



# AgVetLink

ISSN 1174 - 3735 ISSUE NO 1T SEP 2004

## SPECIAL ISSUE FOR PAR TRADERS

### What's it all about?

*The ACVM Group has received applications from people and organisations who wish to become approved traders in prescription animal remedy (PAR) veterinary medicines. It is apparent from these applications that the concept of trading in PAR products is not clear.*

*This special issue of AgVetLink has been published to answer frequently asked questions about trading in PARs and to help people understand the new system. It includes information on:*

- *what constitutes trading in PARs*
- *who must apply to become a trader*
- *what must be included in an application*
- *how veterinarians are affected*
- *how feed manufacturers are affected*
- *advertising*
- *ACVM and HSNO terminology.*

### Contents

- 1 What's it all about?
- 2 What constitutes trading in PAR products?
- 2 Are people or organisations approved as traders?
- 3 What is required to become an approved trader?
- 3 Why must traders be approved by the ACVM Group?
- 4 Who must be approved as trading entities?
- 4 Operational responsibility
- 5 Advertising PARs
- 6 Trading in PARs: frequently asked questions
- 8 Animal feed manufacturers
- 8 Potential confusion over terminology:  
ACVM and HSNO legislation

*The articles should provide sufficient guidance in most cases. However, for unusual circumstances or where it is uncertain what the requirements are in any particular case, contact the ACVM Group.*

*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](http://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](mailto:gill.wilson@nzfsa.govt.nz), website: [www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)

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

## What constitutes 'trading in PAR products'?

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 specifies that sale includes:

barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale; and also includes:

- a) delivering or disposing of by way of gift, loan, or otherwise; and
  - b) giving or distributing, in the course of business, as a sample or otherwise, without charge.
- 'General sale' means to sell to the public at large.

### Trading

The *ACVM Standard for Prescription Animal Remedy Veterinary Medicines*, using this definition as a base, states that trading includes:

general sale and sale to specified/ approved persons (wholesale and retail sales transactions as well

as distribution, transport and storage). It also includes gifting or offering as samples as stated in the definition of sale. 'Trader' has a corresponding meaning.

This is a comprehensive statement of the range of activities associated with the supply chain from the registrant/ manufacturer through to the end user of the products. However, the area of primary concern is the end-point sale of PAR products to the public, i.e. to the person who will use the products to treat animals.

The sale of PAR products by veterinarians or the filling of veterinary prescriptions and subsequent sale of PAR products (and all associated activities) by an approved trading entity constitute trading in PAR products.

### NOT trading

However, there are persons acting under contract to a trading entity or under the authority, instruction or direction of a veterinarian who are not directly involved in the sales transactions.

Examples of such activities are:

- transport and delivery of PAR products from an authorised person (veterinarian or approved trader) to a person specified by that authorised person, including postal or courier delivery or bulk transport delivery;
- storage on behalf of and in accordance with the instructions of an authorised person; and
- incorporation of PAR products into other non-PAR products, such as animal feeds, where the products are incorporated under a veterinary prescription as a coincidental service.

The ACVM Group does not consider that persons or organisations engaged in the above activities are trading in PAR products in their own right. The responsibility for the trading remains with the authorised person who retains ownership of the products until the sales transaction is completed.

## Are people or organisations approved as traders?

The ACVM Group will approve 'trading entities'. These may be companies/organisations or individuals. To be approved the entity must:

- have a quality system that governs every aspect (relevant to the particular business being operated) of the ordering, purchase, reconciliation of stocks, storage, security, dispensing, sales transactions, transport and supply of the PAR products they handle;
- specify the person(s) operationally responsible for ensuring the quality system is implemented, particularly in regard to sales transactions and supply;
- specify the retail sites (relative to the person specified as responsible for those sites) at which sales transactions occur.

The approval is contingent on the provision and acceptability of all the above (see page 3).

## What is required to become an approved trader?

The ACVM Group will approve a 'trading entity', which may be an individual or a company/organisation.

Approval will be based on evidence that the entity has:

- the capacity, capability and control to manage PAR products appropriately;
- specified the places where PAR products will be traded, in particular all retail outlets; and
- specified the person(s) responsible for:
  - the trading activity
  - the staff involved in transactions
  - the management of the PAR products.

### Application

Any person or entity wanting to become an approved trader must lodge an application with the ACVM Group. The form can be found on the ACVM Group website ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)).

Lodging the application is a statement of interest and is only the first step. Further information will be required. Receipt of an application form will be acknowledged and arrangements will be made (if considered necessary) to review the operational systems to confirm that the capacity, capability and controls are adequate and appropriate. When providing the ACVM Group with a full description of their business, applicants will have to specify the trading sites and the person(s) responsible for the trading activities relevant to their business.

### Responsible person

Each person(s) specified as responsible will have to be confirmed as 'fit and proper' to hold that responsibility. When that person is not known to the ACVM Group, the minimum requirement for the responsible person will be confirmation that they have no

felony convictions relevant to the responsible control of drugs. This is confirmed via advice from the New Zealand Police. Applicants must lodge a permission for disclosure of information for each person specified as a person responsible for trading activity.

Where persons are already known to the ACVM Group, the Group will advise the applicant whether or not it will require advice from the New Zealand Police to confirm them as fit and proper (see box on page 4).

### Entry

Where an applicant and his or her trading operation is not already known to the ACVM Group, an entry 'verification visit' will be carried out, at the expense of the applicant, by a representative of the ACVM Group.

Approval will be issued upon a satisfactory visit report, confirmation of the fit and proper person status of

each responsible person and notification of trading sites. Any change in the sites, responsible persons or areas of responsibility must be notified to the ACVM Group within ten working days. Failure to do so may result in suspension or withdrawal of the approval.

The following should be noted:

- Although the approval is issued for the trading entity, each person who has been specified as a responsible person must also be confirmed as appropriate.
- Confirmation that a person is fit and proper must be backed up by the trading entity's quality systems that place adequate control in the responsible person's hands.
- The quality system must specify what activities the person is responsible for, e.g. the specific retail sites under that person's responsibility.

## Why must traders be approved by the ACVM Group?

The ACVM Group's interest in trading stems from the restrictions it has imposed on the availability of PAR products. Such products must be held securely and supplied only to people who have the appropriate authorisation and only in accordance with a veterinary prescription, authorisation or instruction.

Approval of 'trading entities' (see article above) is the tool the ACVM Group will use to ensure that PAR products are being managed according to the *ACVM Standard for Prescription Animal Remedy Veterinary Medicines* and the conditions of registration for such products.

The appropriate authorisation for holding PAR products can come only from a registered veterinarian or an approved trading entity. Authorisation for supplying PAR products to end users can come only from a registered veterinarian.

## Who must be approved as 'trading entities'?

The ACVM Group expects the following to apply for approval as a trading entity:

- any organisation (or individual) that establishes and operates a wholesale or retail supply of PAR products to end users;
- any registrant for PAR products who is involved in the distribution and supply of those products to end users.

This gives the Group a more comprehensive picture of the movement of PAR products in the marketplace, and it also recognises that wholesale operations have, very occasionally in the past, filled veterinary prescriptions and supplied PAR products directly to the public. It is expected that, in the future, wholesale operations are likely to be asked to fill veterinary prescriptions or supply PAR products under veterinary authorisations.

In summary, the basic rule is that anyone who offers PAR products for sale to the end user has to be approved by the ACVM Group. Depending on whether or not PAR products are supplied to the public, the following may have to be approved:

- veterinarians who operate a retail outlet supplying PAR products;
- pharmacists who operate a retail outlet supplying PAR products;
- people (including organisations or businesses) who are neither veterinarians or pharmacists who operate retail or wholesale outlets supplying PAR products;
- registrants of PAR products who at any time supply (wholesale or retail) those products to anyone other than a registered veterinarian or an approved trader;

- animal feed manufacturers or feed millers who stock PAR products without specific veterinary authorisations to hold them for use under that veterinarian's direction or prescription.

### Veterinarians

The ACVM Group has advised that all registered veterinarians are already considered to be approved traders (i.e. approved trading entities). Some veterinarians do not operate a retail outlet for PAR products. They only sell products directly to their clients as a result of their veterinary consultations.

They do not involve any other non-veterinary staff in the sales transactions. The contact information associated with their veterinary registration is sufficient for the Group's purposes. Veterinarians who operate in this way do not have to provide any additional information.

Veterinarians who operate retail outlets and/or involve non-veterinary staff in sales transactions must advise the ACVM Group of the name(s) of the person responsible for the retail outlet and for the staff involved in the sales transactions. They must also provide the address of each retail outlet location.

## Operational responsibility

Before approval of a trading entity, the ACVM Group must be confident that the operation will comply with the *ACVM Standard for Prescription Animal Remedy Veterinary Medicines*. The persons specified as operationally responsible for the trading activities must be confirmed as fit and proper persons:

- through a history of acceptable behaviour that is known to the ACVM Group; or
- via the annual re-registration process for veterinarians and pharmacists; or
- if the person is not a veterinarian or pharmacist and not known to the ACVM Group, through the procedure specified in part 2 of the application for approval as a trader (this only involves a check with the New Zealand Police to confirm that the person has no felony convictions relevant to the responsible control of drugs).

The ACVM Group has received applications in which agents were designated as responsible and yet those persons appeared to have no operational responsibility. The ACVM Group will ask for confirmation of operational responsibility for trading activities and for sales personnel if the information provided in the application does not make this obvious.

Management of individuals in accordance with the quality system upon which the approval was granted is the responsibility of the approved entity. Failure to manage PAR products adequately may result in suspension or withdrawal of the approval to trade issued to the entity, limiting further access to the products. The list of approved traders will be public information.

## Advertising PARs

The ACVM *Standard for Prescription Animal Remedy Veterinary Medicines* states that:

A trader may advertise as an approved trader in PAR products and may indicate the types of PAR products stocked.

A trader must not display PAR products in public view.

As a basic principle, a trader should focus any advertising or promotion of PAR products to registered veterinarians who can legitimately prescribe the products. They should provide accurate and technically supportable information about their products that allows prescribing veterinarians to make informed judgements in regard to their use.

It is quite appropriate for traders to provide technical information on products and to foster awareness and understanding of disease conditions or health and production management options directly to end users. In doing this it is reasonable for them to identify themselves or their company with the information and advise that they market a product or products that could be used to treat a particular disease condition or contribute to the management of health or production.

However, they must not promote the products as the preferred choice and must emphasise that end users should discuss treatment options with their veterinarian. They must not offer any purchasing incentives to end users or carry out any advertising campaigns targeting end users or face-to-face contacts with end users to promote particular PAR products.

These requirements relate only to advertising or promoting PAR products directly to the end user.

### Conflicting opinions

Some members of the veterinary profession and other animal health care specialists have argued that the advertising practices of some parties have resulted in serious conflicts between them and their clients who, as a result of the advertising or promotion, demand products that the veterinarians do not consider appropriate under the particular circumstances. This same concern (and for the same reason) has been raised in regard to direct to consumer advertising of human medicines.

On the other hand, some veterinarians, end users, registrants of products, wholesalers and retailers have argued that the ACVM Group's requirements are unnecessarily restrictive. They consider that the prohibition on advertising may deny end users access to products because their veterinarians may be unaware of the products or, for some non-technical reason, would not prescribe some acceptable alternative.

The ACVM Group accepts that both arguments are reasonable and likely to be correct at times.

### Standards

If all parties acted in a responsible manner there would be little need for the ACVM Group to set requirements in regard to advertising. However, experience has shown that such reasonable behaviour does not always prevail.

The ACVM Group's preference is that all parties set standards for responsible behaviour when it comes to advertising PAR products. Some industry associations and the New Zealand Veterinary Association have attempted to establish such a standard, but self-regulation has not always been effective across the wider industry.

The ACVM Group's *Standard for Prescription Animal Remedy Veterinary Medicines* states the expectation that persons authorised to sell PAR products will exercise care not to jeopardise the ability of a veterinarian to prescribe the product considered most appropriate under the circumstances.

However, it recognises that there is often important information that the end user should have access to that could be supplied at the point of sale. The ACVM Group does not consider such information to be advertising.

The ACVM Group reserves the term 'advertising' for promoting a particular product in preference to other comparable products in order to increase the sales of that product. The Group recognises that traders are in business to sell the products they stock. Its restrictions on advertising focus on practices that encourage the end user to demand particular PAR products when the prescribing veterinarian may consider the use of some other PAR product (or not treating an animal at all) is the more appropriate course of action. However, this is only guidance and the ACVM Group intends to adjust the requirements stated in the standard and in the labelling guide to make this clear.

The Group will actively participate in discussions with interested and affected parties to develop any refinements in its standard that make information on products readily available to all parties while protecting veterinary prescription as a mechanism to ensure the most appropriate products are used effectively and safely.

If it is essential that a product not be advertised, the ACVM Group will impose a specific prohibition in the conditions of registration for the product. This prohibition will override the discretion inherent in the guidance provided above.

## Trading in prescription animal remedies: frequently asked questions

### Part A: General

**Q Can the approved trader be a company or does it have to be a specific person?**

The ACVM Group will approve 'trading entities'. These may be companies/organisations or individuals. See box on page 2.

**Q Do all our factory workers and people in distribution depots have to be approved?**

No. You need to specify the responsible person who will control the quality systems for recording and sales of PAR products. If you have several distribution centres, you need to advise us of the address and contact numbers for each site, but you might have only one person who is responsible for the quality systems for all the sites. This is the person who needs to be specified.

**Q Do all our field reps have to be approved?**

No. You need to specify the responsible person who will control the quality systems for recording and sales of PAR products. In most cases, field reps do not sell directly to end users anyway.

**Q Does each staff member operating under the specified responsible person have to be confirmed as fit and proper?**

No. It is expected that the specified person will take responsibility for confirming the appropriateness of staff to deal with PARs. Failure to take due care is a non-compliance issue for the specified responsible person and may result in loss of approval of the trading entity or even prosecution.

**Q Is the approved trader responsible for goods while they are being transported by a courier or other company?**

The trading entity is responsible for the product until the sales transaction has been completed. Consignment of the purchase to a transporter is the responsibility of the trader but the trading entity is not responsible for the actions of the courier or transport company.

**Q Do we have to check that veterinarians buying our products are approved traders?**

No. The ACVM Group has deemed veterinarians to be registered traders. However, you should sight the veterinary registration certificate if the veterinarian is unknown to you.

**Q Do all product registrants have to be approved as traders and complete the fit and proper person part of the application?**

No. If a registrant does not supply to end users, this is not needed. However, registrants who supply their products to end users must specify a person responsible for those transactions to be confirmed as a fit and proper person.

**Q Does the responsible person have to be the person based on the site where we process orders?**

No. The specified responsible person should be the person (or persons) operationally responsible for ensuring the quality system is implemented, particularly in regard to sales activities. This person may be responsible for several sites.

**Q Will there be fees charged for notifying the ACVM Group of responsible persons and trading sites?**

At this stage in the development of the approved trader programme, the ACVM Group is not charging any fees for processing notifications of specified responsible persons and/or trading sites, or for subsequently removing names from the list. The only fees will be for a verification visit (see page 3) if this is considered necessary.

**Q Are traders allowed to hold stocks of specially compounded medicinal preparations and sell them to parties other than the veterinarian who placed the order?**

The ACVM Group's current expectations regarding compounding, which can be found in the draft *ACVM Standard for Unregistered Veterinary Medicines Requiring Veterinary Overview*, are that traders may not hold such stocks. However, consultation on the standard has brought up several issues relating to compounding that require further consideration. For this

visit our website ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)) for information/updates

reason a working party has been set up to examine options. Developments will be advised on the website and in *AgVetLink*. In the meantime, the expectations stated in the standard apply.

## Part B: Veterinarians

### **Q Do all veterinarians have to apply to become approved traders?**

No. All veterinarians have already been deemed to be approved traders. They may hold PAR products under their own authority and enter into transactions to supply PAR products without a specific written prescription from themselves or any other veterinarian. The ACVM Group will use the list of registered veterinarians from the Veterinary Council of New Zealand (VCNZ) to identify all veterinarians who may be trading.

### **Q Are all veterinarians who write prescriptions for PAR products actually trading in PAR products?**

No. Veterinarians who write prescriptions for PAR products but do not supply them directly from their own stocks (i.e. those who write prescriptions to be filled by some other trader) are not considered to be trading in PAR products. They are not directly involved in the supply transaction. They are deemed to be approved traders but that is irrelevant in this case.

### **Q Do all veterinarians in a practice have to be identified to the ACVM Group as a responsible person who manages the supply of PAR products?**

No. It is assumed that all veterinarians

may, under their own authority and based on their own instructions, enter into transactions to supply PAR products. All veterinarians are already known to the ACVM Group via their veterinary registration. It is assumed that almost all of these transactions relate to that veterinarian's own veterinary consultations and treatment instructions rather than in association with the operation of a veterinary medicine trading outlet. Most practices have a senior veterinarian or office manager who should be specified as the responsible person.

### **Q Do individual veterinarians have to contact the ACVM Group and identify themselves as a principal responsible for the management and sale of PAR products?**

No. The ACVM Group has sent letters to veterinary practices asking them to nominate the principal in the practice who is responsible for the management and sale of PAR products. These were sent to practices rather than to individual veterinarians on the assumption that practices are more likely to establish trading outlets specifically to sell veterinary medicines to the public and to fill prescriptions.

Even though the person who is responsible for the management of stock and for the staff who carry out the transactions is a veterinarian, the ACVM Group wants to know about the outlets and who is particularly responsible for the operation. Although more than one veterinarian in a practice will provide for a transaction through an outlet, they are often not equally responsible for the management and sale of the products. It is expected that one person would be responsible for the behaviour of non-veterinary sales staff and the management and security of stock.

Individual veterinarians would not have received the letter sent to practices unless they were identified in the VCNZ

records as being the contact in a practice. This was intentional and, at this stage in the development of an approved trader programme, the ACVM Group is not expecting those veterinarians to provide any information. However, if a veterinarian who did not receive the letter considers that he/she is operating a veterinary medicine trading outlet, then he/she should contact the ACVM Group to discuss adding their name to the ACVM list of principals responsible for trading in PAR products.

### **Q How do non-veterinary members of staff involved in the management and sale of PAR products go about gaining fit and proper person status?**

Only the responsible person in the practice must be confirmed as fit and proper, and that person becomes the approved trader in the practice who takes full responsibility for the trading. This confirmation is only an issue if the specified responsible person is not a registered veterinarian or registered pharmacist (both these groups have to notify convictions in order to be registered and this is considered sufficient). The ACVM Group requires all other responsible persons to be confirmed as fit and proper as per the application documentation (see page 3).

As for staff operating under the control of the specified responsible person, confirming the appropriateness of a person is the responsibility of the specified person. It is expected that the responsible person will be very careful (and have adequate checks in the trading system) to designate only persons who are appropriate to carry out the PAR trading activities in their job descriptions.

Failure to take due care is a non-compliance issue and is a responsibility of the specified responsible person in the practice and may result in loss of approval of the trading entity or even prosecution.

## Animal feed manufacturers

*When prescription animal remedies are incorporated into animal feeds at the point of manufacture, it may be appropriate for the feed manufacturer to be approved as a trader by the ACVM Group. Under other circumstances it may not be necessary. See below.*

### Do all feed manufacturers have to be approved as traders in prescription animal remedies?

No. It is up to individual feed manufacturers to make the business decision to trade in PAR products and to become an approved trader.

### Traders

Any party who intends to stock prescription animal remedies in order to fill veterinary prescriptions must be approved as a trader. This means that

they are intending to stock PAR products under their own authority, speculating that veterinarians may send prescriptions to them to be filled or that members of the public may bring prescriptions to them to be filled. Trading in PAR products would be a stated purpose of their business. Any feed manufacturer who also wants to have a business trading in PAR products must be an approved trader and must apply to the ACVM Group.

### NOT traders

Feed manufacturers who only provide a service of incorporating PAR products into feed but do not intend to set up a PAR trading business do not have to be approved as traders. To make the distinction clear, the feed manufacturer who is only providing a feed mixing

service can hold in stock only the PAR products that are specified in an authorisation to hold particular PAR products issued by a registered veterinarian to fill his/her prescriptions. (Approved traders do not have to have such authorisations.)

### Intent

The ACVM Group considers the intent is sufficiently specific to make it unnecessary for those few feed manufacturers who are simply supplying a mixing service to be approved as traders in PAR products.

If feed manufacturers do not want to become approved traders, they must make it clear in the way that they operate and record their activities that they are providing a mixing service only.

---

## Potential confusion over terminology: ACVM and HSNO legislation

Many PAR products will also be 'hazardous substances' that must comply with controls imposed under the Hazardous Substances and New Organisms (HSNO) Act 1996. While the ACVM Group is working closely with ERMA New Zealand, the regulatory requirements are different under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

### Approved handler requirements

Most PAR products have not been transferred into the main framework of the HSNO Act. However, when they are transferred under the HSNO Act there may be 'approved handler' requirements relating to the safe handling of some products during transport, storage and sale. These are not matters that are managed under the ACVM Act and the approved handler requirement will be irrelevant to the

ACVM regulatory requirements. The ACVM Group does not require traders in PAR products to be approved handlers under the ACVM Act.

Likewise, the ACVM Group is not going to require licensing or approval of persons using PAR products. When prescribing PAR products to be used by non-veterinarians, the prescribing veterinarian must be confident that the person is capable of using the products safely and only according to instruction. The ACVM Group considers this to be adequate management of these products. ERMA New Zealand has yet to decide if it will impose approved handler requirements on persons using particular PAR products.

### Responsible persons versus persons in charge

The ACVM Group will require

approved trading entities to specify the persons in their organisation responsible for particular trading activities. These will be called 'responsible persons'. The responsibility relates specifically to the need to keep the products secure and to supply them only to persons holding a relevant veterinary prescription.

Under the HSNO Act there may have to be a person specified as the 'person in charge' who is responsible for ensuring that the products are transported, stored and handled safely. The 'responsible person' in regard to ACVM matters may or may not be the same person as the 'person in charge' in regard to HSNO matters.

Whether or not both responsibilities are placed with the same person, it must be remembered that the obligations are distinct under the two pieces of legislation.