Advertising guidelines for products authorised under the ACVM Act

ACVM guideline (May 2021)

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, and
- ensure the provision of sufficient consumer information about agricultural compounds.

All products meeting the definition of an agricultural compound under the ACVM Act require an authorisation. The two main authorisation mechanisms are registration or exemption from registration via regulations.

As a consequence the term 'authorisation (or authorised)' in this document refers to:

- Products registered under the ACVM Act and claims approved as part of the product and manufacturing specifications (i.e. registered products); and
- Products exempt from registration under the ACVM (Exemptions and Prohibited Substances) Regulations that comply with the scope of the exemption and any conditions placed on that exemption (i.e. products exempt from registration).

Those products registered under the ACVM Act, in the main, 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. In particular, restricted veterinary medicines containing antibiotics have a condition restricting who these products can be advertised to (known as condition 58). Refer section 6 for specific guidance on these products.

Products that are exempt from registration under the ACVM (Exemptions and Prohibited Substances) Regulations are required to comply with Regulation 13 of these Regulations on advertising products exempt from registration. Regulation 13 states that no advertisement or label for any exempt compounded product or compounded veterinary medicine may include any comment, reference, or explanation in relation to the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, proportion, ingredients, or components of the product or preparation, or its effectiveness for any particular purpose, that is inconsistent with the conditions to which that product or preparation is subject under the regulations

Veterinary Consultation

The discussion between the veterinarian and the client on the choice of treatments as part of the veterinary consultation is not considered to be advertising or information transfer.

Purpose and scope

This document provides guidance to registrants, advertisers, publishers, marketers (including suppliers, retailers and distributors), MPI approved resellers, and veterinarians to help all parties understand requirements for advertising of products authorised under the ACVM Act. It also discusses the difference between advertising and information transfer.

Other legislation, such as the Misuse of Drugs Act 1975, may have advertising restrictions but these are outside the scope of this guideline.

References

- Agricultural Compounds and Veterinary Medicines Act 1997
- ACVM (Exemptions and Prohibited Substances) Regulations 2011
- Veterinarians Act 2005
- Veterinary Council of New Zealand's Code of Professional Conduct for Veterinarians

2. Legislation

Advertising of agricultural compounds is regulated under:

1. Agricultural Compounds and Veterinary Medicines Act 1997;
2. Veterinarians Act 2005

3. Veterinary Council of New Zealand's Code of Professional Conduct for Veterinarians
4. Medicines Act 1981
5. Misuse of Drugs Act 1975
6. Relevant consumer legislation such as the Fair Trading Act and the Consumer Guarantees Act

3. 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, newsletters, newspapers, podcasts, flyers, websites and social media apps (including You Tube, Facebook and other web-related media), or any other media that is or will be generally available to members or sectors of the public.

Community in this context refers to the public, or sections of the public. This means private discussions over an agricultural compound on one to one or few would not normally be considered community. However, private discussions must be consistent with the conditions (controls) placed on the agricultural compound.

Advertising may include any item branded with all (or part of) the trade name. Some examples of these items include merchandising such as clothing, pens, stationery, vehicles and stickers. For requirements regarding restricted veterinary medicine antibiotic, please see section 5.

General advice is not considered advertising. However, it is sometimes challenging to differentiate between what is considered advertising and what is general advice, so this area is covered in more depth in section 9 Information Transfer.

4. Advertising DOs and DON'Ts

Authorised products include trade name products with an ACVM registration number (typically veterinary medicines, agricultural chemicals and vertebrate toxic agents), and products authorised by exemption from registration. This guideline covers advertising of any authorised product.

Please note section 5 has additional guidance for restricted veterinary medicines (RVMs), whilst section 6 outlines requirements for RVMs containing antibiotic.

Trade name

The complete trade name of the product must be used when advertising your product. In the case of a registered product, the trade name must be identical to that specified on the ACVM public register. This avoids confusion with other products that may have similar trade names and helps in searching for trade name products on the ACVM public register.

Family brand

A family brand is a marketing practice involving the use of a single brand name for the sale of two or more related products. Any advertisement must not mislead or create confusion about specific claims etc. for individual trade name products. For example, family brand 'X' relates to 10 products and 5 have a claim for cats and dogs, while the other 5 only have a claim for dogs. The advertisement must not infer all 10 products can be used on cats. Advertising seeking to differentiate between claims for registered products should use the individual trade names.

The advertisement must state the registration numbers for all relevant individual trade name products under the family brand.

Regulatory statements

For registered products, you must state that the product is registered under the ACVM Act in New Zealand. For example, 'ACVM Registration No. (A/P/V)XXXX'.

For products exempt from registration (i.e. it has no ACVM registration number) you may state the product is exempt from registration under the ACVM Act. For example 'Exempt from registration under ACVM Act 1997'. Note: You must not state or imply a MPI ACVM registration status (of any product and/or claims) for products that are exempt from registration

Claims

Claims advertised must be consistent with those authorised for that product. This includes:

- formulation ingredients;
- label information such as uses, application rate/method, timing, crop, target pest(s), species, withholding periods and so on.

Testimonials used in advertising and promotional material

A testimonial may be used only if the information in the testimonial is consistent with authorised product claims.

Comparative advertising

Comparisons with other authorised products are permitted, provided the advertisement is consistent with claims of all authorised products in the advertisement. Comparative advertising is also subject to other legislation.

Scientific papers, journals, or conference presentations

Presentation of trial results of a product that are not consistent with its authorisation, in a scientific journal or equivalent type publication are not considered to be advertising. Rather it is considered to be information transfer.

However, there is a responsibility to ensure the type of publication is appropriate for the publishing of the trial results, meaning some publications could be considered an advertising rather than

information transfer forum. For example, a factor to consider would be the target audience for the publication and its publisher.

For further information on information transfer refer to section 9.

Overseas claims

For a harmonised product label that 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.

Where the same product is also marketed overseas with uses not approved in New Zealand, the advertisement must not state or imply such uses are approved in New Zealand.

Registered products with specified limitations

Certain registered products have conditions of registration that place controls, such as who can use it, where it can be used, or how it could be used. (Note: requirements for restricted veterinary medicines are covered separately). Every advertisement must clearly state these limitations. For example:

- Registered products are 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).

Internet and Websites

Online search engines

There are two relevant aspects when a person uses an online search engine. These are:

- the information retrieved; and
- sponsored/paid for advertisements associated with the search results

Search engines often rely on the metadata associated with a website and therefore, it is important that the terms used for the metadata will not lead to results being returned that display information inconsistent with the conditions of registration. The same requirements apply where the sponsored/paid content is displayed in the associated search results.

This is particularly important for RVMs containing antibiotic (refer to section 6).

Websites

Marketers (such as registrants) of authorised products must ensure their website is compliant with requirements in this document. This is especially pertinent to New Zealand based websites including search terms.

Listing authorised products on a website irrespective of whether a price is included is not considered to be advertising (see Listings and Price Lists section below).

There are extra requirements for RVMs containing antibiotics, refer to section 6.

The above requirements for search engines and websites relate to organisations that are responsible for creating and maintaining them covered by NZ law. Overseas websites can only be included on product labels or advertisements if all content of the website is consistent with the product registration or exemption conditions.

Social media and other platforms

Marketers (such as registrants) of authorised products must ensure any of their advertisements is compliant with requirements in this document. This includes (and is not limited to) Facebook, Twitter, YouTube, TradeMe etc.

Listings and Price lists

Generally product listings of and price lists for authorised products are not considered advertising. Any information that may be associated with both situations should be limited to either information from the label or the label itself. Use of superlatives or comparison claims with either would be considered advertising. Price lists can be both paper and electronic format, including being listed on websites.

A price list for unauthorised product(s) may be sent to distributors/retailers (including registered veterinarians, RVM resellers) under certain circumstances without being considered advertising. Sending out a price list for unauthorised product(s) to end users (eg farmers) is not acceptable.

There is further information on Listings and Price Lists under section 8 on Human Medicines used as Veterinary Medicines and Compounded Veterinary Preparations.

Unacceptable advertising

Examples of unacceptable advertising includes, but is not limited to:

- the use of generalised pictograms or graphics that do not accurately reflect the bounds of the authorisation, 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 authorised product, 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

Prohibited statements include those that:

- are false or misleading
- have claims that state or imply that MPI/New Zealand Food Safety/ACVM team guarantees, warrants, recommends or assures the safety or efficacy of a product (that is, manufacture, quality etc.). The MPI and/or New Zealand Food Safety logos must not be used on advertising material for your product
- imply endorsement by MPI/New Zealand Food Safety/ACVM team (that is, you cannot claim 'approval' by ACVM -- you can only state it is authorised (see earlier section on registration statements). The sole exception is for agricultural chemicals and vertebrate toxic agents 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. For further information please see Requirements for dairy maintenance and cleaning products and Approved maintenance compounds (non-dairy) manual

Products that must not be advertised

No advertisement may be made to sell a product:

- that is not authorised but should be (if you are unclear, see our website information on class determination), taking into account the section above on Listings and Price Lists
- 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)
- that is a compounded veterinary preparation or prescription human medicine authorised by a veterinarian for use as a veterinary medicine for patients under their care.
- that has special approvals/conditions, such as those for biosecurity purposes.

5. Restricted veterinary medicines (RVMs)

RVMs are registered products that require a veterinary authorisation before they can be administered or sold to an end user. RVMs containing antibiotics cannot be advertised to end users. There may be other situations where a RVM is prohibited from being advertised at all (such as vaccines against exotic diseases).

In addition to the general advertisement guidelines that apply to all authorised 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 RVMs available under a veterinary authorisation, the recommended statement is “Available only under a veterinary authorisation”.

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 (including electronic such as newspapers and magazines). The 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) if space permits. Otherwise, it is acceptable to state only the trade name of the RVM.

For the audio media (such as radio, podcasts). The statement must be spoken in a manner that can be clearly understood by the listener.

For the audio-visual media (such as TV, smartphone apps, podcasts). The 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.

For social media (such as Facebook, Twitter, YouTube). The 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.

6. Restricted Veterinary Medicines containing antibiotics

There are extra requirements for RVMs containing antibiotics.

These products have a condition of registration (condition 58 – see section 7 for details of the condition) which means advertising of the product must not be targeted at end users such as farmers or pet owners. This condition was introduced to help enable judicious use of antibiotics (with a focus on the management of antibiotic resistance) and good product stewardship.

This condition means that any advertising of RVMs containing antibiotic can only be directed to registered veterinarians, or persons or organisations holding an ACVM approval to trade in the product (MPI approved RVM resellers).

It is acceptable for registrants and veterinarians to provide product label information and safety data sheets to end users such as farmers and pet owners following veterinary authorisation. Also refer to section 9 on information transfer.

Requirements for publications

Advertising RVMs containing antibiotic should be directed to registered veterinarians or an individual/organisation that has an ACVM approval to trade in the product. For example, VetScript or Hoofprint (the NZVA Dairy Cattle Veterinarian quarterly newsletter) are directed at veterinarians. Whilst these publications could be sighted by non-veterinarians, the intended target audience is clearly veterinarians.

Good judgement must be used when directing advertising to the veterinary target audience. This could include contacting the publisher on publication readership and other market research.

If there is a reasonable potential for the publication to be seen by end-users such as farmers, then the advertisement should not be placed in the publication. Examples of publications that are not specifically directed at veterinarians include Farmers Weekly and the NZ Dairy Exporter.

Requirements for websites

Advertising of these products must be restricted to those persons for which advertising is permitted (i.e. not to the end user). For example, advertising on registrant, distributor, third party websites, RVM resellers or veterinary websites could be limited to veterinarians and or persons holding an ACVM approval to trade in the product via a password protected area of the website.

Online search engines should not (or at least minimise this as much as possible) return results for these products.

Registrant websites may contain safety data sheets and label information on RVMs containing antibiotics that can be accessed by end-users. See section 8 below in information transfer.

Requirements for social media and other platforms

As advertising of these products must be restricted to those persons for which advertising is permitted (i.e. not to the end user), it is important that only the appropriate persons have access to the social media and other platforms. If this is not possible, then advertising of these products must not occur.

Requirements for Merchandise

Merchandising items (e.g. clothing and pens) that are marked with an RVM containing antibiotic trade name would be considered as advertising. Ensuring these merchandising items are not directed to non-approved parties is a requirement under condition 58.

Product availability statement

These are the same as stated above for RVMs.

Requirements for product availability statement

These are the same as stated above for RVMs.

7. Conditions of Registration relevant to advertising

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: 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: 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.
58	Advertising and promotion must only be directed to registered veterinarians or persons with an ACVM approval to trade in this product.	Applies to RVMs that contain antibiotics.
66	No advertisement for the product may: (a) include content or be presented in a manner that does not conform to the approved product and manufacturing specifications (this includes approved uses) (b) contain false or misleading claims, statements or information in relation to the product, or	This condition means that no advertisement must: differ from that approved in the registration make false claims.

	(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.	The advertisement must not make false statements about the following stated on the label: claims/uses restrictions on who can use it, or how it is used legal requirements the withholding periods.
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. 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.

8. Human Medicines used as Veterinary Medicines and Compounded Veterinary Preparations

Human Medicines used as Veterinary Medicines

Advertising of human medicines for use on animals is not acceptable. However, a product listing and price list of human medicines would not be considered advertising, on the condition that no accompanying material on its use as a veterinary medicine is present.

Compounded Veterinary Preparations

The advertising of a compounded veterinary preparation is not acceptable. A listing or price list of compounded veterinary preparations is not acceptable.

9. Information transfer

Advertising does not include general information transfer or disease state awareness. It is important industry provides good advice on using agricultural compounds and veterinary medicines. It is necessary to understand when information transfer become advertising.

Advertising versus information transfer in publications

Two of the key factors to consider are:

1. Vested interest (e.g. direct financial gain from the sale of the product); and
2. Specifying a trade name product.

These factors often go hand-in-hand. If, for example, an independent research industry group publishes an evidence-based brochure on best practice use of agricultural chemicals or veterinary medicines without referencing any specific trade name products, the publication would be considered information transfer. On the other hand, a brochure solely promoting the merits of using Product X would be considered advertising.

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

Type of publication. Generally, information in scientific publication papers/articles would not be considered advertising. On the other hand, articles in a grower/farmer publication endorsed by a registrant, are more likely to contain information that may 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? Is there an educational element that helps improve product stewardship, diagnosis, or crop and animal health outcomes?

Author of the information. Does the author have a vested interest (or a third party contracted by the vested party) rather than providing impartial and evidence based best practice information?

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.

It should be remembered that a publication includes speaking and therefore, when communicating at a field day, or specific forums like conferences, care must be taken to avoid drifting into advertising of a product.

Incentives such as 'Farmers win your dry cow antibiotic therapy purchase price back' and giveaways are not considered appropriate product stewardship for RVMs containing antibiotics.

Information transfer on restricted veterinary medicines containing antibiotics

It is recognised there will be situations (that are not considered to be part of a veterinary consultation) where the end users such as farmers need information about treatment options that specifically relate to use of antibiotics. This means information transfer should reference the appropriate use of antibiotics and not specific trade name products. This may occur as veterinary newsletters or social media contact, at farmer field days, on the registrant's website, or specific forums for end users.

What is considered acceptable information transfer can also be dependent on the forum.

Examples of what may be acceptable for general information transfer include:

- information on how an active ingredient works and when it would be appropriate to use it.
- general information on how antibiotics are classified for educational purposes.
- surveillance data on antibiotic sensitivity in NZ dairy herds.

Any materials intended for end users or to which end users might be exposed, should not reference information such as links to the internet (based in New Zealand or overseas) that the use of trade name products containing antibiotics.

Websites advertising RVMs containing antibiotics (including products for purchase) in accordance with Condition 58 should be managed so access is restricted to veterinarians and/or those with appropriate ACVM approvals.

Provision of Advice

NOTE: End users and retailers are advised to contact the product registrant if additional information is required regarding product use.

The following examples show the difference between advertising and information transfer in advisory situations.

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 compounds might be effective. The retailer can then direct the grower to products containing those compounds.

However, the person choosing to use the product must take ultimate responsibility for ensuring that such use will not harm the crop (directly due to toxicity issues or as a result of failure to treat the problem) or cause residues in the produce when sold.

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

An animal owner may require an over-the-counter (OTC) product to treat intestinal worms in their llama. Registered OTC products for that purpose may not be available, so the person seeks advice from a veterinary medicine supplier. The supplier may advise that compound x would be suitable for llamas, and Product Y contains that compound (that is, providing 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 must not be advertised.

MPI appreciates that for minor crops/species there are not many registered products with approved label claims. Therefore:

- Any person (this could include a veterinarian[1]) *recommending* use of a product off-label has the responsibility of ensuring that all ACVM Act risks are managed. In addition, the person in charge of the animals also has some responsibilities.

- *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 and/or pose a food safety risk in treated 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.

Data supporting off-label use or associated information must not state or imply this use is approved in New Zealand.

* There is a condition of registration that requires the end user to comply with the Food Notice: Maximum Residue Levels for Agricultural Compounds for treated produce whether the use is on- or off-label.

10. What happens if advertising is non-compliant?

When it is brought to MPI's attention that anyone is advertising a product in a way that is not consistent with the authorisation, we will investigate accordingly.

Where a breach is identified, MPI will require the non-compliant party to cease, withdraw, or modify the advertisement to bring it into compliance.

If complaints do not relate to areas managed under the ACVM Act, the complainant may be referred to the Commerce Commission.

It is an offence under section 55 of the ACVM Act to knowingly contravene any condition applied to the authorisation of a product.

To avoid potential non-compliance with the ACVM Act, you can request MPI review your advertisement. Note that costs (calculated on a cost versus time basis) are associated with providing advice on advertising material, and there is no statutory time frame.

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

[1] The veterinarian may also have obligations under the VCNZ Code of Professional Conduct