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ACVM Labelling and Advertising Guide for Veterinary Medicines Requiring Registration

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Endorsement:

Date:

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ACVM Labelling and Advertising Guide for Veterinary Medicines Requiring Registration

1 Introduction

This document sets out the requirements for label content of veterinary medicines in accordance with the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, and the ACVM Group's expectations regarding advertising and promoting products.

The ACVM Act emphasises a shift from compliance with the label to placing 'conditions' on registration. These conditions will direct a registrant as to the specific statements that must appear on the label. **(The word 'must' indicates a mandatory requirement. 'Should' is used where some flexibility is allowed.)**

The ACVM Group approves label content only as it relates to the ACVM Act to ensure compliance with these registration conditions. This approval does not include any specific requirements under other relevant legislation that may affect the label, eg Hazardous Substances and New Organisms (HSNO) Act 1996 and accompanying Regulations, but there has been an effort to ensure that requirements do not conflict. The ACVM Group will advise on label content to ensure that sufficient information is provided to allow the product to be used safely and effectively. However, it is the applicant's responsibility to comply with all other relevant legislation.

This document contains:

- a section covering the items that must appear on the label of all veterinary medicines
- a section containing additional items that must appear under certain circumstances
- a section detailing the ACVM Group's policy on advertising and promotion under the ACVM Act.

Labels of agricultural compounds and veterinary medicines that are exempt from registration under the ACVM Act must be factual, scientific and must not mislead. All these labels must comply with the requirements as outlined in Regulation 6 of the ACVM Regulations 2001.

Where a mandatory requirement is stated, the labelling guide must be followed unless a waiver has been granted by the ACVM Group.

1.1 Scope

This document must be followed by all registrants of trade name products where a condition on the product registration states that compliance with the labelling guide is required.

This document covers specifications for:

- mandatory label information for all veterinary medicines
- mandatory label information for specific circumstances
- advertising and promotion policy
- general labelling advice.

1.2 Definitions and abbreviations

Active ingredient: The chemical(s) in a formulated product that is (are) principally responsible for the biological effects.

Advertisement: 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*; and 'to advertise' has a corresponding meaning (ref: section 2 ACVM Act). Advertising does not include general information transfer or disease state awareness.

Anthelmintic: A chemical that, when administered to animals by any means, will reduce or control their internal parasitic population.

Broad spectrum: Controls or is toxic to a wide range of pests when applied correctly.

Label: Any written, pictorial or other descriptive material (including cartons, vials, leaflets), affixed to or contained in or on the packaging, which gives information about the veterinary medicine that is to be marketed or sold.

Label content: The content of the label as required under the ACVM Act and Regulations.

Outers: Outer containers used for shipment of products from one destination to another.

Parasiticide: Any veterinary medicine used for the control of internal and/or external parasites.

Primary label: The label on the container that is in physical contact with the veterinary chemical product, eg bottle, blister pack, tube, syringe etc.

Secondary label: The label on the packaging in which the primary container is enclosed for sale, eg the immediate packaging around the bottle, blister pack, tube, syringe etc.

Withholding period: The minimum period that should elapse between the last treatment and collection of produce for human consumption in order to meet the relevant maximum residue limit (MRL).

1.3 References

ACVM Registration Information Requirements for Veterinary in New Zealand

Booklets to be read in conjunction with this document:

- The Commerce Commission has drafted a guide for manufacturers and distributors on environmentally friendly claims and the Fair Trading Act
- HSNO Labelling Guide (when completed)
- OSH: refer to the Dangerous Goods (Labelling) Regulations 1978

2 Labelling Guide for Veterinary Medicines Requiring Registration

2.1 Mandatory label information for all veterinary medicines requiring registration

Labels must be factual, scientific and must not mislead. All veterinary medicine labels must include the following information:

- The statement: “FOR ANIMAL TREATMENT ONLY”
- Trade name
- Active ingredient(s)
- Therapeutic or clinical claim(s)
- Directions for use
- Registration statement (including registration number)
- Registrant’s name and New Zealand agent if the registrant resides overseas
- Batch number
- Expiry date
- Net contents
- Storage instructions
- Adverse effects, cautions and contraindications.
- The following sections set out requirements for each of these items.

2.1.1 “FOR ANIMAL TREATMENT ONLY”

This statement must appear on all labelling. It should appear below the ‘Schedule Heading’ (if required by relevant legislation) and/or above the ‘Trade Name’ where this is possible.

2.1.2 Trade name

- The full chosen trade name, as specified on the application form, must appear clearly.
- The trade name should be placed below the “FOR ANIMAL TREATMENT ONLY” statement.
- The trade name should be consistent throughout the label.
- The trade name must not be identical to the active ingredient name, eg not Levamisole but Levamisole Purple.

- Wherever any trade name appears on the label, the full trade name should be used.
- The chosen trade name must be obvious especially when it occupies more than one line.
- Any product description must be distinctly separate from the trade name.

2.1.3 Active ingredient(s)

The name of any active ingredient(s) must appear on the label as either:

- the International Standards Organisation (ISO) common name/International Nonproprietary Name (INN) or
- the full chemical name in cases where a common name has not yet been approved.

2.1.4 Therapeutic or clinical claim(s)

All labels must have accurate and objective claim(s). This must reflect the conditions related to the end use on the registration. The claim(s) should, where possible, specify all the species of animal for which the product is specifically approved. These claims should appear near the 'Trade Name' and 'Active Ingredient(s)'.

Labels must be factual, scientific and must not mislead. Advertising type words and superlatives should not be contained on labels.

Labels must refer only to diseases/parasites that occur in New Zealand. For the purposes of harmonisation with Australia, diseases/parasites occurring in Australia may be included accompanied by a disclaimer, for example: "This disease/parasite does not occur in New Zealand".

2.1.5 Directions for use

Directions for use must be simple, clear and concise. Where a specific dose is recommended, the label must indicate the dose rate per unit liveweight, eg mg/kg. (This may not always be applicable, eg supplements.)

Directions for use must include:

- dose rates or use levels
- the route, timing, frequency of application
- duration of treatment, and
- other information that may affect the efficacy and safety of the product.

Where a specific injection site is required to be stated on the label, it will be stated as a condition on registration.

Refer to section 2.2 for special requirements for labelling in specific circumstances.

2.1.6 Registration statement (including registration number)

The registration statement (including the registration number) must appear on all labelling and is generally located near the bottom of the label. The standard statement is: “Registered pursuant to the ACVM Act 1997, No....”

This standard statement may be shortened to “ACVM No. ...” on very small containers such as vials, sachets etc.

Labels are required to include the statement: “See www.nzfsa.govt.nz/acvm for registration conditions.”

2.1.7 Registrant/New Zealand agent

The registrant’s full name must appear on all labelling. Where the registrant is not a New Zealand company or individual, the New Zealand agent’s full name must also appear on all labelling.

Where another company name appears on the labelling, in addition to the registrant, (eg manufacturer, distributor etc) the words “Registered to ...” must appear before the registrant’s name to identify the registrant.

2.1.8 Batch number

This label requirement is the number or letter (or combination) by which the manufacturer uniquely identifies each production batch and should be preceded by the words “Batch number (or No.)” or the symbol “B” or another appropriate indicator that can be understood.

2.1.9 Expiry date

All labels must show the expiry date that relates to the approved shelf life for the formulation. This is the date (month and year) after which the product should not be used. The shelf life will be stated as a condition on registration.

2.1.10 Net contents

Net contents of the product(s) must be stated in metric units, for example:

- g (gram)
- kg (kilogram)
- mL (millilitre) or
- L (litre),

and must be clear and readable.

Where units of veterinary medicines are individually packaged (eg tablets in foils or blisters, vaccine vials, bottles of product) and then included in multiple numbers in containers, the actual number of individual units included per container does not need to be stated on the label approved by the ACVM Group provided the container in which the individual units are sold does not contribute to the stability profile of the product. In consequence, where changes are made to the number of individual units included per container no formal ACVM approval is required provided there are no changes to the individual unit or ACVM-relevant approved label text.

2.1.11 Storage instructions

These are instructions regarding storage that are necessary to ensure the stability of the product, for example:

- “Store below 30°C.”
- “Store in a dry place.”
- “Keep tin closed.”
- “Keep away from light.”

Any mandatory storage instructions will be stated as a condition on registration.

2.1.12 Adverse effects, cautions and contraindications

Registrants must state possible adverse effects, cautions and any contraindications of significance on labels. Adverse effects, cautions and contraindications relate to safety and/or efficacy of a product. Examples of each are given below. Those that are compulsory in certain circumstances are listed in this document. Others will be stated as conditions on registration, for example:

- “This product can cause anaphylactic shock.” (adverse effect)
- “Use with care in animals with renal failure.” (caution)
- “Not for use in lambs under 15 kg bodyweight.” (contraindication)

It should be noted, however, that those adverse effects, cautions or contraindications stated as registration conditions may not form an exhaustive list and the registrant may add others.

2.2 Mandatory label information for specific circumstances

Specific labelling requirements are mandatory in certain circumstances such as the following:

- Withholding periods
- Prescription Animal Remedy (P.A.R) statement

- Misuse of Drugs Act requirements
- Parasiticides
- Anthelmintics for sheep, goats and cattle
- Selenium products
- Oral copper-containing veterinary medicines
- Injectable veterinary medicines and intravenous infusions
- Products containing ionophores
- Hormonal growth promotants (HGPs)
- Bloat remedies
- Pour-on formulations
- Labelling of dry cow products
- In-water and in-feed medications
- In-use stability statement for multi-dose vaccine vials
- HSNO requirements (the ID regulations – priority and secondary identifier information for hazardous substances).

For further information on these requirements see the Annex, which will be updated as needed (<http://www.nzfsa.govt.nz/acvm/>).

Other product specific conditions may be placed on the registration.

2.3 Labelling of packaging

2.3.1 Primary and secondary container labelling

Where the product is packaged within secondary packaging, all labelling must comply with the minimum requirements of the relevant legislation.

2.3.2 Outers

The following wording must be shown on outers:

- trade name
- New Zealand registrant
- registration statement and number
- net contents

- active ingredient(s).

2.3.3 Labels of restricted size

Vial labels must show the following information:

- trade name
- registration number
- net contents
- P.A.R Class I, II or III
- batch and expiry date.

For labels of reduced size, the registration number and P.A.R Class I, II, or III statement may be omitted provided that these are conveyed on outer packaging labels, and the product is not marketed as a separate unit. The reduced size label must, however, contain the active ingredients in addition to the trade name and a suitable phrase consistent with the P.A.R statement.

2.3.4 Labelling of combined product

It is acceptable for two registered products to be sold in 'convenience packs' where the registered products are sold bound together by outer packaging without specific ACVM approval. Both products must be sold in their registered packs with all approved label text and in full compliance with the conditions of registration. Any external packaging used must contain at minimum all relevant information that is required for outer packaging as per section 2.3.2. In addition, where the external packaging obscures the approved product packaging, including information necessary for the consumer to access when deciding upon an appropriate product selection, this information must be included on the external packaging.

3 Advertising and Promotion

3.1 Compliance with conditions

All product registrations (or as a condition on an exemption from registration) shall have a condition imposed to the effect that any advertisement, by any person, of the product must comply with the relevant ACVM labelling guide and, if a registered product, be consistent with any specific advertising conditions on the registration.

3.2 Websites

The only websites that may be referenced on the approved label content and in an advertisement for a registered product are those where the content of the website is under the complete control of the registrant. The registrant who uses a website to advertise a product will be responsible for ensuring that the advertisement is consistent with the registration or the conditions on the exemption from registration. Any third party who advertises a product via a website will be held responsible for the compliance of that advertisement.

3.3 Reference to registration

No advertisement for a trade name product may make reference to the registration of that product, except for the statement that it has been registered under the ACVM Act.

3.4 Restrictions on use

Where there are restrictions on the use of a trade name product, every advertisement of that trade name product shall contain a statement to that effect.

3.5 Products that may not be advertised

No advertisement may be made for a trade name product:

- that is not registered but is required to be, or
- that is subject to a provisional registration/research approval if the product is not a registered product, or
- that is subject to a provisional registration/research approval and is a registered product where the advertisement is inconsistent with what is already approved in the full registration, or
- where the advertising is inconsistent with the current registration, or
- where the advertising is inconsistent with the conditions imposed on an exemption from registration under the ACVM Regulations 2001.

3.6 Imminent registration

Where registration is imminent, ie only administrative approval remains to be undertaken, advertisement or promotion may be undertaken with the written permission of the appropriate ACVM Decision Maker, via the ACVM Group. This permission is likely to be given only under exceptional circumstances, eg for presentations to professional bodies, scientific forums etc.

3.7 Claims exceeding approval

Claims published in advertisements must not exceed those that have been approved during the registration of the trade name product or exceed the use(s) specified in the relevant exemption from registration.

3.8 Compliance

Where an advertisement contains any inaccurate or misleading statements or contravenes any conditions of registration or exemption from registration, the person advertising the product shall modify the advertisement in such a manner as to be in compliance. The ACVM Decision Maker may require that every subsequent advertisement to be published by the offender in relation to that trade name product be submitted to the ACVM Decision Maker for prior approval.

3.9 Diseases/parasites not present in New Zealand

Where any part of an advertisement includes reference to diseases/parasites that do not occur in New Zealand, a disclaimer for those diseases/parasites must be included in the advertisement.

3.10 Registration statement

Every advertisement for a registered trade name product must contain the registration phrase:

“Registered pursuant to the ACVM Act 1997 No....” with the registration number to be included in the phrase.

In the case of radio advertisements, where it is difficult for the listener to retain a letter/number sequence, it is considered acceptable to exclude the registration number from the above statement so it will read: “Registered pursuant to the ACVM Act 1997”.

Advertisements in print must include the full registration statement with the registration number. Advertisement in all other media (television, website, etc) that contain a visual component must include the full registration statement, including the registration number.

3.11 Prescription Animal Remedies

Every advertisement for a veterinary medicine that has been classified as Prescription Animal Remedy (P.A.R) veterinary medicine must contain the appropriate PAR phrase for that product.

The appropriate phrases are:

“Prescription Animal Remedy (P.A.R) Class I. For use only under the authority or prescription of a veterinarian.”

“Prescription Animal Remedy (P.A.R) Class II. For use only by, in the presence of, or under the control of a veterinarian.”

“Prescription Animal Remedy (P.A.R) Class III. For use only by a veterinarian.”

Advertising or promotion activities (ie activities that encourage the sale of a particular trade name product) for PAR veterinary medicines should be directed toward veterinarians who can legitimately prescribe the products. Advertisers should provide accurate and technically supportable information about the products to allow prescribing veterinarians to make informed judgements regarding their use.

An approved trader may advise the types of PAR veterinary medicines they stock.

PAR products must not be displayed in public view, prompting the interest of purchasers.

It is appropriate for traders to provide technical information on products and to foster awareness and understanding of disease conditions or health and production management options. (Such information transfer is not considered advertising in this context.) In doing this it is reasonable to identify themselves with the information and to inform that they market a product or products that could be used to treat a particular disease condition or contribute to the management of health or production.

A trader may advertise or promote (including offering purchasing incentives) PAR products to end users where advertising or promotion is not likely to jeopardise the risk management role of the prescribing veterinarian. For example, advertising would be acceptable if the veterinarian’s risk management involvement is in relation to how or when a PAR product should be used (eg oestrus synchrony products) rather than deciding if a particular product should be used (eg disease treatment products). In all cases, the person must emphasise that end users should discuss treatment options with their veterinarian. This distinction will require discretionary judgement from the person based on the type of product. If in doubt, the ACVM Group will offer its opinion.

For trade name PAR products that must not be advertised to end users (eg antibiotic products and anabolic steroids), the ACVM Group will expressly state that prohibition in a condition on the

registration. This means that there is no discretionary judgement to be made. The products must not be advertised or promoted, and no purchase incentives may be offered.

When such a condition has been applied to a PAR product, the following activities are **not** defined as advertising and are considered acceptable by the ACVM Group:

- the use of product brand names and trade names on merchandise such as pens, jotter pads, calendars and whiteboards
- including trade names, MSDSs, graphics of the label and product pack shots on company websites that are accessible to the public.

3.12 Human medicines

No human medicine may be advertised for use on animals.

3.13 Offences

Where it is brought to the attention of the ACVM Group that any party is advertising a product in a way that is inconsistent with the registration, or the conditions on exemption from registration, the ACVM Group shall advise that party of the inconsistencies in their advertisement with that product's registration, or ACVM Regulations 2001 and/or ACVM Act. They will be advised that they may be committing an offence under section 55 of the Act.

3.14 Assessment service

The ACVM Group will provide a service to assess advertisements and give advice to parties who are unsure if their advertisement conforms to the product's registration. Obtaining the ACVM Group's advice on advertisement is not compulsory. Where advice is requested, the requester will be charged on an hourly basis.

3.15 Other relevant legislation

Registrants will be referred to ERMA NZ (www.ermanz.govt.nz) for the advertising requirements imposed under the Hazardous Substances and New Organisms Act 1996. Both the ACVM Group and ERMA NZ requirements should be met. However, the ACVM Group will enforce only the requirements imposed under the ACVM Act.

Note: Under the ACVM Act there is no specific section regarding the advertising of trade name products. Section 23 Conditions on trade name products (1) (d) states that: "The Director-General may register a trade name product in accordance with section 21, subject to all or any of the following conditions: (d) A condition specifying the labelling, advertising, or other information requirements for the trade name product."

4 General Advice for Labelling Veterinary Medicines

The registrant should ensure that the label complies with other relevant legislation, such as the Fair Trading Act and the HSNO Act, and that the product does not infringe on any proprietary rights, eg trademarks, patents.

4.1 Pictograms and graphics

In addition to written precautionary advice, pictograms (giving a pictorial representation of a subject) may be used on labels. If they are employed they should be added to the base of the label.

Preferred pictograms to use are those developed by the FAO. Appropriate information on them may be obtained from the FAO website:

(<http://www.fao.org/ag/agp/agpp/pesticid/code/download/label.doc> - A pictogram is a symbol).

Graphics may be included on labels but the registrant should ensure that they do not interfere with the legibility of the text. Pictures or illustrations must not depict or imply usage contrary to the current approval.

4.2 Colouring

Colours are often used on labels and they can assist the readability of the text. However, some colour combinations are easier to read than others. An indication of good and bad colour combinations is given below:

Good colour combinations	Don't use these
Black on yellow (best)	Yellow on black
Green on white	White on red
Red on white	White on green
Blue on white	White on black
White on blue	Red on yellow
Black on white	Green on red
	Red on green (worst)

Generally, dark prints on a dark background and light prints on a light background should be avoided.

4.3 Reprinting

Before reprinting ensure that the label still complies with ACVM requirements by referring to the latest ACVM labelling guide.

ANNEX:

Mandatory label information for specific circumstances

Contents

1. Withholding statements
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13. In-water and in-feed medications
14. In-use stability statement for multi-dose vaccine vials
15. HSNO requirements (the ID regulations – priority and secondary identifier information for hazardous substances)

1 Withholding statements

Withholding statements may take the form of withholding period statements or exclusion statements. Withholding periods must appear on all labelling where such a withholding period has been set. A withholding statement must be included for every edible tissue (meat, milk, eggs, honey) as appropriate for all label species.

Regulatory statements such as 'Do not use' must not be used in place of a label withholding period for any product bearing claims for use in animals that produce meat, milk or eggs for human consumption. Where acceptable residue data or technical argument is not supplied to enable a withholding period to be set for each potential edible commodity, the relevant standardised default withholding period must be stated on the label. This rule does not apply to pre-ruminant animals and current 'Do not use' statements will continue to apply.

Any non-regulatory withholding time or recommendation (eg wool residues) must not be represented as a regulatory withholding period and must be clearly separated from any regulatory periods that apply.

All withholding period statements must stand out and be separate from the main body of the text.

Approved wording or equivalent wording is required as follows:

1.1 Meat withholding periods

Statement: "Animals (or specific species where WHP is species stratified) producing meat or offal for human consumption must not be sold for slaughter either during treatment or within ... days of the last treatment."

The meat withholding statement must appear on at least one labelling component where practicable. It is acceptable for vial labels to condense withholding period information to:

"Withholding periods: Meat: eg

Cattle...days/weeks

Sheep...days/weeks

Pigs...days/weeks"

1.2 Milk withholding periods

Statement: "Milk intended for sale for human consumption must be discarded during treatment for not less than X milkings or approximately (X*12) hrs following the last treatment."

The **entire** milk withholding statement must appear on at least one labelling component where practicable. It is acceptable for vial labels to condense withholding period information to:

“Milk withholding period (or WHP): X milkings (X*12 hours).”

1.3 Egg withholding periods

Statement: “Eggs from treated birds must not be sold for human consumption for ... days following the last treatment.”

1.4 Antimicrobials for bobby calves

All sulphonamides and any antimicrobial drug indicated for use in calves must carry the following statement on the label: “Not for use in bobby calves.”

If the indication for an antimicrobial is for adult cattle, the following statement must appear on the label: “Not for use in bobby calves.”

1.5 Other

For any injectable long-acting product intended for subcutaneous administration only and for which intramuscular residue data has not been assessed by the ACVM Group and factored into the calculation of the withholding period, the following label statements will be required:

“Ensure injection is subcutaneous. Intramuscular injection will result in prolonged residues. Where intramuscular injection may have occurred, animals producing meat and offal for human consumption must not be sold for slaughter within 91 days of the last treatment.”

Other withholding statements may apply depending on the type of product, for example:

- “Not for use on lactating dairy cows (dry cow products).”
- “Not for use in horses for human consumption.”

2 Prescription Animal Remedy (P.A.R) statement

If a product is a Prescription Animal Remedy, the class of P.A.R into which it falls will be stated as a condition. The label must contain the appropriate P.A.R statement (see below):

“Prescription Animal Remedy (**P.A.R**) Class I. For use only under the authority or prescription of a veterinarian.”

“Prescription Animal Remedy (**P.A.R**) Class II. For use only by, in the presence of, or under the control of a veterinarian.”

“Prescription Animal Remedy (**P.A.R**) Class III. For use only by a veterinarian.”

The abbreviation ‘**P.A.R**’ must appear in bold print. The prescription statement should be placed in the vicinity of ‘Directions for Use’.

3 Misuse of Drugs Act requirements

The Misuse of Drugs Act 1975 and Regulations 1977 apply to veterinary medicines that contain substances scheduled in the Act. Regulation 25 states the requirements, including the one stating that labels have (in the upper part of the Principal Display Panel):

- a scheduling statement (eg CONTROLLED DRUG [B2]);
- the general nature of the remedy
- the name of the controlled drug
- directions for use
- the name and address of the manufacturer, packer or seller.

4 Parasiticides

In addition to general claims, species and strains of parasites for which efficacy is claimed must be listed on the label where size permits and on the leaflet where label size restricts the length of text. Specific claims regarding effects on resistant species must be noted if these have been supported by objective data.

The terms ‘Broad Spectrum’ and ‘Wide Spectrum’ may be used, provided claims for control of an acceptable number of economically important New Zealand parasites have been approved, and the group names of the parasites are listed on the label.

While label wording must not contain superlatives, including inferences of superiority over other similar products, wording relating to the best use of the product is permissible, for example:

“For the best results, dip sheep 6 to 8 weeks after shearing.”

Label dose tables must not refer only to stock type (eg lamb, hogget) without bodyweights.

Dose recommendations for bodyweight steps for lambs and sheep must be in multiples of 5 kg or 10 kg increments.

4.1 Anthelmintics for sheep, goats and cattle

All labels for anthelmintics for sheep, goats and cattle must contain, at a minimum, the following statements:

- “(Name of product) contains (name of active ingredient), a member of the (*name of the anthelmintic group*) family of chemicals.”
- “It is effective against sensitive strains of the following internal parasites (list of scientific and common names used in New Zealand and Australia).” Parasites not occurring in one of the countries should be marked with an asterisk, for example: “* not present in New Zealand.”
- “Resistance may develop to any chemical.”
- “Correct drenching technique should be used.”
- “Ask your local veterinary practitioner or animal health adviser for recommended parasite management practices for your area to reduce development of resistance.”
- “It is advisable that a resistance test be conducted regularly when using any parasite treatment.”

Applicants may propose additional wording specific to their products in addition to the above statements. Labels may also show claims that a product is effective against resistant parasites, provided convincing data are presented to satisfy registration requirements.

The dose rate of anthelmintic for sheep, goats and cattle is to be expressed as x mL per y kg bodyweight. Dose volume tables are to be shown for cattle up to 650 kg and sheep up to 75 kg.

All labels of LEVAMISOLE drenches must contain the following statements:

- “Doses of 3 or more times those recommended can cause symptoms of Levamisole toxicity, so estimate liveweights carefully.”
- “Dehydrated animals may be more susceptible to toxicity.”
- “Fatal interactions may occur between Levamisole and Organophosphate dips.”

4.1.1 Sheep and goats

Labels must also include dose/volume tables with increments of 5 or 10 kg of bodyweight for animals up to 75 kg bodyweight. The following statements must appear after the dose/volume tables:

- “Animals heavier than 75 kg to be dosed at x mL per y kg.”
- “A representative sample of animals should be weighed before treatment.”
- “Dose the mob to the heaviest animal by liveweight in each group (ewes, wethers, rams, lambs); (bucks, does, kids). Do not underdose.”

- “Where there is a large variation in size within the group, dose rate should be based on the label directions for each weight range. Drafting into two or more lines may be appropriate, to avoid excessive overdosing.”

4.1.2 Cattle

Labels of products for cattle must include dose/volume tables with increments of no greater than 50 kg of bodyweight up to 650 kg bodyweight.

The following statements must appear on the labels after the dose/volume table:

- “Cattle heavier than 650 kg should be dosed at x mL per y kg
- “A representative sample of animals should be weighed before treatment either with scales or a weighband.”
- “Dose rate to be based on heaviest cattle in each group (bulls, cows, steers, calves etc). Do not underdose.”
- “Where there is a large variation in size within the group, draft into two or more lines based on bodyweight, to avoid excessive overdosing.”

5 Selenium products

The following information must be printed on the labels of products containing selenium:

1. The dose rate of selenium.
2. The word ‘selenium’ in **BOLD PRINT**, except for products containing 3 mg/kg or mg/L of selenium or less.
3. The statement or similar: “Do not use at the same time as any other selenised fertiliser, prill or product and do not exceed the stated dose or frequency without consulting a veterinarian.”

6 Oral copper-containing veterinary medicines

The following statement must appear on labels for all oral copper-containing veterinary medicines that are for use in sheep and are over the counter products (OTCs).

“Caution: In sheep, liver levels of copper may be quite variable. Consequently, there is always a risk of copper-poisoning (death) occurring following copper supplementation in this species.”

7 Injectable veterinary medicines and intravenous infusions

Where significant site reaction is likely, the following label statement or similar must be used:

“There may be pain and prolonged inflammatory reaction at the injection site.”

8 Products containing ionophore

All ionophore product labels must include the following statement (or similar): “Do not use on horses or dogs as fatal toxicosis may result. Ensure recommended doses are not exceeded. Care must be exercised when feeding concurrently with other antimicrobials.”

Where the concurrent use of specific antimicrobials (eg tiamulin, erythromycin) or use in certain animal species (eg adult turkeys) are a known contraindication for a particular ionophore type (eg monensin, lasolacid), it must be stated on the label of any product containing them.

9 Hormonal growth promotants (HGP)

In addition to standard labelling requirements, the following compulsory label statements must be prominently displayed in the accompanying package insert and/or other packaging of a hormonal growth promotant:

- “Use of this product in animals other than beef cattle is strictly prohibited.”
- This product must not be used in cattle producing or intended to produce milk for human consumption.”
- “For food safety reasons, cattle must be implanted only under the skin of their ears.”
- “Treated cattle must be identified at the time of implantation, and remain so identified for the rest of their lives with the NZFSA-sanctioned means of identification.”
- “Removal of this identification is strictly prohibited.”
- “Use of this means of identification for any other purpose is strictly prohibited.”
- “Subsequent purchasers of stock must be informed of the above requirements.”
- “Failure to abide by conditions outlined in the packaging, package insert or accompanying NZFSA-approved leaflet could result in prosecution and fines of up to \$100,000 and could expose the export and domestic food industry to unnecessary trade risks.”

The following compulsory label statement must be prominently displayed on all outer packaging that represents the smallest saleable unit: “All users must read and abide by their obligations in the accompanying NZFSA leaflet.”

10 Bloat remedies

Labels of detergent-based bloat remedies must contain the following warning: “Traces of detergent-based bloat remedies may be toxic to calves especially pre-weaning. Wash mixing buckets and containers thoroughly before reusing.”

11 Pour-on formulations

If data have not been supplied to show that the formulation is rainfast, the following statement (or words to the effect) must be added to the label: “Do not use if rainfall is pending.”

12 Labelling of dry cow products

Labels for dry cow intramammary products must contain the following standardised labelling statements:

- “Dry cow therapy should be used at drying off only.”
- “Treatment to be at least ‘x’ days before calving.”
- “If calving occurs within ‘x’ days of the last treatment, milk to be sold for human consumption may be taken only after the full ‘x’ days from treatment and a further 8 milkings have elapsed.” (Note: ‘x’ is the ACVM approved treatment to calving or pre-natal treatment interval.)
- “Lactating cow products should be used if retreatment is required during the dry period.”
- “Milk (colostrum) from the first 8 milkings after calving should be prevented from directly entering the human food chain.”

13 In-water and in-feed medications

The labels of in-feed and in-water veterinary medicines must carry a sufficient amount of information to ensure animals undergoing treatment receive the required daily dose. Minimum information to be included is:

- a dose rate for each label species, eg in mg/kg, and

where feed or water inclusion rates are recommended a statement that they are based on the notion that animals have a certain assumed intake, and should be adjusted as necessary to achieve the required dose rate where intakes vary from that assumed.

Where sufficient information is provided to show the product is not absorbed significantly and efficacy is based only on the concentration in ingesta not on a mg/kg dose rate, an in feed inclusion rate alone may be considered sufficient information to provide accurate dosing. This will be considered on a case by case basis for individual products.

14 In-use stability statement for multi-dose vaccine vials

Where no in-use stability data is or has been supplied at the time of registration for non-Clostridial multi-use vaccines, where appropriate the following statement will be required: “Unused vaccine must be discarded within 12 hours of opening.”

For Clostridial vaccines, a similar statement limiting the period of use to the next day (maximum 36 hours) may be included instead. Advice regarding appropriate resealing practices including at minimum the removal of the delivery tube, disinfection of the stopper and storage of the vaccine in a refrigerator must also be stated on the label.

15 HSNO requirements

The HSNO Act applies to veterinary medicines that contain substances that meet the thresholds specified in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. The following labelling information is required under the HSNO Act:

- Priority identifiers: (Signal words, for example: Dangerous Poison, UN/EU pictograms:
- Secondary identifiers: (Substance name, New Zealand contact details, nature of all toxic and ecotoxic hazards-warning/precautionary statements [eg harmful if swallowed, avoid skin contact], identification and concentrations of toxic ingredients).

For precise labelling requirements under the HSNO Act, please contact ERMA New Zealand (<http://www.ermanz.govt.nz>).