

**ACVM GROUP OPERATIONAL POLICY -
TOXICOLOGICAL DATA REQUIREMENTS
FOR ANIMAL REMEDY APPLICATIONS
WHERE THE ACTIVE INGREDIENT IS
ALSO IN A MEDICINE THAT HAS BEEN
GIVEN CONSENT UNDER
THE MEDICINES ACT 1981**

1 BACKGROUND

The Animal Remedies Board is required to assess the safety of an animal remedy that is the subject of an application. This has been translated to mean that data is requested to cover:

- safety to people (residues);
- safety to the environment (ecotoxicity considerations);
- safety to the user (Occupational Safety and Health requirements); and
- safety to the animal (target animal safety).

In the past, the applicant has been required to provide toxicology data to support the application to assess the product safety. It is the applicant's responsibility to either:

- supply the toxicology data; or
- provide a cross reference for the toxicology data; or
- advise of another regulatory source of the toxicology data that can be legitimately and readily accessed by the Board.

Where a product has already been assessed under the Medicines Act 1981 (i.e. given consent under sections 20, 21 and 22), and the product is not going into the food chain, there is an opportunity to expedite the licensing process and to reduce costs to applicants while still covering the Animal Remedies Board considerations for the safety of the product.

1.1 Rationale

1.1.1 Safety to people

Where the product is not being used in the food chain (e.g. it is intended for use only in companion animals such as cats and dogs), residues are not of interest.

The use of a remedy on food-producing animals raises the question of residues and possibly also the need for a Maximum Residue Limit. Even when residues are not detectable, an assessment as to the acceptability of residues at the limit of detection is required, and this acceptability can only be determined when an acceptable daily intake (ADI) has been estimated. The ADI can only be determined from a full toxicology data package; hence the toxicology waiver could not be given if food-producing animals are to be treated with the proposed remedy.

1.1.2 Safety to the environment

If products are used only on non-food-producing animals, with the exception of disposal of unused product, environmental issues are not significant.

1.1.3 Safety to the user

While the Animal Remedies Board could require the applicant to provide a clearance from the Ministry of Health - Therapeutics Group, confirming that they had no objection to licensing the product as an animal remedy, the Ministry of Health evaluation would be unlikely to take into account the inadvertent nature of any exposure of humans to animal remedies compared with the intentional nature of exposure to a person taking medical treatment. They would also be unlikely to consider the potential hazards to the humans using the remedy on animals. Thus, such a clearance would not satisfy the requirement that the Board consider if the remedy is a danger to public health (Section 21(2)(d) of the Animal Remedies Act 1967).

An evaluation is not necessary if the labelling requirements that will apply to all such products provide adequate human safety information. The National Poisons Information Centre will already be aware of the product as a human medicine and they will be able to advise on the hazards and a recommended treatment regime in the event of human exposure.

1.1.4 Safety to the animal

There will need to be target animal safety data provided to the level specified in the current *ACVM Registration Standard and Guideline for Target Animal Safety*.

1.1.5 Other considerations

The criteria for deciding if the animal remedy should be classified as a Prescription Animal Remedy will apply, and if the human medicine is a Prescription Medicine, the animal remedy will automatically be a Prescription Animal Remedy.

If the data on an active ingredient in the animal remedy is subject to the 5-year data protection period under the Medicines Act and toxicology data was included in this protection, then the Board will require a letter of consent from the owner of the data. Technically, such a requirement would seem to be unnecessary because the Board would not be seeking to cross reference toxicology data in any case. However, avoidance of requiring such a letter of consent would undermine the data protection provided by the Medicines Act because the animal remedy licence would be granted on the basis of the Medicines Act consent which was given on the strength of the data submitted to the Ministry of Health.

If an applicant seeks a licence for a generic animal remedy, and the licensed product is still under data protection, a letter of consent from the licensee of the licensed remedy will also be required in line with current Board policy. If a letter of consent was not required, the proposed policy would undermine the data protection provisions of the Animal Remedies Act.

1.2 Purpose

The purpose of this policy is to establish the toxicological data requirements for animal remedy applications where the active ingredient is also in a medicine that has been given consent under the Medicines Act 1981

2 POLICY

2.1.1 Where an animal remedy licence application is for a product that contains the same active ingredient as a medicine that has already been given consent to be sold under the Medicines Act 1981, the requirement for toxicology and ecotoxicology data to support the application will be waived, provided the applicant can confirm that:

- the product is not to be used in food-producing animals;
- the toxicology data on the active ingredient is not subject to data protection under the Animal Remedies Act 1967;
- the active ingredient is not subject to data protection under the Medicines Act 1981;
- target animal safety data is provided to the level required in the standard;
- the National Poisons Information Centre has been notified of the product; and
- the product label will include the statements as detailed below.

All other established Animal Remedies Board policies applicable to the application remain in force.

If the above requirements are met, the product label must include the following statements:

Keep out of reach of children.
(In a prominent place on the label)

Exercise care in using this product.

Avoid accidental exposure, wash hands and exposed skin after use.
(Under a heading "Precautions")

Disposal: Do not dispose of this product onto drains, sewerage systems, or water-bodies. Dispose of in municipal waste or contact the manufacturer* or your local authority for further information.

First Aid: If exposure occurs, seek medical advice.

* Note that the actual name of the manufacturer and/or a contact telephone number can substitute for the words "the manufacturer" if the applicant so wishes.

3 REFERENCES

ACVM Registration Standard and Guideline for Target Animal Safety
Animal Remedies Act 1967
Medicines Act 1981