



## VETERINARY MEDICINES: DOES YOUR PRODUCT REQUIRE REGISTRATION?

A veterinary medicine or veterinary product requires registration if it fits the definition of a veterinary chemical product. Section 5(2) of the *Agvet Code* states that:

'...a veterinary chemical product is a substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:

- preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or
- curing or alleviating an injury suffered by the animal; or
- modifying the physiology of the animal so as to alter its natural development, productivity, quality or reproductive capacity or so as to make it more manageable; or
- modifying the effect of another veterinary chemical product.'

Therefore a product requires registration if it makes a **claim** that fits the definition of a veterinary chemical product, or it contains **ingredients** that are used for a purpose that fits the definition of a veterinary chemical product, or both.

### What claims are likely to require that a product be registered?

Any claim that the product is intended to modify the health, production, performance or behaviour of animals, whether made on a label, advertisement, website, or any other representation, will render the product liable for registration.

These claims apply whether the product achieves its effect by absorption, injection, ingestion, inhalation, or application to any part of an animal's body.

### What ingredients are likely to require that a product be registered?

- chemicals or chemical products declared by the Regulations to the *Agvet Code* to require registration (see below);
- active constituents already approved by the APVMA; and
- chemicals which in the opinion of the APVMA are normally used as veterinary chemical products. These are dealt with in more detail below.

## What are the “declared” veterinary chemical products?

Declared veterinary chemical products are those which are declared to be so by the regulations of the AgVet Code. They include:

- allergenic substances supplied for administration or consumption by an animal;
- medicated licks or blocks;
- enzymes supplied or used for administration or consumption by an animal;
- direct fed microbial products;
- sheep branding Substances;
- Stockfeed non-active constituents unless those non-active constituents are included in an Order ([“The Stockfood Non-active Constituents Order”](#)) in the Regulations to the Agvet Code.

Note also:

- even if a stockfeed constituent is listed in the above Order, it cannot be regarded as a non-active constituent if it is included at a level that has biological or other effects; in these cases the constituent is an active constituent and the product is a veterinary chemical product.
- Several permits are in place which allow supply and use without registration of stockfeed non-active constituents that are veterinary chemical products (that is, they are not included in the above Order). These include (as at October 2010) permits 10987, 11051 and 10753 (zeolites).

## How can I find out whether an active constituent is approved by the APVMA?

This can be found by searching the Public Chemical Register Information System (PUBCRIS) on the APVMA website:

<http://services.apvma.gov.au/PubcrisWebClient/>

By typing in the active constituent, the PUBCRIS database will show whether the active constituent has been approved.

## What about substances that in the opinion of the APVMA are normally used as veterinary chemical products?

By way of example, antibiotics, anaesthetics and many other classes of chemical are only used for therapeutic purposes. These medicines cannot be marketed with the therapeutic claims deleted, in an attempt to avoid registration.

APVMA scientists understand that some substances are only used as veterinary chemical products in certain situations. These types of chemicals will be assessed on a case-by-case basis, and may require registration.

## Where can I find written information on product registration requirements for specific product types?

The APVMA website has considerable information at the following locations:

<http://www.apvma.gov.au/registration/>

<http://www.apvma.gov.au/publications/guidelines/>

[http://www.apvma.gov.au/morag\\_vet/](http://www.apvma.gov.au/morag_vet/)

### **Nutritional products**

In general, nutritional claims will not result in a requirement for registration, but this depends on the type of claim being made. More information can be found in a Gazette notice at:

[http://www.apvma.gov.au/publications/guidelines/docs/gl\\_08\\_stockfeed.pdf](http://www.apvma.gov.au/publications/guidelines/docs/gl_08_stockfeed.pdf)

Inclusion of some nutrients at or above a certain level may be considered to have therapeutic rather than nutritional purposes. These products are referred to as “nutraceuticals”. Such products require registration.

### **Herbal and other natural medicines**

Herbal and other natural medicines, therapies or remedies for use in/on animals require registration in Australia.

### **Homeopathic medicines**

Homeopathic medicines, therapies or remedies for use in/on animals require registration in Australia. However the manufacturers of such products are exempt from the requirement for a manufacturers license.

### **Sperm and ova products including semen extenders**

In general, products that do not contain antibiotics, or that contain antibiotics in amounts less than or equal to 0.01% total antibiotic concentration do not require registration if they do not make a therapeutic claim. More information can be found in an operational notice at:

[http://www.apvma.gov.au/registration/morag/notices/op\\_notice\\_sperm\\_ova.php](http://www.apvma.gov.au/registration/morag/notices/op_notice_sperm_ova.php)

### **How can I get APVMA assistance to tell me whether my product requires registration?**

In order to establish whether a product is a veterinary medicine by representation or function, you must provide APVMA with a copy of the intended market label and a copy of any advertising claims from printed or website material, plus a copy of the full formulation. Note that the APVMA is committed to maintaining commercial confidentiality for material submitted to it.

You must ensure that any confidential information supplied is clearly identified as such and clearly identifies the name and street address of the owner of such information. The APVMA will normally respond to requests for advice presented on this form in the same medium used to send in the request.

Should you require specific advice regarding your product, complete the Registration Requirement Advice Request Form (below) and email it to [vetmedicines@apvma.gov.au](mailto:vetmedicines@apvma.gov.au)

**NOTE:** This form must not be used for the reconsideration of existing registered products. If you wish to enquire about the need to continue to register a particular product, write to the Program Manager, Veterinary medicines Program, APVMA at the contact address below.

*No advice will be given unless this form is completed.*

Return this form either by email to [vetmedicines@apvma.gov.au](mailto:vetmedicines@apvma.gov.au), by fax to (02) 6210 4741 or by mail to:

**Vet Contact Officer**  
**Australian Pesticides and Veterinary Medicine Authority**  
**PO Box 6182**  
**KINGSTON ACT 2604**

## REGISTRATION REQUIREMENT ADVICE REQUEST

I wish to request specific advice to assist in determining whether my product is a veterinary chemical product as defined in the Agvet Code.

<b>Name of person seeking advice:</b>	
<b>Contact details including full street address, phone, fax and e-mail:</b>	
<b>Name of product:</b>	
<b>Purpose of product (ie what is it used for?):</b>	
<b>Species the product will be used in/on:</b>	
<b>Other product details:</b>	

Please supply a complete list of **ingredients** in the table below. The concentration must add up to 100% and the purpose in the formulation must be provided.

<b>Constituent (common chemical name)#</b>	<b>Compendial Standard or manufacturing specification</b>	<b>Concentration [g/kg or g/L] (including overages)</b>	<b>Purpose in the formulation</b>	<b>Other comments</b>
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### Active constituent/s


### Other constituent/s


# Australian approved names should be used where they exist

### Claims

Please include a copy of the label and advertising claims with your completed form and if advertising is on the website please include a hyperlink.