# Advertising guidelines for products registered under the ACVM Act

ACVM guideline

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## 1. Introduction

The purpose of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 is to:

- manage risks (public health, animal welfare, trade, agricultural security);
- ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards;
- ensure the provision of sufficient consumer information about agricultural compounds.

Conditions are placed on product registrations to help achieve this purpose.

The vast majority of products registered under the ACVM Act have a condition of registration about advertising the product. This condition requires that advertisements do not:

- misrepresent, mislead or make false claims about approved product and manufacturing specifications (for example, what the formulation contains, claims on the labels, storage of the product) and;
- make false or misleading claims about the regulatory status of the product.

Certain types of products, such as restricted veterinary medicines, have other advertising conditions as well.

### PURPOSE AND SCOPE

This document provides guidance to registrants, advertisers, publishers, marketers (including suppliers, retailers, distributors etc) to help you understand requirements for advertising ACVM registered products. It also discusses the difference between advertising and information transfer.

Other legislation, such as the Misuse of Drugs Act, may have advertising restrictions but these are outside the scope of this guideline.

### REFERENCE

Agricultural Compounds and Veterinary Medicines Act 1997 (External website)

# 2. Advertising

The ACVM Act (s 2) defines advertisement as “any publication to the community or to any section of the community of any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device, used to promote the sale of any agricultural compound”.

Publication includes TV, radio, magazines, brochures, books, newspapers, websites (including you tube, Facebook and other web-related media), or any other publication that is or will be generally available to members or sectors of the public.

Promotional material is also considered advertising. This includes any item branded with all (or part of) the trade name. ‘Items’ cover all goods that could be branded with the trade name. Some examples of this are clothing, pens, stationery, vehicles and stickers.

General advice is not considered advertising. However, it is sometimes hard to differentiate between what is considered advertising and what is general advice. Grey areas exist, and these are discussed in the section on information transfer.

# 3. Advertising DOs and DON’Ts

When advertising an ACVM registered product, some things are required, some are permitted, and some are prohibited.

### FULL REGISTERED TRADE NAME

The **full** registered trade name must always be used when advertising your product. This avoids potential compliance issues, as members of the public are easily able to search the register and see that your product is registered. It also avoids confusion with other registered products that may have similar trade names.

### REGULATORY STATEMENTS

You may state that a product is registered under the ACVM Act, but it is not mandatory. As a suggestion, you could use wording such as ‘Registered under the ACVM Act 1997 No. XXXX’, or ‘ACVM Registration No. XXXX’

### CLAIMS

Simply, if a claim requires approval and has been approved, you may advertise it. If a claim requires approval but hasn’t been approved, you must not advertise it. Claims advertised must be consistent with the approved product and manufacturing specifications. This includes approved uses, application rate/method, timing, crop, target pest(s), species, withholding period and so on.

### TESTIMONIALS USED IN ADVERTISING AND PROMOTIONAL MATERIAL

A testimonial may be used if the information in the testimonial is consistent with the approved product and manufacturing specifications (see Claims above). Statements supporting claims that are not approved (but need to be) as part of the registration must not be used.

## COMPARATIVE ADVERTISING

Comparisons with other registered products are permitted, provided that what is being advertised is consistent with label claims of all registered products in the advertisement. Unless unapproved claims are being made, all disputes regarding the nature of comparative advertising must be resolved via the Commerce Commission. Note that comparative advertising may mean that claim-supporting data, which would normally be considered 'commercial in confidence', may become of relevance to the public and subject to release.

## ADVERTISING IN SCIENTIFIC PAPERS, JOURNALS, OR CONFERENCE PRESENTATIONS

Product information that is not consistent with the approved product label may become available as a result of published trial data in a scientific journal (or material of a standard publishable in such a reputable journal). You are not necessarily prohibited from reporting such information in scientific papers or at conferences/seminars. However, information reported in these circumstances **must not** be used for the purpose of advertising or promoting the product. In particular, registrants/ distributors need to take care when involved in such circumstances.

## OVERSEAS CLAIMS

If the label includes a use not relevant to New Zealand (for example, a pest only present in Australia), the advertisement must not state or imply that use is approved in New Zealand.

## RESTRICTED PRODUCTS

If there is a restriction on the product, every advertisement must clearly state the restriction. For example:

- restricted veterinary medicines (RVMs) require an availability statement, such as printing/stating "Only available under veterinary authorisation" (also see RVM section below);
- restricted products available only under an MPI approved operating plan **and** that don't have other advertising restrictions require a statement that accurately reflects the operating plan restriction, for example: "The use of this product must comply with the MPI approved operating plan";
- requirements in any "By law …" statements, such as no off-label use;
- requirements around holding a controlled substances licence (CSL).

## UNACCEPTABLE ADVERTISING

Unacceptable advertising includes:

- the use of generalised pictograms or graphics that do not accurately reflect the bounds of product approval, for example:
  - using a picture of an adult dog and puppy together if the product is approved only for use in animals older than 3 months of age;
  - showing a picture of an apple on the label if the product is only approved as a herbicide in pasture;
  - having a picture of a bunch of grapes infected with botrytis when the product is approved as an insecticide for use in vegetables;
- making specific efficacy claims if only generalised claims are approved (for example, making speed of kill claims for a topical flea product if only a non-specific 'flea kill' claim is approved);

- inaccurately portraying the applicable withholding period (WHP) for any veterinary medicine, but particularly where more than one use pattern and WHP apply (for example, advertising the shorter approved WHP in an advertisement that relates to the product's use pattern that has a longer WHP);
- making claims regarding the safety profile of a product if such claims have not been specifically assessed (for example, stating that a NSAID will not cause stomach ulceration if this has not been specifically addressed in the registration package).

## PROHIBITED STATEMENTS ABOUT REGISTERED PRODUCTS

Prohibited statements include those that:

- are false or misleading;
- have claims that state or imply that MPI/ACVM Group guarantees, warrants, recommends or assures the safety or efficacy of a product (that is, manufacture, quality etc). The Ministry for Primary Industries ("MPI") logo may not be used on advertising material for your product
- imply endorsement by MPI/ACVM Group (that is, you cannot claim 'approval' by ACVM -- you can only state "registered under the ACVM Act"). The sole exception is for agricultural chemicals that are approved for use in Animal Products Act facilities under the Maintenance Compound Approval System. In this case, it is appropriate to use an MPI approval statement as dictated in the guidance for this system.
  Approved maintenance compounds (non-dairy) manual (382 KB PDF)

## PRODUCTS THAT MAY NOT BE ADVERTISED

No advertisement may be made to sell a trade name product:

- that is not registered but should be (if you are not certain, see our website information on class determination);
- that has a provisional registration/research approval or any other approval under special circumstances (the condition of approval in these situations does not permit advertising in any way);
- if the advertising is inconsistent with the current registration (for example, advertising claims not approved on the label, such as off-label claims);
- that has special approvals/conditions, such as those for biosecurity purposes.

# 4. Restricted veterinary medicines (RVMs)

RVMs, including antimicrobials, may be advertised to veterinarians as well as to end users. However, certain exceptions may apply. For example, MPI may prohibit certain products (such as vaccines against exotic diseases) from being advertised.

In addition to the general advertisement guidelines that apply to all registered trade name products, RVMs have the following specific requirements.

## PRODUCT AVAILABILITY STATEMENT

When advertising RVMs, the target audience must have a clear understanding that the product is available only under a veterinary authorisation or an approved operating plan. For products available under veterinary authorisation, the recommended statement is "Available only under veterinary authorisation". The phrase "Restricted Veterinary Medicine" may be included, but it is not required.

For RVMs available only under an MPI approved operating plan **and** that don't have any other advertising restrictions, a statement that accurately reflects the restrictions imposed by the

operating plan must be included. For example, you could say “The use of this product must comply with the MPI approved operating plan”.

### REQUIREMENTS FOR PRODUCT AVAILABILITY STATEMENT

- **For the print media**. The recommended product availability statement must be placed clearly and legibly in the advertisement. This requirement should also apply to brand promotion items (for example, pens and key chains) where space permits. Otherwise, it is acceptable to state only the trade name of the RVM.
- **For the audio media (such as radio).** The recommended statement must be spoken in a manner that can be clearly understood by the listener.
- **For the audio-visual media (such as TV).** The recommended statement must be placed conspicuously and legibly, displayed on the screen long enough to be read by the viewer, and also spoken in a manner that can be clearly understood by the listener.

## 5. Advertising conditions of registration

As discussed above, advertising conditions vary according to the type of product. The following table explains commonly used conditions. (Note this is not an exhaustive list.)

| Number | Condition of Registration | Explanation |
|---|---|---|
| 22 | The product must not be advertised or sold. | This means it is an offence for any person to advertise or sell this product. This condition is mostly used in conjunction with provisional registrations and research approvals. |
| 45 | If the label indicates the product can only be sold to and/or used by a person holding a controlled substances licence (CSL) then:<br><br>Any advertisement or promotion for this product must clearly state that it can only be sold to a person who holds a controlled substances licence. | Applies to vertebrate toxic agent (VTA) products that require a CSL to be held. |
| 46 | If the label indicates the product can only be sold to and/or used by a person holding a controlled substances licence then:<br><br>The product **must not be displayed for the general public to see**. It must be kept secure from unauthorised persons and individual containers marked for trace back purposes. A register of sales must be kept (minimum of 3 years), recording who the product was sold to (controlled substances licence reference) and the container(s) serial identity. | Applies to vertebrate toxic agent (VTA) products that require a CSL to be held. |

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| 66 | No advertisement for the product may:<br><br>(a) include content or be presented in a manner that does not conform to the approved product and manufacturing specifications (this includes approved uses);<br><br>(b) contain false or misleading claims, statements or information in relation to the product; or<br><br>(c) without limitation to the generality of (b), directly or by implication make false or misleading claims or statements about the regulatory status of the product under the ACVM Act. | This condition means that no advertisement may:<br>• differ from that approved in the registration;<br>• make false claims;<br>• mislead people that the product is not registered when it is.<br>The advertisement must not make false statements about the following stated on the label:<br>• claims/uses;<br>• restrictions on who can use it, or how it is used;<br>• legal requirements;<br>• the withholding period. |
| 70 | For the purposes of this condition, 'veterinary authorisation' means that a registered veterinarian with a current practising certificate issued under the Veterinarians Act 2005 has issued a valid authorisation for its purchase and use.<br><br>Any advertisement of this product must contain a statement that the product is available for purchase and use only under and in compliance with a veterinary authorisation. | The advertisement must clearly state the availability restrictions. |

# 6. Information transfer

Advertising does not include general information transfer or disease state awareness, and MPI encourages industry efforts to provide good advice on using agricultural compounds. The question is: When does information transfer become advertising?

## ADVERTISING VERSUS INFORMATION TRANSFER IN PUBLICATIONS

Two of the key factors to consider are vested interest (that is, direct financial gain from the sale of the product) and product specificity, which often go hand-in-hand. If, for example, an industry group publishes a brochure on best practice use of agricultural chemicals, the publication would be considered information transfer. On the other hand, a brochure on the merits of using Product X would likely be considered advertising.

The following will help to determine whether published information is advertising or not:

- **Type of publication**. Generally, information in scientific publication articles would not be considered advertising. On the other hand, articles in a grower/farmer publication are more likely to contain information that would be considered advertising.
- **Content and style of the information**. Does the style extol the benefits of the product rather than provide factual information or information transfer?

- **Author of the information**. Does the author have a vested interest (or is a third party contracted by the vested party)?
- **Owner of the publication**. Does the owner have a vested interest (or is a third party contracted by the vested party)?
- **Payment.** Is payment for the information to appear in the publication made by the person who has a vested interest (or is a third party on behalf of the vested party)?

One, some or all of these factors may need to be considered when determining whether or not the information in the publication is advertising.

## ADVICE

The following examples show the difference between advertising and information transfer in advisory situations. (Note that advising customers to contact the product registrant is another option open to retailers.)

### Agricultural chemical example

If a grower walked into a retail outlet seeking advice on what fungicide would be efficacious for use on blueberries (a minor crop for which there are no registered products), then it would be acceptable for the retailer to give information on what products might be effective.

However, it would not be acceptable in that same scenario if a grower walked into a retail store and saw posters advertising a fungicide for use on blueberries when that fungicide was not registered for that use (that is, advertising an off-label use).

### Veterinary medicine example

A person may require a product to treat intestinal worms in a llama. Registered products for that purpose may not be available, so the person seeks advice from a veterinary medicine supplier. The supplier may advise that Product X could be suitable (that is, provide product information transfer). However, the person choosing to use the product must take ultimate responsibility for ensuring that such use will not harm the animal (directly due to toxicity issues or as a result of failure to treat the problem) or cause residues in the produce (for example, meat) of that animal when sold.

If, following successful use on the llama, the supplier chose to contact all llama farmers and advise that they had Product X available for sale as a llama wormer, such an activity would be considered promotion/advertising of an unregistered claim.

Retailers need to be careful in providing advice for off-label uses. Such advice could be construed to be promotion (that is, advertising) and hence not in compliance with the condition of registration relating to advertising only approved claims of products.

However, we would consider that a retailer responding to a query from a customer about using a product off-label is likely to fall into the category of advice or information transfer. This is not the case if the retailer actively promotes or recommends use of a product outside its label claims without prompting from the end user.

### Risks with off-label use

Any use of a product off-label has the potential to cause residues, animal welfare/plant safety or efficacy issues that were not assessed during the registration process. Therefore, off-label uses should not be advertised. However, we appreciate that for minor crops/species there are not many registered products with approved label claims.

Any person *recommending* use of a product off-label has the responsibility of ensuring that all ACVM Act risks are managed. *Use* of the product off-label requires users to ensure all ACVM risks are managed. Breaching any conditions of registration (for example, exceeding an MRL*) may drastically affect international trade in primary produce. The important point to note is it is the end

user who must comply with conditions of registration, and not the third party recommending off-label use.

* One condition of registration requires the end user to comply with the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards for treated produce whether the use is on- or off-label.

# 7. What happens if advertising is non-compliant?

When it is brought to our attention that anyone is advertising a product in a way that is not consistent with the registration, we will advise them that they may be committing an offence under section 55 of the ACVM Act and will investigate accordingly.

If an advertisement contains any inaccurate or misleading statements or breaches any conditions of registration, we will require the advertisement to be withdrawn or modified to bring it into compliance.

Advertising of a registered product for a purpose that is not consistent with the approved label (off-label claims) or with claims that are false or misleading is an offence under the ACVM Act. If complaints do not relate to areas managed under the ACVM Act, the complainant will be referred to the Commerce Commission.

To avoid potential non-compliance with the ACVM Act, you can have your advertisement reviewed by MPI. Note that costs (calculated on a cost versus time basis) are associated with vetting advertising material.

For more information, contact us (approvals@mpi.govt.nz).