

# ACVM Group info on:

## animal welfare concerns

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### Animal welfare

One of the risk areas managed by the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 is animal welfare. The ACVM Group, which administers the Act, considers animal welfare concern (defined in terms of *unnecessary* pain or distress) when determining how much regulation is needed for a product.

### Regulatory control

In one way or another, the ACVM Group assesses the impact of using a veterinary medicine product on the treated animal. Consideration of a product from an animal welfare perspective requires balancing harms to benefits. For example, a product may be toxic or cause undesirable side effects, resulting in pain or distress, but the benefits to the animal may be sufficient to outweigh some pain or distress.

Regulatory control of efficacy can be justified if a product's failure to do what is claimed would result in the treated animal suffering significant pain or distress. On the other hand, if there are no ill effects if the product does not work, regulatory control of efficacy cannot be justified.

When deciding on regulatory control, the determinant factor will be the severity of the pain or distress that the product is intended to prevent or alleviate. The following definitions are used.

- **Mild pain or distress** is insufficient to alter normal behaviour except in a very transient way. The animals are easily distracted from the pain or distress.
- **Moderate pain or distress** does not prevent normal behaviour but the animal remains aware of the pain or distress and is not easily distracted.
- **Severe pain or distress** debilitates the animal and prevents normal behaviour.

### Product inefficacy

When considering animal welfare risks from inefficacy of a trade name product, clinical signs of pain or distress must be at least *moderate* to prompt welfare concern. Conditions for which the clinical signs are no more than *mild* pain or distress, and for which there are alternative products available, would not prompt regulatory animal welfare concerns because judgements can be made or advice taken about the appropriateness of a particular product for a particular animal.

Therefore, welfare concern is based partially on the ability of persons to observe clinical signs and take action to alleviate pain or distress, and partially on the ability to take the time to choose between products or take advice on products, without compromising the welfare of the animal.

### Efficacy studies needed

Trade name products that are promoted or sold to prevent, treat or cure any condition that is commonly characterised by at least moderate pain or distress, especially if clinical signs can develop rapidly, must be efficacious. Therefore, efficacy information must be considered when assessing such products for registration.

Where specific tolerable endpoints for efficacy have been specified in ACVM efficacy standards, data must confirm that those endpoints will be achieved. Where tolerable endpoints for efficacy are not specified, data must show that a treated animal is better off (alleviating clinical signs, or preventing, treating or curing the condition), having taken into consideration the pain or distress caused by the treatment. Where efficacy information is not provided to support the claims to prevent, treat or cure a condition of welfare concern, a product will not be registered. Adequate efficacy information must be provided at the time an application is lodged or the application will not be processed.

### Efficacy information not required

The ACVM Group recognises that there are other conditions that are usually characterised by only mild pain or distress and there is time to choose between alternative products to achieve the most relief for the treated animal(s). There are also products that are used on animals to achieve an effect (e.g. oestrus control) that has nothing to do with treating conditions of animal welfare concern or alleviating clinical signs of pain or distress. Therefore, products marketed to treat such conditions are not of animal welfare concern in regard to their efficacy, and efficacy information will not be required.

It must be noted that, even though efficacy would not be relevant to registration under the ACVM Act, failure to

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

support claims of efficacy for such products may result in breaches of the Fair Trading Act 1986.

### Examples of conditions of welfare concern

The following examples of conditions of welfare concern can be characterised by at least moderate pain or distress

and commonly by severe clinical signs. Clinical signs can also develop very quickly, providing no opportunity to make judgements about alternative products. NZFSA considers that efficacy information would be required in all cases for registration of products marketed for use to prevent treat or cure any of the conditions in the box below.

- Any parasitic (internal or external) infestation characterised by at least moderate pain or distress and which can escalate to more severe clinical signs +/- shock;
- Any gastro-intestinal disorders characterised by any of the following: abdominal pain, distension, tympani, vomiting, diarrhoea, unusual peristalsis or physiological dysfunction;
- Any urogenital disorders characterised by any of the following: pain, distension, anuria, obstruction or physiological dysfunction;
- Any in utero condition that causes post-natal pain or distress in the offspring;
- Any respiratory disorders characterised by any of the following: pain, compromised respiration, coughing, compromised oxygen/carbon dioxide exchange or physiological dysfunction;
- Any musculoskeletal disorders characterised by pain or compromised movement;
- Any cardiovascular disorders characterised by any of the following: pain, compromised oxygen/carbon dioxide exchange (either general or localised), compromised blood flow (either general or localised), or physiological dysfunction;
- Any central nervous system disorders characterised by any of the following: pain, irritation (either general or localised), compromised senses (either general or localised), disorientation or motor dysfunction;
- Any neoplasia characterised by any of the following: pain, compromised physiological functions or homeostasis, compromised immunity or resistance to secondary infections (either systemic or localised);
- Any immune system disorders characterised by any of the following: pain, compromised immunity or resistance to secondary infections (either general or localised), irritation (either general or localised), or auto-immune reactions;
- Any disorders of the eye or conjunctiva characterised by any of the following: pain, spasms, intra-ocular pressure, or unusual lacrimation;
- Any disorder of the middle or inner ear characterised by pain or loss of hearing or balance;
- Shock;
- Any trace element or nutrient deficiency requiring parenteral administration of the deficient element, nutrient or precursor to alleviate pain or distress;
- Trauma characterised by at least moderate pain or distress;
- Any behavioural condition resulting in hypersensitivity, marked irritability or anxiety, or self-mutilation;
- Any skin abnormality characterised by pain or distress or which compromises the integrity of the skin as a barrier to disease;
- Most infectious diseases.

### Where can I get more information?

For more information visit the ACVM Group website ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)) or contact the ACVM Group directly at:

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If you are interested in general ACVM information, you can subscribe to the ACVM Group's free newsletter, *Agvetlink*, which is also available on the website.

Comments on discussion documents or any other matter related to agricultural compounds and/or veterinary medicines are always welcome.