as the basis for approval of people and organisations operating in this area. We have also included the requirement for persons operating as traders to have confirmation that they are ‘fit and proper’ persons in the same way that operates for VPC licence holders at present.

This means that registrants must be aware that **all New Zealand manufacturers and importers of PAR products, as well as any person or organisation in the PAR supply chain, including wholesalers and dispensing veterinarians, will need to be approved as traders in the future**. It is proposed that the policy will be implemented in a cost-effective way by recognising (at no cost) all organisations currently trading PAR products.

Over the next 18 to 24 months the ACVM Group will request a number of audits (initially at no cost) to determine the level of verification that will be required in this area. This information will be used to allow an audit programme to be established. In that time it is expected that the companies trading will develop codes of practice (either individually or collectively), which will be approved under the ACVM Act, to assist them in meeting the requirements in the ACVM trading standard.

One of the other concerns raised has been the lack of a competency standard for traders, especially those at the dispensing end of the supply chain. The ACVM Group notes that many of the products attracting PAR status will also require ‘approved handler’ status under the HSNO Act.

This will mean that people working with the products must be trained to cover HSNO risks (public health and the environment) and maintain their status in order to work with the products. We will discuss this further with ERMA NZ staff to investigate opportunities for co-operation.

Revised fees associated with the Data Assessment Service and regulatory process

With the recent separation of the Data Assessment Service (DAS) from the regulatory process, the ACVM Group has established new fees associated with the regulatory process.

The DAS involves the assessment of data to support an application for registration. The fees associated with this service are based on an estimate of time (\$108.00 + GST per hour) that is likely to be taken to complete the assessment. A screening fee of \$243.00 must accompany the request to assess the data, unless the applicant is an approved creditor (see page 7). The ACVM Group will then inform the applicant of the estimated number of hours, costs and likely time to complete the DAS.

The regulatory process consists of reviewing data assessment reports and evaluating the risks that must be managed under the ACVM Act 1997. It is estimated that this part of the process will be quicker, and therefore attract a lower fee. Fees associated with this process are also based on an estimate of time to review the data assessment reports (\$108.00 + GST per hour), plus operational charges and any disbursements associated with the application.

For further information on fees associated with the Data Assessment Service and regulatory process, refer to the website (<http://www.nzfsa.govt.nz/acvm/publications/fees/index.htm>).

Registrant obligations for imported products

We would remind all registrants that the product imported must be exactly the same as the product registered or exempted from registration in New Zealand. This means that it must be fully compliant with labelling and pack sizes that have been approved. Recent activity has shown non-compliances in this area.

Manufacturing

If you are importing a registered product that requires overlabelling, you should be aware that this constitutes a manufacturing process step and that **all** manufacturing sites must be listed in the manufacturing specifications for a registered trade name product.

It is a breach of the ACVM Act to import registered or exempted products that are not correctly labelled. In the near future we expect to introduce a level of physical checking at the border to ensure compliance.

Manufacture, in relation to any agricultural compound, means to make

up, prepare, produce, or process the agricultural compound; and includes the packing (and labelling) of an agricultural compound in a container for the purposes of sale. Therefore any site that carries out any of these activities (or any subdivision of these activities such as quality testing) must be listed in the manufacturing specification.

Any changes in manufacturers or manufacturing sites must be notified to the ACVM Group so the approved manufacturing specification can be updated. If you are concerned that a manufacturing site may not have been included in the manufacturing specifications that were provided with the application to register a product, you should notify the ACVM Group.

Modifying the manufacturing specification on the product file presumes that:

- its absence from the manufacturing specifications was an historical oversight; and

- the site is actually an approved manufacturing site.

If the site is a new site, then a registrant must lodge an application to vary a registration to get the new site properly approved. Failure to provide comprehensive manufacturing specifications may jeopardise the continued registration of a product.

Pack sizes

Under the ACVM Group policy covering additional pack size approval, the ACVM Group will approve a range of pack sizes at initial registration, provided the appropriate data and information are supplied. From that point, all pack sizes with risk profiles that fall within the assessed range (such as the same packaging material) will be considered approved.

For existing products, a normal C3 application can be made to approve a range of pack sizes with referencing to data already on file, or via the provision of additional information. In either case, the ACVM Group will require notification of the actual pack sizes being marketed in the form of an official letter, which must be provided each time a new pack in the approved range is introduced to the market.

In addition, any subsequent application requiring a product data sheet to be submitted must state the marketed pack sizes as well as the approved range. Labels for additional packs will not require approval provided the content does not differ from that approved.

For new packs falling outside of the approved risk profiles, new data and a C3 application will be required.

Public information about applications and registered products

Applicants and registrants are reminded that 'Part A' of the product data sheet (PDS) is **public information**.

For applications that need gazetting this information is supplied in response to any queries. We are hoping in the near future to put the information that is gazetted and the additional public information on the website so that interested and affected people have easier access to it.

Where there are queries about already registered products, Part A of the PDS will be made available.

Please advise us of any changes to your contact details.

'Slice of life' audits and positive compliance checking

The NZFSA Compliance and Investigation Group (CIG) is undertaking a series of 'slice of life' audits to check the effectiveness of the ACVM regulatory process.

These are undertaken at no direct cost to the people and organisations being audited – costs are recovered from the compliance component of the product registration fee, or from the compliance part of the annual fee.

Information from the audits will be used to estimate the required frequency of future verification checks, as well as to adjust the level of regulatory intervention. In some cases we may be

able to reduce controls; in others we may have to increase them or look for more effective mechanisms.

If there is evidence of non-compliance discovered during an audit, in most cases the ACVM Group will work to educate the parties involved on responsibilities under the ACVM Act. However, serious non-compliances will always trigger investigation activity. One component of the education process will require the parties concerned to participate in a positive compliance programme.

The ACVM Group is developing the programme covering proactive audits

where non-compliances have been identified in the 'slice of life' audits, investigations or via other means. It is envisaged that there will be a programme of three or four audits within a two year period to ensure that the organisation is in compliance with the ACVM Act (via the appropriate standards or codes of practice), with a longer time period where there are identified failures.

Positive compliance audits are cost recovered from the organisations being audited. The ACVM hourly rate of \$121.50 per hour (inclusive of GST) plus any disbursements such as travel will apply.

Prohibition notices

The Compliance and Investigation Group (CIG) and the ACVM Group have issued a number of prohibition notices recently for contravention of the ACVM Act and Regulations.

A prohibition notice, which is a written notice issued by an inspector, means that the affected product may not be manufactured, sold or used until the identified contravention of the ACVM Act is rectified to the satisfaction of the inspector. A prohibition notice may be issued to any person manufacturing, selling or using a product – not just the registrant.

Other powers of inspectors under the ACVM Act provide for information gathering and sampling of products for the purpose of determining compliance with the Act and Regulations. In many cases, this will mean that the affected product is recalled and returned to the supplier at their cost. It is an offence to contravene a prohibition notice or to permit a contravention of a notice.

Prohibition notices are not issued for importation because every product must be cleared for entry by an inspector and any products of concern are notified to the MAF Quarantine Services staff at the border where they are held or returned to the supplier.

Notices can be varied or withdrawn, and there is an opportunity to appeal a notice within 14 days of issue to the District Court on the grounds that it is unreasonable.

Labels on the ACVM website

All products that are updated to ACVM Act registrations now have the approved label (or the approved label content) posted on the ACVM website in the list of registered products.

Registrants are reminded that where there is a valid reason, such as an imminent product launch, they can negotiate with the ACVM Group to delay the posting of the label information.

It is also important that you check the information and advise us as soon as possible if there are any problems.

Dual approval – GMP inspections

At its meeting on 21 November, AVMAC endorsed an ACVM Group proposal to accept inspections for good manufacturing practice (GMP) compliance carried out by Medsafe pharmaceutical inspectors for the purpose of issuing a NZFSA Certificate of GMP Compliance.

Inspections

Inspections of manufacturers of registered veterinary medicines are carried out at regular intervals for the assessment of compliance with the ACVM standard and guidelines, where relevant, for GMP. We have learned from the routine inspections carried out that a small number of manufacturers are involved with the production of veterinary and human pharmaceutical products and are therefore inspected under both the ACVM and Medsafe inspection programmes.

We believe that these duplicate inspections comprise excessive regulatory control for a number of reasons:

- Veterinary and human pharmaceutical manufacturing activities associated with specific types of products are generally very similar.
- The scope, outcomes and procedures for both types of inspection are similar.
- Both inspection groups are applying the same standard for GMP to the assessment.
- Both inspection groups operate under the same mutual recognition agreement for GMP assessment with the European Community.
- Inspections of manufacturers of human and veterinary pharmaceuticals are often carried out by the same inspectors in other regulatory systems such as the EC.

- The ACVM Group has contracted to Medsafe for specific technical expertise for GMP inspection in the past and may wish to do so in the future.

Dual inspection process

The dual inspection process would work as follows. The inspection cycle time for a combined veterinary and human GMP inspection would remain the same, that is every two years. Prior to the Medsafe inspection all parties would agree that the particular inspection would be a dual one. The ACVM Group would advise Medsafe of any specific issues brought to notice since the last inspection that should be addressed.

The Medsafe inspection would include an additional time component when veterinary medicines (or a sample of them if a significant number are being manufactured) will form the focus of the inspection. The ACVM Group will then provide an ACVM GMP Certificate on receipt and review of the Medsafe inspection report. The cost of the additional time component payable to

Medsafe for the veterinary medicine component of the inspection will be recovered from the manufacturer.

Benefits

We believe there are significant benefits for the manufacturers and for the regulators from this proposal. The total inspection cost to the manufacturer will reduce because only one slightly longer inspection instead of two separate inspections will be cost recovered.

The collaboration on inspections will strengthen the technical link between ACVM Group and Medsafe on standards and processes for inspections and will provide a link into the development of the trans-Tasman single pharmaceutical agency.

Finally, only a few people with the training and experience required to conduct pharmaceutical inspections are available. A formal collaboration will make best use of scarce resources and will make it easier to call on alternative technical expertise if required in the future.

Operations Advisor Linley Thorburn checking an application (see page 8).



photo: Warren Hughes

ACVM approved creditors

Registrants and applicants are reminded that it can save valuable time in the processing of applications if you are an ACVM approved creditor. The form is available on the website (<http://www.nzfsa.govt.nz/acvm/publications/policies-procedures/approved-creditor-ins.htm>).

On receipt of an application, the ACVM Group will check that:

- the applicant has had dealings with the ACVM Group for at least six months;
- the invoice payments for the previous six months show that payment has been received by the 20th of the month following issue of an invoice.

If the application meets these criteria, the ACVM Group will accept the applicant as an approved creditor.

Acceptance

Once an applicant has been initially accepted as an approved creditor, the ACVM Group will send out two copies of the terms and conditions (at right) to

be signed by the applicant. One copy must be returned to the ACVM Group; the other is to be held with the applicant's records.

Approved creditor status will apply only after the signed terms and conditions have been returned to the ACVM Group and only for any new applications. The approval is **not** retrospective so it will not include earlier applications.

Terms and conditions

Payments

- Once approved creditor status is assigned, payment of all invoices is to be received by the 20th of the month following the date of issue of the invoice.
- Any person or organisation that is an approved creditor who fails to pay invoices on time on three occasions will lose their approved creditor status and will be required to pay all application fees in advance for a period of no less than six months.
- All payments must be made out to the invoicing organisation.

- Where payment is to be made by direct credit, you should contact the ACVM Group for bank details.

Invoicing

- If a prescreen fails, payment for that prescreen is still required.
- An application advice letter and fee estimate sheet will still be forwarded to you and an invoice will be sent from our head office. Please do not pay on the modular fee sheet.
- One invoice will be issued for prescreen and application fees. The application will not be held up while waiting for payment of these fees.
- If the invoice is not paid by the date the appropriate Decision Making Committee meets, your application will not be sent to that meeting and will be delayed until payment has been received.

For further information, contact Sarah Smyth, Coordinator Business Services (contact details below).

ANNUAL FEES REMINDER

The ACVM Group sent out letters to all registrants on 5 May 2003. The letter included a list of registered products specific to each registrant for confirmation of correctness. If you have not received your letter, then please advise us immediately. Invoices will be sent out this month, and payment for all annual fees will be required by no later than **20 August 2003**.

Unpaid annual fee invoices will attract a penalty interest of 10% if not paid by the due date, and products affected will not be able to be imported or manufactured. This prohibition of importation is a requirement under section 82 of the ACVM Act, and it will be implemented in the case of any overdue invoices. A further 10% penalty interest will be added for each 6 months that an invoice is overdue. The ACVM Group policy is to place the recovery of all unpaid fees in the hands of a debt recovery company.

For enquiries on ACVM annual fees, please contact:
Sarah Smyth, Coordinator Business Services
Phone: 04 463 2553 or email: sarah.smyth@nzfsa.govt.nz

UPDATING ACVM ACT REGISTRATIONS

Registrants of pesticide and animal remedy products are reminded that they have **until 1 July 2004** to provide updated product data sheets to the ACVM Group.

Unlike the Pesticides or Animal Remedies Acts, under the ACVM Act it is illegal to import, manufacture, sell or use unregistered products. This means that products **must be updated** in order to remain as legally existing.

The ACVM (Transition Provisions) Regulations 2002 came into force in July 2002. The Regulations deemed all applicable animal remedy licences and pesticide registrations to be ACVM registrations. They imposed a limited registration period with an expiry for all deemed registrations of 1 July 2004.

This provided a period in which the products could continue to be marketed under their existing conditions and approved labels. Therefore, while the products are now registered under the ACVM Act, many of them still look like animal remedy or pesticide products.

To take advantage of the limited registration period provisions of the Regulations, a registrant must not request any changes that would alter the identity of products or change how they are packaged or labelled. If such changes are requested, the ACVM Group considers that the products are no longer the products that were first deemed to have been registered under the ACVM Act, and new registrations will be issued.

All registrants must apply for new registrations before 1 July 2004 or the registrations of their products will lapse. The products concerned will not be able to be imported, manufactured, sold or used.

In effect, the new registrations will be updates of the existing registrations, ensuring that the conditions on registration, product data sheets and label contents are made current and approved.

The purpose for the limited duration registration is to allow time so that registrants have to make changes only once to incorporate both new ACVM conditions and any controls imposed under the Hazardous Substances and New Organisms Act 1996.

To date, updates have been coming in very slowly. With the number still outstanding, the ACVM Group estimates that it would need to update ten per day and the Decision Making Committee would need to consider 50 per week to complete the task by the 1 July 2004 deadline. **Because of the number of products, the ACVM Group urges registrants to submit their updated product information as soon as possible.**

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