Ministry for Primary Industries
Manatū Ahu Matua

ACVM Requirement

Labelling Veterinary Medicines

ACVM Labelling Requirements for Veterinary Medicines Requiring Registration

26 April 2017

Issued under the Agricultural Compounds and Veterinary Medicines Act 1997

New Zealand Government

TITLE

ACVM Requirement: Labelling Veterinary Medicines

COMMENCEMENT

This ACVM Requirement comes into force on 26 April 2017

REVOCATION

This Requirement revokes and replaces Labelling Veterinary Medicines, issued 6 May 2014.
It revises clause 1.14.1 and some numbering in the previous version.

ISSUING AUTHORITY

This ACVM Requirement is issued under section 10 of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997

Dated at Wellington this 26th day of April 2017.

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(acting under delegated authority of the Director-General)

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Contents

Page

Introduction

This introduction is not part of the ACVM Requirement but is intended to indicate its general effect.

Purpose

(1) This document specifies the ACVM requirements for label content of veterinary medicines that must be registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Background

(1) Before being imported, manufactured, sold or used in New Zealand, agricultural compounds (including veterinary medicines) must be authorised under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. Authorisation is required:

a) to manage risks to trade in primary produce, public health, animal welfare, and agricultural security
b) to make sure that the use of agricultural compounds does not result in breaches of domestic food residue standards, and
c) to ensure the provision of sufficient consumer information.

(2) Authorisation of veterinary medicines usually takes the form of a product registration, and approval of label content related to the ACVM Act risk areas is part of that registration. MPI approves label content only as it relates to the ACVM Act to ensure compliance with the relevant registration condition (that is, "The product must be labelled in accordance with the product and manufacturing specifications approved as part of this registration").

(3) This document sets out the generic and some specific requirements for label content of veterinary medicines requiring registration under the ACVM Act. The word 'must' indicates a mandatory requirement if flexibility will not normally be allowed unless MPI grants a deviation. 'Should' is used if you are allowed some flexibility in the wording to meet the needs of harmonised labels (see Part 4) or to improve readability in a particular circumstance.

(4) This document includes guidelines intended to provide examples and more detailed information. The guidelines reflect the principles accepted as appropriate to achieve compliance. MPI does, however, recognise that alternative methods are capable of achieving the desired outcome. Guidelines are within the text boxes and do not form part of the requirements.

Who should read this ACVM Requirement?

(1) This ACVM Requirement applies to:

a) all persons registering veterinary medicines in New Zealand
b) all persons acting as consultants for registering veterinary medicines in New Zealand.

Why is this important?

(1) If you fail to comply with this requirement, your application for product registration will be declined.

Contacts

(1) If you have any questions, contact us (approvals@mpi.govt.nz).

Other information

(1) This document does not include any specific conditions or controls imposed under other relevant legislation that may affect the label (for example, the Hazardous Substances and New Organisms

[HSNO] Act 1996, and accompanying Regulations, Misuse of Drugs Act [MODA] 1975, or the Fair Trading Act 1986).

(2) For labelling requirements under the HSNO Act and the MODA, contact the Environmental Protection Authority (EPA) (http://www.epa.govt.nz/) and the Ministry of Health (http://www.moh.govt.nz/) respectively.

(3) In order to meet all the statutory labelling requirements, read this document in conjunction with HSNO labelling guides such as the one produced by Agcarm. This guide includes information that must appear on the label of all veterinary medicines: *Product labelling and documentation guide for agricultural chemicals and veterinary medicines* (http://agcarm.co.nz/?page_id=162)

Part 1: Mandatory label information

(1) All labels must include:

a) the statement “FOR ANIMAL TREATMENT ONLY”*
b) the statement “RESTRICTED VETERINARY MEDICINE”, if applicable*
c) trade name*
d) active ingredient(s) and quantities*
e) use claim(s)
f) directions for use
g) registration number*
h) withholding statements, if applicable*
i) registrant/New Zealand agent and contact information (name, address, phone number)
j) batch number*
k) expiry date*
l) net contents
m) storage instructions
n) regulatory statements
o) adverse effects, cautions and contraindications.

* Required to be on the primary label

(2) For labels of restricted size (such as vial labels) the following minimum information would be acceptable provided the complete information is conveyed on secondary labels and/or the package leaflet, and the product is not marketed as a separate unit:

a) trade name
b) active ingredient(s) and quantities
c) registration number
d) net contents
e) “RVM”, if applicable
f) withholding period(s), if applicable
g) batch number
h) expiry date.

The following sections set out requirements for each of these items.

1.1 FOR ANIMAL TREATMENT ONLY

(1) 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 if this is possible.

1.2 RESTRICTED VETERINARY MEDICINE

(1) This statement must appear in bold immediately above the trade name on those veterinary medicines that are classified as having restricted access status classification. On labels of restricted size, the abbreviation “RVM” in bold is acceptable.

1.3 Trade name

(1) The full trade name, as specified on the registration application form, must appear clearly in a prominent place, and must be consistent throughout the label.

a) The trade name must be distinctive and not misleading. It is your responsibility to ensure that the trade name is unique so as to not cause confusion in the marketplace.
b) Words, numbers or phrases included in company logos or trademarks, which are also positioned near the trade name, are not considered part of the trade name.

c) If the trade name does not include the physical form and route of administration and possibly its intended purpose, then the label should describe this information, such as oral powder, feed additive, oily injection, inhalant, tablet, spray-on, dip, oral paste, dip and spray, pessary, injectable suspension, oral suspension.

d) If the trade name is not distinctive, such as a generic active ingredient (international non-proprietary name [INN]), then the trade name must be distinguished by another word to make it distinctive. It is preferable that the other word precedes the trade name. The use of indication or species on their own is not considered sufficient to distinguish the product from others with similar trade names.

> Guidance
> - The company name could, for example, be incorporated into the trade name to distinguish it from other products having similar trade names.
> - Examples of acceptable trade names:
> - Company X Levamisole
> - Levamisole Company X
> - Purple Levamisole oral drench for sheep.

e) A trade name such as Levamisole oral drench for sheep or Cloxacillin LA would not be acceptable.

f) If numbers are used as part of the trade name, they should relate to the level or concentration of active ingredient in the product. Exceptions permitted by MPI may include references to dose rates in relation to weights of target animals in the product name, such as “Flea Killer 20” if a unit of the product was the dose for a 20 kg dog or “5 in 1” for multivalent vaccines.

(2) Ensure the trade name complies with trademarks and is not too similar to existing trade names. MPI does not routinely check these other than to ensure the trade name is not misleading (for example, if the trade name suggests the product controls a pest when in fact the label does not mention control of that pest).

(3) If you wish to adopt a previously used trade name for a new product, both products must have the same active ingredients (or combinations) and the same formulation type.

1.4 Active ingredient(s) and quantities

(1) The names of all active ingredients must appear on the label along with their concentrations and units. The names must be described as either:

a) the International Standards Organisation (ISO) common name/International Non-proprietary Name (INN) or

b) the full chemical name in cases where a common name has not yet been approved or recognised.

(2) Units of concentration must be appropriate to the formulation type (for example, grams/litre or grams/kilogram).

(3) If the active is present as a salt, the label description and concentration should be for the active molecule on which efficacy calculations are made (for example, each ml contains 150mg Amoxicillin [as Amoxycillin trihydrate]).

(4) For biological products, stating potency is optional.

1.5 Use claim(s)

(1) All labels must have accurate and objective claim(s). The claim(s) should, if possible, specify all the species of animal for which the product is specifically approved.

(2) The primary label claim should appear near the Trade Name and Active Ingredient(s) as an immediate description of the product's intended use.

(3) Claims on the label must be consistent with the claims approved as part of the registration application. They must not overstate or misrepresent approved claims.

(4) The Linnaean scientific name (either in italic font or underlined) and the common name used in New Zealand should be given for each pest, parasite or disease organism for which control is claimed if they are not listed elsewhere on the label.

1.6 Directions for use

(1) These must be simple, clear and concise. If a specific dose is recommended, the label must indicate the dose rate per unit live weight (for example, mg/kg).

(2) Directions for use must include:

a) dose rates or use levels
b) the route, timing, frequency of application
c) specific injection site when required
d) duration of treatment, and
e) other information that may affect the efficacy and safety of the product.

(3) Refer to Part 2 for special requirements for labelling in specific circumstances.

1.7 Registration number

(1) The registration number must appear on all labelling and is generally located near the bottom of the label. You may include this in one of the following ways:

a) Registered pursuant to the ACVM Act 1997, No …..
b) ACVM Registration No. ….
c) ACVM No. ….. (on small containers, such as vials).

(2) All labels, including very small containers such as sachets or outer packs, must have the registration number on them.

(3) Labels must also include the statement: "See www.foodsafety.govt.nz for registration conditions."

1.8 Withholding statements

(1) Withholding periods (WHPs) are guidance to avoid non-compliant residues if the produce from the treated animal is intended for human consumption.

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

(3) Regulatory statements such as "Do not use" must not be used in place of a label WHP for any product bearing claims for use in animals that produce meat, milk or eggs for human consumption. This rule does not apply to pre-ruminant animals and current "Do not use" statements will continue to apply.

(4) All WHP statements must stand out and be separate from the main body of the text.

(5) Approved wording or equivalent wording is required as follows:

Withholding period for	Statement
Meat	"Animals (or specific species if the 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 entire meat withholding statement must appear on at least one labelling component if practicable. It is acceptable for vial labels to condense WHP information to: "Meat WHP: Cattle: …days/weeks Sheep: …days/weeks Pigs: …days/weeks"
Milk	"Milk intended for sale for human consumption must be discarded during treatment and 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 if practicable. It is acceptable for vial labels to condense WHP information to: "Milk WHP: X milkings (X*12 hours)."
Egg	"Eggs from treated birds must not be sold for human consumption for ... days following the last treatment."
Antimicrobials for bobby calves	All sulphonamides and any antimicrobial drug indicated for use in calves must carry the following statement on the label. The statement must also be included for oral and injectable antimicrobial products indicated for use in adult cattle. "Not for use in bobby calves."
Other	For any injectable long-acting product intended for subcutaneous administration only and for which intramuscular residue data has not been assessed by MPI and factored into the calculation of the withholding period, the following label statement is required: "Ensure injection is subcutaneous. Intramuscular injection will result in prolonged residues. If 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."

1.9 Registrant/New Zealand agent

(1) The registrant's full name must appear on all labelling. If the New Zealand agent differs from the registrant, the agent must also appear on all labelling.

(2) If another company name appears on the labelling in addition to the registrant (for example, manufacturer or distributor) the words "Registered to ..." must appear before the registrant's name to identify the registrant along with contact information such as address/phone number(s).

1.10 Batch number

(1) This label requirement is the number or letter (or combination) by which the manufacturer uniquely identifies each production batch. It should be preceded by the words "Batch number (or No.)" or the symbol "B" or another appropriate indicator that can be easily understood by the end user.

1.11 Expiry date

(1) 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 date should be preceded by the words “Expiry Date” or “Expiry”. The abbreviation “Exp.” or the symbol “E” may be used for very small containers.

1.12 Net contents

(1) Net contents of the product(s) must be stated in metric units, for example:
g (gram)
kg (kilogram)
ml (millilitre)
L (litre).
This must be clear and readable.

(2) If units of veterinary medicines are individually packaged (for example, 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 MPI provided the container in which the individual units are sold does not contribute to the stability profile of the product. In consequence, if changes are made to the number of individual units included per container formal MPI approval is not required unless there are changes to the individual unit or relevant MPI-approved label text.

1.13 Storage instructions

(1) Provide any instructions regarding storage that are necessary to ensure the stability of the product, for example:
“Store below 30ºC.”
“Store in a dry place.”
“Keep container closed.”
“Keep away from light.”

1.14 Regulatory statements

(1) Labels must have regulatory statements if compliance by the user is a statutory obligation imposed by the conditions of registration. These are distinct from label statements that have no statutory obligations for user compliance. Examples of these generally fall into the adverse events, contraindications and safety-type statements (see Part 1.15).

(2) Regulatory statements must be in the most appropriate place on the label near use instructions and in bold. If appropriate, place the regulatory statements together.

1.14.1 Management of residues

(1) The following regulatory statement must be printed in bold near the WHP statement to make users aware of their obligations regarding residues:
“It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels of Agricultural Compounds.”

1.14.2 Off-label use

(1) Any use of a veterinary medicine that has not been specifically approved by MPI is considered to be an off-label use. Unless specifically prohibited on the label, off-label use is not illegal for veterinary medicines with unrestricted access status classification.

(2) The following regulatory statement, which must be printed in bold near the use directions (but not necessarily on the primary label), is to make users aware of their obligations when using a product in an off-label manner:
"By law the user must take due care, obtaining expert advice when necessary, to avoid unnecessary pain and distress when using the product other than as directed on the label."

(3) Veterinary medicines with restricted access status classification do not have the above regulatory statement as their use will be controlled either by veterinarians (who are allowed to make off-label use of the product by the registration conditions) or by an approved operating plan.

(4) Restricted veterinary medicines whose distribution and use are controlled exclusively via an approved operating plan must have a regulatory statement (on the lines suggested below) that accurately reflects the restrictions imposed by the operating plan. This statement must be printed in bold near the use directions (but not necessarily on the primary label):
"By law the distribution and use of this product must comply with the requirements of the relevant operating plan."

1.14.3 Hormonal growth promotants (HGPs)

(1) HGPs intended for use in beef cattle must have the following statements prominently displayed in the package leaflet and/or other packaging:

a) "By law, this product must be used only according to label instructions."
b) "The product must be used only in cattle."
c) "This product must not be used in cattle producing or intending to produce milk for human consumption."
d) "At the time the HGP is administered the treated cattle must be identified with an approved identification ear tag. This may not be removed."
e) "Users of this product have obligations under the Animal Products Act and notices issued under that Act."

(2) 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 package leaflet."

1.14.4 Alternative wording

(1) You may request use of alternative wording for any of the above regulatory statements provided the intent is the same. We will consider this on a case by case basis.

1.15 Adverse effects, cautions and contraindications

(1) Registrants must state possible adverse effects, cautions and any contraindications of significance on labels. The need for label warnings should take account of the frequency of adverse effects as well as the impact on efficacy, animal welfare, trade, public health or residues. Label statements must be factual and not mislead.

(2) Label warnings required for regulatory purposes that have statutory obligations for the user must be made clear by way of the regulatory statements mentioned above.

(3) Label warnings that are discretionary (that is, placed on the label by the registrant) must not be misrepresented as regulatory statements in any way.

(4) Registrants may put other statements on the label, but MPI will decide if these statements misrepresent the scope of the product approval.

Part 2: Mandatory label information for specific circumstances

2.1 Anthelmintics

(1) In addition to general claims, species and strains of parasites for which efficacy is claimed should be listed on the primary label (if size permits) and on the package leaflet. Specific claims regarding effects on resistant species must be noted if these have been supported by objective data.

(2) 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.

(3) 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."

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

2.1.1 Anthelmintics for sheep, goats, cattle and horses

(1) All labels for anthelmintics for sheep, goats, cattle and horses must contain the following statements:

a) "(Name of product) contains (name of active ingredient), a member of the (name of the anthelmintic group) family of chemicals."
b) "It is effective against sensitive strains of the following internal parasites (list of scientific and common names used in New Zealand)."

(2) The following statements must be included on labels for all anthelmintics for sheep, goats and cattle, and the relevant ones for horse anthelmintics:

a) "Correct drenching technique should be used."
b) "Resistance may develop to any chemical."
c) "It is advisable that a resistance test be conducted regularly when using any parasite treatment."
d) "Ask your local veterinary practitioner or animal health adviser for recommended parasite management practices for your area to reduce development of resistance."
e) "A representative sample of animals should be weighed before treatment."
f) "Dose the mob to the heaviest animal by live weight in each group [(ewes, wethers, rams, lambs), (bucks, does, kids), (bulls, cows, steers, calves)]. Do not under-dose."
g) "If there is a large variation in size within the group, draft into two or more lines based on bodyweight to avoid excessive overdosing."

(3) You may propose additional wording specific to your 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.

(4) The dose rate must be expressed as x ml per y kg bodyweight.

(5) Labels of LEVAMISOLE drenches (if appropriate) must contain the following statements:

a) "Doses of 3 or more times those recommended can cause symptoms of Levamisole toxicity, so estimate live weights carefully."
b) "Dehydrated animals may be more susceptible to toxicity."
c) "Fatal interactions may occur between Levamisole and Organophosphate dips."

For sheep and goats

(6) Labels must also include dose/volume tables, starting with 15 kg bodyweight and in multiples of 5 or 10 kg increments for animals up to 75 kg bodyweight. Recommending dosing to lamb and kids below 15kg body weight is not considered to be good agricultural practice.

(7) The following statement must appear after the dose/volume tables:
"Animals heavier than 75 kg to be dosed at x ml per y kg."

For cattle

(8) Labels of products for cattle must include dose/volume tables, starting with 50 kg bodyweight and in multiples of 50kg increments for animals up to 650 kg bodyweight. Recommending dosing to calves below 50kg body weight is not considered to be good agricultural practice.

(9) The following statement must appear on the labels after the dose/volume table:
"Cattle heavier than 650 kg should be dosed at x ml per y kg."

2.2 Selenium products

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

a) The dose rate of selenium.
b) The word "selenium" in bold print, except for products containing 3 mg/kg or mg/L of selenium or less.
c) 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."

2.3 Oral copper-containing veterinary medicines

(1) The following statement must appear on labels for all oral copper-containing veterinary medicines that are for use in sheep and are unrestricted:
"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."

2.4 Injectable veterinary medicines and intravenous infusions

(1) If 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."

(2) Unrestricted intravenous products may require statement on safe administration of the product.

2.5 Ionophore products

(1) All ionophore product labels must include the following statement:
"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."

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

2.6 Phenylbutazone products

(1) Phenylbutazone containing products intended for horses must include the following statement:
"It is a legal requirement that this product is not used in any animal producing or intended to produce food for human consumption."

2.7 Johne's disease vaccines

(1) Johne's disease vaccines have labelling requirements under the Animal Products (Specifications for Products Intended for Human Consumption) Notice 2004. Refer to it for more details.

2.8 Bloat remedies

(1) 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 re-using."

2.9 Dry cow products

(1) Labels for dry cow intramammary products must contain the following statements:

a) "Not for use on lactating dairy cows."
b) "Dry cow therapy should be used once at drying off only."
c) "Treatment to be at least "x" days before calving."
d) "Milk (colostrum) from the first 8 milkings after calving should be prevented from directly entering the human food chain. 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 MPI-approved treatment to calving or pre-natal treatment interval.)

2.10 In-water and in-feed medications

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

a) a dose rate for each label species (for example, in mg/kg)
b) if feed or water inclusion rates are recommended, a statement that the recommendations are based on the assumed daily intake of animals and should be adjusted as necessary to achieve the required dose rate if intakes vary from that assumed.

(2) If sufficient information is provided to show the product is not absorbed significantly and efficacy is based only on the concentration in ingesta and 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.

Part 3: Additional information on other types of packaging

3.1 Primary and secondary container labelling

(1) If the product is packaged in secondary packaging, all label directions must comply with those on the primary label. One exception to this is if small pack sizes are accompanied by an outer primary label such as a brochure/pamphlet.

3.1.1 Fold out labels in pouches/plastic sleeves

(1) A portion of this must be fixed directly to the packaging to ensure that the label cannot be separated from the container. If the portion of the label affixed does not have crucial information, such as the trade name, active ingredient, registration number or registrant contact details, and the label gets removed from the container, there is a high risk that the end user will not know what is in the container. Misuse could result.

3.1.2 Leaflets and booklets

(1) If the size or shape of a container cannot accommodate all the required label information, or the use directions are too lengthy to be listed clearly, some information may be printed in a leaflet or booklet that is supplied with each container. In this case, the leaflet or booklet is part of the label.

3.2 Other types of packaging (if packaging is not considered primary or secondary)

(1) The following must be shown on outers:

a) trade name
b) concentration, units and active ingredient
c) RESTRICTED VETERINARY MEDICINE (if applicable)
d) registration number (may be shortened to “ACVM No…..”)
e) net contents
f) New Zealand registrant/agent and sufficient contact information to allow easy contact (for example, telephone number). Physical address is not necessary.

3.3 Small trial/sample pack sizes

(1) If registrants wish to give away free sample packs or small trial packs for user acceptance in one-off situations, these packs, which must be ACVM approved, must show the following information:

a) trade name
b) concentration, units and active ingredient
c) registration number (may be shortened to “ACVM No…..”)
d) RESTRICTED VETERINARY MEDICINE (if applicable)
e) withholding period(s)
f) net contents
g) batch number
h) expiry date
i) statement referring user to the primary packaging label for use directions.

(2) If the size of the packaging limits label space, alternatives may be acceptable on a case by case basis provided the product is not marketed as a separate single unit.

3.4 Labelling of combined product

(1) Two registered products may be sold in "convenience packs" if the registered products are sold bound together by outer packaging without specific MPI approval. Both products must be sold in their registered packs with all approved label text and in full compliance with the conditions of registration. External packaging must contain, at minimum, all relevant information that is required for other types of packaging (see Part 3.2).

(2) If the external packaging obscures the approved product packaging, including information the consumer needs to see when choosing an appropriate product, this information must be included on the external packaging.

(3) If products are sold together as an active and diluent, both items of packaging must have the appropriate information relating to the registration.

Part 4: APVMA harmonised labels

(1) Labels harmonised for use both in New Zealand and in Australia can be considered if the Australia-specific information regarding the claims and use of the product do not jeopardise the risk areas managed under the ACVM Act. The reverse will also be true: New Zealand-specific information must not contradict, confuse or affect the meaning of the Relevant Label Particulars (RLPs) approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Contact APVMA for more information on Australia's requirements for harmonised labels.

(2) The following New Zealand-specific information has been identified as not conflicting with the RLPs approved by APVMA:

a) ACVM registration statement
b) ACVM classification of the product (restricted or unrestricted)
c) Contact details of New Zealand-based registrant and/or agent.

(3) The New Zealand specific information must be included in a New Zealand box that is prominently identified by words such as "New Zealand Information", or similar, to clearly indicate that the content applies only in New Zealand. The following is provided as an example.

NEW ZEALAND INFORMATION

RESTRICTED VETERINARY MEDICINE

It is an offence for users of this product to cause residues exceeding the relevant MRL.

Australia's trade advice and Export Slaughter Interval information do not apply in New Zealand.

ACVM Registration No. Axxxx. See www.foodsafety.govt.nz for registration conditions.

Registered to:

Agent:

(4) For products supplied in New Zealand that are required to have the statement "RESTRICTED VETERINARY MEDICINE", this statement must be included within the identified New Zealand information box and be printed in upper case bold font. For labels of reduced size the abbreviation "RVM" printed in bold would be acceptable.

(5) For products that are available in New Zealand only under an approved operating plan, the MPI-approved regulatory statement must be printed in bold within the New Zealand box. For example: "By law the distribution and use of this product must comply with the requirements of the approved operating plan." MPI will advise whether or not the phrase "RESTRICTED VETERINARY MEDICINE" must be included on labels for these products.

(6) Veterinary medicines with unrestricted access classification will not have any classification information in the New Zealand box. For these products the following regulatory statement must be included in the New Zealand box:
"By law the user must take due care, obtaining expert advice when necessary, to avoid unnecessary pain and distress."

(7) For products that have WHP recommendations the following regulatory statement must be included in the New Zealand box:
"It is an offence for users of this product to cause residues exceeding the relevant MRL."

(8) Note: the above two regulatory statements are the versions that have been agreed with APVMA in lieu of the statements that are included in New Zealand-only labels.

(9) If diseases/parasites that do not occur in New Zealand are listed on the labels, include a note to that effect in the New Zealand box. For example, “Note: (Parasite name) does not occur in New Zealand”.

(10) Trade advice, including Export Slaughter Interval (ESI) information, on the label is an APVMA requirement that does not apply in New Zealand. To avoid confusion to users in New Zealand, include the following statement in bold in the New Zealand box (as illustrated above):
“Australia’s trade advice and Export Slaughter Interval information do not apply in New Zealand.”

(11) The above requirements apply, if practicable, to all items of packaging (primary label, package leaflet and secondary labels), including outers (shippers) for the product.

Part 5: General advice

(1) Ensure that the label complies with other relevant legislation, such as the Fair Trading Act 1986 and the Hazardous Substances and New Organisms Act 1996.

(2) Ensure that the label does not infringe on any proprietary rights, such as trademarks or copyrights.

5.1 Graphics

(1) Graphics may be included on labels but must not interfere with the legibility of the text.

(2) Pictures or illustrations must not depict or imply usage contrary to the current approval.

5.2 Colouring

(1) Colours can assist the readability of the text, but some colour combinations are easier to read than others. Generally, avoid dark prints on a dark background and light prints on a light background.

5.3 Reprinting

(1) Before reprinting, ensure that your label still complies with MPI requirements by referring to the latest labelling information requirements on our website

Schedule 1 – Definitions

(1) In this document, unless the context otherwise requires:

Active ingredient
means the chemical(s) (or biological component) in a formulated product that is/are principally responsible for the effect being claimed and is/are distinct from other formulation components such as surfactants, carriers or diluents.

Broad spectrum
means controls or is toxic to a wide range of pests or pathogenic organisms when applied correctly.

Label
means 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
means the information that is intended to be included with the product when it is offered for sale. It is supplied as part of the application for registration and must be complied with when generating the actual label, packaging and information sheets. You must ensure that the primary label is affixed so it cannot become separated from the container.

Outers
means outer containers used for shipment of products from one destination to another.

Package leaflet
means a pull-out label inserted into the primary pack of the product that contains the mandatory label information for the user regarding the trade name product.

Primary label
means the label on the primary container that is in physical contact with the veterinary medicine (for example, bottle, blister pack, tube, syringe).

Secondary label
means the label on the packaging in which the primary container is enclosed for sale. In other words, it is the immediate packaging around the primary container (for example, carton, leaflets/inserts).

Withholding period
means the minimum period that should elapse between the last treatment and collection of produce for human consumption in order to meet the relevant residue threshold.

(2) Any words or expressions used but not defined in this document that are defined in the ACVM Act have the meaning given to them in the Act.