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APPENDIX A

ANIMAL REMEDIES LICENCES AND LEGISLATION

Extracted and modified from a memorandum dated Monday 15 February 1999 by Nicholas Charles Whelan, immediate past Registrar of the Animal Remedies Board

- 1 This report addresses the following matters:
 - 1.1 The Animal Remedies Act
 - 1.2 Types of animal remedy licences granted
 - 1.3 Technical criteria for granting animal remedy licences
 - 1.4 Administrative processes
 - 1.5 The Agricultural Compounds and Veterinary Medicines Act

The Animal Remedies Act

2. The Animal Remedies Act 1967 consolidated and amended the Stock Remedies Act 1934 and was to make better provision for controlling the manufacture, importation, sale and use of drugs, medicines, remedies and other therapeutic substances used for treating and preventing animal diseases.
3. The Animal Remedies Act came into force on 1 January 1968.

The Animal Remedies Board

4. The Animal Remedies Act established the Animal Remedies Board. The eleven members of the Board are appointed by the Governor-General on the nomination of the Minister of Agriculture and Forestry, and Minister of Health and other industry groups.
 - 4.1 The Chair is appointed on the nomination of the Minister of Agriculture and Forestry.
 - 4.2 The Registrar is a veterinarian in the Ministry of Agriculture and Forestry nominated by the Director-General.
 - 4.3 A registered medical practitioner nominated by the Minister of Health.
 - 4.4 An analytical chemist nominated by the Minister of Agriculture and Forestry.
 - 4.5 A veterinarian nominated by the Minister of Agriculture and Forestry.
 - 4.6 One person to be nominated by each of the following organisations:
 - New Zealand Veterinary Association Incorporated
 - Veterinary Services Council (now dissolved by the Veterinarians Act 1994)
 - Federated Farmers of New Zealand
 - Agricultural Chemical and Animal Remedies Manufacturer's Federation of New Zealand
 - Pharmaceutical Manufacturers Association (NZ) Incorporated
 - Pharmacy Board of New Zealand
 - certain scientifically qualified persons on the nomination of the Minister of Health and Minister of Agriculture.
5. The general functions and powers of the Board include:
 - 5.1 to exercise control over the manufacture, importation, sale and use of animal remedies;
 - 5.2 to ensure that animal remedies are efficient and safe for use in animals;
 - 5.3 to consider and determine applications under the Act to license animal remedies;
 - 5.4 to report to the Minister and advise him on relevant matters;
 - 5.5 to carry out other functions relevant to animal remedies, such as the dissemination of information in relation to the safe and efficient use of animal remedies.
6. The role of a Registrar of the Board is created by the Animal Remedies Act. The Animal Remedies Act prescribes specific powers and duties which are the responsibility of the Registrar including the maintenance of a register of licences issued by the Board.

7. In addition the Animal Remedies Board has the power to delegate to the Registrar all of its powers, duties and functions relating to:
- 7.1 the approval of labels;
 - 7.2 the approval of advertisements;
 - 7.3 the approval of the sale of any experimental animal under s63A and the imposition of conditions relating to the sale of any such animal under that section.
- Such delegation has been made by the Board.
8. The Animal Remedies Act is administered by the Ministry of Agriculture and Forestry. The Agricultural Compounds and Veterinary Medicines Group (formerly the Agricultural Compounds Unit) of the Ministry of Agriculture and Forestry undertakes this work on behalf of the Board and provides technical and administrative support.

Applications for licence

9. Any adult person(s) or any body corporate may apply to the Board for the issuing of a licence to manufacture or import an animal remedy.

Applications are required to be on a form provided by the Registrar and include the following details:

- trade name of the remedy;
- name and address of the applicant and address of every place where he or his independent contractor manufactures the remedy, or in the case of an importer, the address where the business of importing the remedy is carried out;
- full details of the composition of the remedy, and the recognised scientific name and percentage of each ingredient and the form in which it occurs;
- details of the preventive or remedial properties claimed in response for the remedy.

In addition to this information and draft copies of labels the Board may also require:

- method or methods of analysis used in respect of the animal remedy;
- such experimental or other evidence as the Board may require in support of any statement contained in the application or in any copy of a label deposited with the application.

Such particulars as the Board may require relating to:

- the premises where the process of manufacturing the animal remedy is to be carried out;
- the plant and general techniques to be used in the manufacture of the animal remedy;
- such other particulars as the Board may require.

10. In order to assist applicants fulfil these requirements, the Board has over time developed a number of information booklets identifying the detail and rationale for this information. Inquirers are sent a copy of the current booklet. A copy of the current booklet, *Licensing Requirements for Animal Remedies in New Zealand*, is available from the Registrar. An additional pamphlet entitled *New Zealand Labelling Guide for Animal Remedies* is also sent as part of a response to inquiry in relation to licensing.

Types of Animal Remedies Licences Granted

11. The Animal Remedy Board can issue two types of licences. A provisional licence may be issued where the Board is of the opinion that it is desirable that the animal remedy should be manufactured or imported for sale or use on a restricted basis for a trial period. The maximum time these may be issued is two years. A full licence allows manufacture or importation of an animal remedies indefinitely. Any conditions on manufacture, importation, sale and use may be imposed on a full or provisional licence.

Types of provisional licences

12. The Board has in practice subdivided the provisional licences that it has issued into three classes, referred to as classes 1, 2, and 3.
13. A Provisional Class 1 licence enables basic trial work to be undertaken using experimental animals (as defined in the Animal Remedies Act), but does not allow sale of the remedy. The type of trial work is for the development of safety, residues or basic New Zealand efficacy data. Applicants are required to provide

the following information details of the formulation and the manufacturer, a trial protocol including the site of the trial and the name of the supervising veterinarian, and confirmation of Animal Ethics Committee approval.

14. Only limited information is required before a Provisional Class 1 licence is issued because it generally does not permit the licence-holder to do anything which would not already be allowed by the second proviso to s18(l) Animal Remedies Act. A Provisional Class 1 licence may, however, be of use to the holder because the information required before granting a Provisional Class 1 licence will assist the Registrar in deciding whether to grant approval for sale of an experimental animal remedy under s63A of the Animal Remedies Act.
15. A Provisional Class 2 licence enables an applicant to conduct limited research on a larger number of experimental animals, but does not allow sale of the remedy. More detailed evaluation of the technical aspects of remedy has been completed to the same level as for a Full licence. The manufacturing, residue and target animal safety profiles should be known. The outstanding information should be only efficacy information on a larger number of animals or if there are concerns about the safety profile of the animal remedy.
16. Normally a Provisional Class 2 licence would be sought when a product is nearly ready to be marketed. If the trials under a Provisional Class 2 licence produce satisfactory results, a full licence would normally be sought without difficulty.
17. In order to protect the trial animals from unacceptable suffering, the Animal Remedies Board requires that a full trial protocol be submitted, and confirmation that a valid Code of Ethical Conduct exists and that Animal Ethics Committee approval has been granted, prior to an animal remedies licence being granted. Codes of Ethical Conduct are required for experimental “manipulations” of animals and are regulated by the Animal Protections Act 1960 and the Animals Protection (Codes of Ethical Conduct) Regulations 1987. Under this legislation, any scientific research or trialling that involves the use of live animals must be approved by an Animal Ethics Committee in accordance with an approved Code of Ethical Conduct. The Animal Remedies Board considers that these controls can provide an appropriate framework for it to manage its responsibilities for animal welfare during these preliminary trials. Moreover, it would not wish to appear to approve illegal experimentation on animals.
18. Provisional Class 3 licences are rarely issued. These licences enable larger scale trials to be undertaken on commercial animals, and are issued only when the technical data is largely satisfactory but one or two minor issues remain to be addressed. An animal remedy with a Provisional Class 3 licence may be sold for up to two years, being the maximum term for a provisional licence.
19. Often, a Provisional Class 3 licence is issued when extensive overseas data for the remedy have been supplied that is generally relevant to New Zealand’s farming, climatic and husbandry conditions. Although the Animal Remedies Board has a very high confidence that the product will be effective and safe in New Zealand, confirmatory studies in New Zealand will be undertaken on a Provisional Class 3 licence. The product can be imported or sold in New Zealand while these studies are undertaken. After two years, this licence will lapse, prior to which time the licensee must submit their full New Zealand efficacy study for consideration for the full licence.

Full licences

20. A full animal remedies licence authorises the licensee to manufacture, import and sell the animal remedy in accordance with its terms and conditions. A full licence will not be issued unless the Animal Remedies Board (or its delegate) is confident that the remedy measures up to the claims that are made for it and that none of the grounds for declining a licence set out in s21 of the Animal Remedies Act apply.

Technical Criteria for Granting Animal Remedies Licences

21. The Board requires information on manufacturing and stability, efficacy, target animal safety, residues and toxicology. In rare cases it may also have concerns about trade implications.

Manufacturing and stability

22. Manufacturing and stability deficiencies in an animal remedy impact on its integrity in all other aspects. For example, if the manufacturing method is not sufficiently controlled, the consistency of each batch of the animal remedy is unlikely to be the same, and its pharmacological effects will not be predictable batch by batch. Thus, any residue, safety or efficacy data generated to support licensing of the animal remedy are unlikely to be representative of the animal remedy on an ongoing basis.
23. When considering the quality aspects of an animal remedy, the Board considers the manufacturing method and the quality of raw materials used in the manufacture of the product, the integrity of the processes employed, and the criteria for acceptability and consistency of the product being manufactured. The Board has a programme whereby it approves New Zealand manufacturers of animal remedies following their application, and monitors their compliance with a Code of Good Manufacturing Practice on a regular basis.
24. The manufacturing requirements stipulated in the product licence application data package include:
- formulation details;
 - identification of the proposed manufacturer;
 - manufacturing procedure and process chemistry;
 - specifications of all ingredients and packaging components;
 - quality control and quality assurance information;
 - analytical methods;
 - batch analyses and release specifications.
25. Stability of the animal remedy during its shelf life is also evaluated on the data provided. This evaluation is done to ensure that the expiry date required on the label is correct and that any assumptions which have been made based on this information (e.g. efficacy, safety and residues) are supported by the product retaining its characteristics for the approved period.
26. The data requirements to show stability of the animal remedy for its shelf life include:
- identification of the proposed shelf life;
 - proposed storage conditions for the animal remedy;
 - accepted specifications for the animal remedy at the end of its shelf life;
 - trial procedure and details employed during storage trials;
 - stability trial;
 - stability data for any use dilutions.

Efficacy

27. When considering product efficacy, the Animal Remedies Board considers issues such as the pharmacology, i.e. the absorption, distribution, metabolism and excretion of the animal remedy in the animal. In addition, the technical data are reviewed to ensure that it shows efficacy for all claimed conditions, when used in accordance with the label recommendations. Any factors that might indicate circumstances when the product may not be efficacious are also considered.
28. The data requirements to show efficacy of the animal remedy for each target animal group and species include:
- description of trial methodology to ensure that the trials were conducted in accordance with sound science;
 - copies of the raw research data;
 - trial data for each claimed therapeutic or prophylactic benefit and supporting statistical interpretation.

Target animal safety

29. When considering aspects of product safety, the Animal Remedies Board considers the potential for adverse effects to arise from the formulation or from its physical means of administration. Data describing the safety of the animal remedy at the maximum recommended dose rate, when administered as recommended, are reviewed by the Board. The risks associated with accidental overdosing and long-term use are also considered, as well as contraindications and known side effects.
30. The data requirements to show safety of the animal remedy include:
- description of trial methodology;
 - copies of the raw research data;
 - trial data for each target animal group and species, for varying doses factors relevant to the mode of administration;
 - discussion of label contra-indications, side effects and their severity.
31. Specific issues relating to injectable animal remedies are set out below.

Residues

32. When considering aspects relating to residues, the Animal Remedies Board considers the potential for the animal remedy to impact on the quality and acceptability of primary produce for human consumption. The relevant data requirements include:
- description of trial methodology;
 - copies of the raw trial research data for each trial animal;
 - residue trial data for each target group and species details of all analytical methodology;
 - impacts due to the mode of administration, e.g. injection site lesions, damage to hides and pelts.
33. The level of residues that are acceptable is a complex issue. Acceptable levels for New Zealand may differ to those of overseas countries. When considering aspects of residues, the ACVM Group's residues consultant identifies if there is a significant risk that proposed use of a product will result in residues. The ACVM Group will look at the residue information and determine in association with the toxicology data (using internationally agreed guidelines) whether residues would be acceptable from a human health point of view. A proposal is drafted requesting the Ministry of Health to action the setting of a maximum residue level in the Food Regulations 1984. This proposal is referred to the MAF National Manager - Residues, for consideration as to whether these levels are acceptable with those set by international bodies such as the *Codex Alimentarius* and from a trade point of view. If endorsed, the proposal is formally sent through to the Ministry of Health to consider and action.

Toxicology

34. A further significant area where data are relevant to animal remedies is toxicological and environmental toxicological data. These data areas examine the potential impact of an animal remedy on the health of both animals and humans exposed to the animal remedy (by consumption of produce, or during its administration or handling) and the impact of the animal remedy on the environment.

Issues associated with injectable animal remedies

35. Ideally, an injectable animal remedy should cause minimal irritation with no permanent damage to tissues. In reality, all subcutaneous and intramuscular injections will cause some degree of local trauma and aseptic inflammation, due to the direct effect of the needle and the distension and disruption caused by the injected volume and the composition of the injected substance. However, some subcutaneous and intramuscular injections produce severe local irritation and tissue damage. Some intravenous preparations may also cause severe tissue damage if the drug is administered incorrectly. This change in structure or chemistry of tissue following injection of an animal health product into an animal is known as an injection site lesion. A lesion indicates that damage to or death of tissue has occurred at the site. In some cases, a lesion will abscess, particularly if bacteria are introduced into the wound, either by maladministration or a failure in the sterility requirements during manufacture of the product.

36. Although these injection site reactions are undesirable, the administration of a drug by a parenteral (i.e. injectable) route offers convenience and reliability, and is particularly suitable for mass administration of drugs and some instances where there can be complications with oral or topical use of the drug.
37. There are no hard and fast rules as to what injection site reactions are acceptable. It is necessary to weigh the reaction against the practical benefits that the remedy provides. The most severe reaction that would normally be considered acceptable for an efficacious remedy is one that resolves to fibrous tissue after three to five weeks and is no bigger than a large pea by then. Even copper injections, which are known for their site reactions, usually fall within this range.
38. There are several remedies that do present larger injection site reactions than this. Notable are Neoparasec (a vaccine against Johne's disease, a wasting condition) and Footvax (a vaccine against footrot). These vaccines are intended for use over a limited period only. Once the animals on a particular farm are free of the disease, so long as the farmer buys only disease-free animals the vaccine is no longer needed. These vaccines therefore cannot be compared to remedies that must be injected annually, or more often than that.

Trade implications

39. Trade issues will often not be considered separately when an application for an animal remedy licence is considered. The Ministry of Agriculture and Forestry is closely involved in international trade issues, as are various industry groups, and specific trade issues would usually arise only if these bodies bring unexpected post-licensing problems to the Board's attention.
40. To ensure continued access of agricultural produce into overseas markets (the total value of New Zealand's meat industry export earnings in 1992/1993 was \$3,002.2 million, approximately 17% of our total export earnings), regulators need to carry out extensive meat inspection programmes at the abattoirs. Detected lesions are excised, and carcasses may be downgraded, resulting in financial loss to the farmer and to the industry.
41. Quick detection and removal of injection site lesions from the carcass is therefore essential. The Board's policy is to require injections to be sited in the anterior half of the neck. This facilitates detection and removal without slowing processing of carcasses unduly, and reduces the risk that lesions may go undetected until the carcass is seen by overseas inspectors and consumers. Lesions can indicate the presence of residues. Even where residues are not a problem, diseased or discoloured meat is not visually appealing to consumers.
42. Injection lesions can also cause extensive damage to, and downgrading of, hides and skins, an industry which currently earns about \$650 million in New Zealand. Poor quality hides and skins cannot be used in the high value fashion clothing, shoe and upholstery markets.

Risk to animal welfare

43. Depending on the size and position of the lesion, it can impact significantly on the animal's normal mode of activity. A lesion on the neck of a gazing animal may restrict its movement and make normal drinking and grazing painful.
44. A further significant problem associated with injection site reactions is the risk of infection (particularly in sheep), with the possible resulting fly infestation and/or difficulties with shearing. The injection site is also relevant here, because the approved injection site in the neck is less likely than many other injection sites to become infected. In relation to ruminants, the dewlap is a particularly bad injection site. Ruminants often lie on the ground with their dewlap touching the ground. They then rise by pressing their dewlap into the ground with their back feet, lifting their rump and then their forequarters. An injection in the dewlap will therefore be more likely to cause pain and become infected.

Reduction to site lesions

45. Subcutaneous injection sites have the advantage of minimising damage to valuable hide, skin and/or meat cuts and minimising tissue residues. Where possible, this administration route is preferred to the intramuscular route. Subcutaneous injection is not always sufficient to reduce injection site lesions to an acceptable size.

Administrative Processes

46. An application to license an animal remedy is received by the Agricultural Compounds and Veterinary Medicines Group. The product application is allocated an identification number and is entered into the computer data base. A preliminary check is made to ensure that the application contains the required administrative and technical data sections.
47. A Product Manager is allocated to review the technical information and to determine whether it meets the Board's specified criteria for licensing. These criteria are set out in a document entitled *Criteria Applied in the Technical Assessment of Animal Remedies*. The document does not have any formal status, but was produced to record processes for the ACVM Group's ISO 9002 accreditation. The process is, broadly:
 - approval for the manufacturer is required from the National Manager Conformance;
 - where specific technical expertise is required for the animal safety and efficacy data, the data are sent under a confidential contract to an expert consultant to review against the above criteria;
 - residue data are evaluated by an expert MAF consultant;
 - toxicology data are evaluated within or outside the ACVM Group by an expert toxicologist.
48. The Product Manager reviews the technical information supplied by the applicant, and the experts' reports that have been obtained. The Product Manager then liaises with the applicant with respect to queries from any of the reviewers and identifies any additional data requirements.
49. Once all the information has been provided and reviewed a second time where necessary, the Product Manager prepares a summary report, known as the Scientific Assessment Summary. This is presented to a technical committee set up by the Animal Remedies Board in October 1994, which is known currently as the Agricultural Compounds and Veterinary Medicines Group Scientific Assessment Meeting (ACVMSAM) (previously known as Agricultural Compounds Unit Scientific Assessment Meeting - ACUSAM). ACVMSAM consists of independent members with technical expertise. Its role is to advise the Board on technical issues and policies and to advise and make technical recommendations to the Registrar. In doing so it undertakes an audit review of product manager's recommendations.
50. In February 1996 ACUSAM's membership included: three veterinarians with expertise in meat residues (National Manager - Residues), microbiology, trace elements and minerals, and food animal clinical practice, a pharmacologist/toxicologist from the Ministry of Health and an analytical chemist with expertise in formulation chemistry and residue evaluations in addition to specialist veterinary pharmacology expertise from a veterinarian within the ACVM Group.
51. ACVMSAM makes its recommendations to the Decision Making Committee of the Animal Remedies Board (made up of the Registrar and the Chair of ACVMSAM) as to whether the animal remedy meets the Board's technical criteria for licensing. Appropriate amendments to labels claims may also be recommended as well as licensing conditions (e.g. the committee may recommend that a provisional licence for further trialing be issued if the data do not support a full licence).
52. The Decision Making Committee, the initial decision maker pursuant to delegated authority from the ARB, makes the decision to approve or decline the recommendation. Although the decision maker will generally approve ACVMSAM's recommendation, there may be non-technical reasons for an application to be declined e.g. trade related issues. The decision maker considers all these issues in addition to technical aspects, prior to making a decision.
53. The decision maker may in rare circumstances seek further technical information prior to the licensing decision being made.

54. The final administrative processing stage is then undertaken. This includes the licence applicant being informed of the Animal Remedies Board's decision and the reasons for it, and notified of any necessary amendments. Applicants are requested to provide final labels, which will be approved before a licence is issued. The applicant's rights of rehearing through the Board and appeal through the High Court are also provided.

Rehearing by the Board under section 35

55. If an applicant requests a rehearing of a decision, the Animal Remedies Board will consider the information supplied by the initial decision maker, in addition to the oral and/or written submission put forward by the applicant. Additional appropriate specialist advice may be obtained by the Board. The Board may either uphold or reverse the Registrar's decision, or uphold it with amendment(s).

Post registration adverse event reports (adverse drug reactions)

56. As noted above, an extensive data review is undertaken prior to Board approval of any Provisional Class 2, 3 or Full animal remedies licence. In spite of this, there are occasions when complaints and reports of adverse events occur following the administration of the animal remedy to animals. Any reports notified to the Board are recorded, investigated and monitored as required. In some circumstances, improved label warnings or directions for use may be sufficient to minimise the occurrence of future incidences.
57. If these reports indicate that the adverse events are significant, either in terms of their severity or incidence, following a thorough review, the Animal Remedies Board may suspend the licence for that animal remedy. Suspension allows the licensee the opportunity to fully investigate and rectify the causes of the adverse events. Sales of the animal remedy will cease while the problems are being addressed. If the problems associated with the animal remedy are not able to be resolved, the Animal Remedies Board can revoke the animal remedies licence. In arriving at the decision to suspend or revoke an animal remedies licence, the Animal Remedies Board will consider the need for, and risks of, a particular animal remedy and the availability of satisfactory alternative animal remedies.

The Agricultural Compounds and Veterinary Medicines Act

58. The Agricultural Compounds and Veterinary Medicines Act was enacted on 21 November 1997. It is due to come into force on the same date as the hazardous substances provisions of the Hazardous Substances and New Organisms Act 1996. The Agricultural Compounds and Veterinary Medicines Act will repeal the Animal Remedies Act 1967, the Stock Foods Act 1946 and the Fertilisers Act 1960. Together with the Hazardous Substances and New Organisms Act, it will also repeal the Pesticides Act 1979.
59. The basic philosophy of the Agricultural Compounds and Veterinary Medicines Act is that all agricultural compounds are required to be registered unless they are exempted by regulation. There is a change from prescriptive general regulatory control to management of stated risks to trade in primary produce, animal welfare, and agricultural security and ensuring that there is no breach of the domestic food standards, e.g. residues in food, by a range of means related to risk.
60. An agricultural compound is anything used to manage animals or plants. Under this legislation, all agricultural compounds are required to be registered unless they are exempted by regulation. Those compounds exempted from registration may be subject to controls via prescribed standards and conditions.
61. Following a transition period the new legislation shifts responsibility from the Animal Remedies Board to the Director-General of Agriculture.

62. An advisory body known as the Agricultural Compounds and Veterinary Medicines Advisory Council will provide support on policy strategies standards and procedures. This body is comprised of a number of members from many organisations including:
- AGCARM
 - Animal Remedy and Plant Protectant Association
 - Animal Welfare Advisory Committee
 - Federated Farmers of New Zealand (Inc)
 - New Zealand Veterinary Association
 - New Zealand Vegetable and Potato Growers Federation Inc
 - New Zealand Fruitgrowers Federation
 - New Zealand Dairy Board
 - New Zealand Meat Industry Association (Inc)
 - Poultry Industry Association of New Zealand (Inc)
 - and observers from the Environmental Risk Management Authority and the Animal Remedies Board and Pesticides Board.
63. The role of the ACVM Advisory Council is to act as a conduit for the exchange of information and views on the impact of products on trade in primary produce, animal welfare and agricultural security.
64. Thresholds have been identified and a risk assessment is then undertaken in accordance with specified criteria. Risk is considered to be the product of the probability that a specified threshold will be exceeded times the magnitude of the consequential negative impact.
65. For example the thresholds that have been agreed to for assessing the risks to animal welfare are:
- (i) the use of a compound having the potential to result in unacceptable pain or distress in the target animal;
 - (ii) the failure to achieve the products claims to cure or control conditions that are characterised by unacceptable pain or distress in the target animal.
66. The criteria used when assessing a product will be:
- (i) whether the use of the compound could produce demonstrable evidence of unnecessary pain or distress;
 - (ii) whether the use of a compound could result in demonstrable evidence of the failure to achieve product claims that result in unnecessary pain or distress in the target animal.
- As an example using these thresholds and criteria, an injectable zinc preparation claiming to prevent facial eczema, a disease identified by unacceptable pain or distress, would be required to be registered under the Agricultural Compounds and Veterinary Medicines Act. The applicant would be required to provide information to show that the product did indeed provide adequate protection against the disease. A group of products like this would not be exempted from registration
67. Although there is to be legislative change governing animal remedies, there will be no drastic alteration to the factors considered when assessing an animal compound to determine if it should be registered and with what conditions of manufacturing, importation, sale and use.

APPENDIX B

PRACTICE LETTERHEAD

CONSENT TO THE USE OF A DRUG IN A WAY NOT LICENSED BY THE ARB

I.....Name

of

.....Address

.....

having been fully informed by.....veterinarian,

of the need to use the drug..... for the treatment of on an animal/animals

under my care, and having been made aware that this drug is not licensed by the Animal Remedies

Board for such use, hereby give my informed consent for this use on this occasion.

..... Signed owner/authorised agent

(delete one)

Date.....

APPENDIX C

REGULATORY CONTROL OF ANIMAL REMEDIES

Prescription Animal Remedies and Prescription Medicines

Veterinarians have the sole right to prescribe restricted categories of drugs for animal treatment (Animal Remedies Act 1967, its Amendments, Regulations and Schedules). That 'right' to prescribe is not sacrosanct and (as noted by the Swann Committee) the "continuation of the privilege is, in the last resort, conditional on the responsible exercise of the power it confers".

A veterinarian may only prescribe or dispense a Prescription Animal Remedy or Prescription Medicine for administration to an animal under the immediate care (*) of that veterinarian and following a veterinary consultation (**) in respect of that animal.

* For an animal to be 'under the immediate care' of a veterinarian, the following conditions must be met:

- (i) The veterinarian must have been given and accepted responsibility for the health of the animal.
- (ii) The ongoing and continuing care of the animal is a reality and not merely nominal.

** A 'veterinary consultation' in relation to the administration, prescribing, or dispensing of any Prescription Animal Remedy or Prescription Medicine by a veterinarian to or in respect of an animal, means:

- (i) An examination of that animal by that veterinarian; or
- (ii) The obtaining by that veterinarian of sufficient information about that animal to enable that veterinarian to make an informed decision with respect to the administration, dispensing, or prescribing of a Prescription Animal Remedy or Prescription Medicine to or in respect of that animal.

Prescribing and dispensing animal remedies

Veterinarians are responsible for ensuring that a Prescription Animal Remedy or Prescription Medicine is used only with the specific authority of the prescribing veterinarian or, in that veterinarian's absence, the authority of a colleague fully conversant with the case.

Veterinarians using lay staff to supply any Prescription Animal Remedy or Prescription Medicine must ensure the lay staff supply only on the specific authority of a prescribing veterinarian. A record of that authorisation must be kept.

Veterinarians must exercise particular care when using an animal remedy in a manner or for a purpose for which it is not licensed (so called 'extra label' use). This includes variation in administration route, dose rate, species treated and indications for treatment. The same caution must be exercised when dealing with medicines (as defined in the Medicines Act 1981) which do not carry recommendations by the manufacturer for veterinary use.

The veterinarian prescribing an animal remedy or medicine or who supplies a material compounded by that veterinarian or material compounded and supplied by a pharmaceutical chemist pursuant to a prescription by that veterinarian, must ensure that the client is aware of the efficacy, correct method of use, side effects, withholding time and special precautions relevant to that animal remedy, medicine or compound. If an accident or animal welfare problem arises from the misuse of the animal remedy, medicine or compound, the veterinarian may be held culpable.

Requirements of racing conferences and similar organisations

When treating or prescribing for any animal before a race, show or other event, veterinarians should attempt to ensure that the relevant rules of the Racing or Harness Racing Conferences, Greyhound Association or similar bodies are followed. Veterinarians should, whenever possible and within reason, be familiar with the relevant requirements of these organisations.

‘Over the counter’ products

Veterinarians receive specialised training in veterinary therapeutics and pharmacology and the public should be made aware, through promotion and extension, but more importantly, by indirect means through the delivery of a high standard of professional service, that veterinarians are the most appropriate professionals to give expert and unbiased advice and information regarding the correct use of animal remedies.

Veterinarians are obliged to ensure that the supply of animal remedies is consistent with the needs and best interests of the animal and its owner. It is wholly appropriate for veterinarians to supply clients with animal remedies.

Any advertising of unrestricted animal remedies should be done in such a manner as not to jeopardise the public’s confidence in the scientific integrity and impartiality of the veterinarian or practice involved.

Veterinarians must be impartial and discerning in their sale of drugs so that clients obtain and, equally importantly, know they can obtain an unbiased opinion on the safety, efficacy and worth of an animal remedy under their particular conditions.

Veterinarians and lay staff employed in clinical practice and engaged in the sale of animal remedies should endeavour to supply the most appropriate, economical and efficacious animal remedies to meet the particular needs of clients.

The employment and direction of any lay travelling salesperson by a veterinarian or practice should be undertaken with great care. Only unrestricted animal remedies may be supplied by this means.

APPENDIX D

SUMMARY OF THE MEDICINES ACT 1981

The Medicines Act 1981 was enacted to regulate the manufacture, sale and supply of medicines, medical devices and related products. There have been a number of minor amending acts.

Statutory Instruments

The Medicines Regulations 1984 (and amendments).

Definitions

Medicine is anything for administration to people for a therapeutic purpose (treating or preventing disease, diagnosing disease, contraception, inducing anaesthesia, altering the human body, interfering with physiological functions or cleaning contact lenses) or for pregnancy testing. Does not include animal remedies.

New medicine is any medicine which has not been generally available in New Zealand in the last five years.

Pharmacy only medicine is one declared by regulation or notice that may be sold only in a pharmacy or hospital, or a licensed shop.

Prescription medicine is one declared by regulation or notice that may be sold only pursuant to a prescription written by a practitioner or veterinarian.

Restricted medicine is one declared by regulation or notice that may be sold only by a pharmacist in a pharmacy or hospital.

(Note: drugs controlled under the Misuse of Drugs Act 1975 are not classified under this Act.)

Administration

The Minister of Health may appoint committees to advise him. The Medicines Classification Committee makes recommendations to allocate new medicines to one of the three classes above, or not to classify them in which case they become general sales medicines. The Medicines Review Committee hears appeals against decisions by the Minister to allow (or not) distribution of the medicine or to grant a licence.

Manufacture and sale of medicines

Manufacturers, wholesalers and packers of medicines must be licensed. Retail sale of prescription medicines and restricted medicines must be by a pharmacist from a pharmacy or hospital; pharmacy only medicines must be sold only in a pharmacy or hospital, or in a licensed shop. These medicines must not be sold in a public place. Prescription medicines must be administered according to the prescription.

New medicines must not be sold or advertised until consent to distribute them has been given by the Minister of Health. Applications must include: details of the applicant and manufacturer, details of the contents, manufacturing process, indications, directions for use, labels, reports on efficacy and safety and whether the drug is licensed in any other countries. The Director General may ask for other information. Information on new medicines must be kept confidential, except to protect public health, or if required by a committee, the World Health Organization or overseas regulator. The Minister must weigh the benefits against any possible risks associated with the medicine. If he refuses consent, he must give reasons. He may give provisional consent, subject to conditions, for two years.

Section 25 allows practitioners (and MoH legal opinion indicates that this includes veterinarians) to manufacture, pack or procure medicines without consent for named patients under their care, or at the request of another practitioner for a patient under his care.

Pharmacists do not need licences to make or sell medicines. Veterinarians can manufacture, sell, supply or administer medicines to animals under their care, or under the care of another veterinarian. Anyone can supply drugs to a veterinarian or to anyone for administration to an animal under that veterinarian's care.

If a practitioner supplies a new drug to a patient, he/she must inform the Director General. The Director General may allow import or manufacture of a new medicine for clinical trials.

The Minister can revoke consent if the safety, efficacy, specifications or standards are no longer considered satisfactory. He can also ask for additional information on the safety and efficacy of any medicine at any time, and impose conditions on the supply of the medicine. The Minister can ban the import, sale, possession or use of any drug or medical device for a specified period of up to a year.

The Director General can ask for safety data on medical devices and stop their sale if he is not satisfied.

It is illegal to adulterate medicines. If a standard is prescribed for a medicine, then it must comply with that standard.

Importers and manufacturers of medicines must report adverse effects, either in New Zealand or elsewhere, to the Director General.

Every batch of medicine must be tested.

No person may possess a prescription medicine without reasonable excuse.

Medicines must be packed in a suitable container and labelled.

Anyone who manufactures or sells medicines must keep records and make them available to officers of the Ministry of Health or police.

Medicines must be stored in a suitable container, and away from food, drink and young children. Medicines must not be prepared or packed in a room used for preparing or eating food. Medicines must not be left unattended in buildings or vehicles unless they are secured.

The Minister may prohibit specific veterinarians from prescribing medicines on the recommendation of the Veterinary Council. A Medical Officer of Health may prohibit anyone supplying prescription medicines to anyone who is addicted to them.

Licences

The provisions relating to licences to manufacture, pack and sell by retail or wholesale are detailed in ss50 - 55.

Advertisements

Restrictions on advertisements are contained in ss56 - 62.

Enforcement

Sections 63 - 87 deal with powers of officers and of the courts to enforce provisions of the act. Sections 88 - 93 deal with appeals.

Related products

Cosmetics, foods etc. for which claims for therapeutic efficacy are made, must have consent from the Minister unless they are exempted by regulations.

Miscellaneous

The Director General may issue statements about drugs for the purpose of protecting public health. He shall publish lists of general sales medicines from time to time.

The Governor General may make regulations concerning most aspects of medicines' manufacture supply and use, on recommendation of the Minister of Health after consultation with people likely to be substantially affected.

The Minister may classify medicines by a notice in the *Gazette*.

The Misuse of Drugs Act 1975 and its regulations takes precedence over the Medicines Act 1981 and its regulations.

The Animal Remedies Board shall not issue a licence for an animal remedy which is also a prescription medicine without the consent of the Director General of Health.

The Medicines Regulations 1984 / 143

Classification

The First Schedule lists prescription medicines, restricted medicines and pharmacy only medicines.

Permitted colouring substances are listed.

Part III deals with advertisements.

Labelling

Medicines must not be sold unless they are properly labelled. The specifications for labels are detailed.

Manufacture, packing, storage and handling

Conditions must be such that the medicine is not contaminated. The types of containers are specified.

Prescriptions

A veterinarian may only write prescriptions for animals under his/her care. Only three months supply of medicine may be prescribed. The form of prescription is specified.

Data sheets

All prescription and restricted medicines must be accompanied by a data sheet that has been approved by the Director General. The form and contents are specified.

Records

Records of sales and prescriptions must be kept for three years.

Medical devices

Medical devices must act by means that can be physically measured, and must demonstrably have the properties claimed.

APPENDIX E

NEW ZEALAND VETERINARY ASSOCIATION DRAFT CODE OF PRACTICE FOR THE DISCRETIONARY USE OF HUMAN AND VETERINARY MEDICINES BY REGISTERED VETERINARIANS

Introduction

The Agricultural Compounds and Veterinary Medicines (ACVM) Act provides a legislative basis for prevention or management of the risks associated with the use of agricultural compounds (of which veterinary medicines are a subset), in the management of animals or plants.

The risks to be managed are:

1. Risks to trade in primary produce;
2. Risks to animal welfare;
3. Risks to agricultural security.

It is also a requirement that the use of agricultural compounds does not result in breaches of domestic food residue standards.

VETERINARY MEDICINE is defined in the Act as “any substance, mixture of substances, or biological compound used or intended for use in the direct management of animals”.

It is an offence under this legislation to import, manufacture, sell or use a veterinary medicine, that is not encompassed under this legislation, by being specifically registered as a trade name product, or exempted as a defined group.

It also states in the ACVM Act s55 (3) that “Every veterinarian commits an offence who knowingly fails to provide a client with information to prevent the occurrence, in any primary produce from any animal treated with an agricultural compound, of residues of that compound which contravene any requirements of the Dairy Industry Act 1952, the Meat Act 1981 or the Food Act 1981 or any regulations or notices in force under those Acts.”

It is recognised:

1. that there is an ongoing need for human medicines to be used by veterinarians for animal treatment; and
2. that it will be necessary on occasions for veterinarians to compound, or prescribe for a pharmacist to compound, specific preparations for animals in their direct care.

To enable the use of human medicines or compounded preparations as described above, while ensuring that the risks identified in the ACVM Act can still be managed, “human medicines” and “specifically compounded medicines” have been exempted under the condition that they be used by or under the authority of registered veterinarians, acting in accordance with this approved code.

It is also recognised:

3. that from time to time it will be necessary, in the interest of animal welfare and/or productivity, to use veterinary medicines on species or in ways not specified in the general conditions of registration or exemption for those veterinary medicines (traditionally known as “off label” use).

To enable such use a generic condition has been placed on registered veterinary medicines to allow discretionary use (see definition), by, or on the authority of registered veterinarians, for animals in their immediate care, and acting in accordance with this approved code.

Before discretionary use of veterinary medicines, human medicines or specially compounded medicines, there must be a veterinary evaluation as described below, and the requirements as listed below must be met.

Veterinarians should note that failure to comply with this code may result in a complaint being laid before the Veterinary Council of New Zealand for professional misconduct, and/or prosecution under the ACVM Act, or the Animals Protection Act (or its successor).

Civil liability may also be a consequence as a result of losses incurred by a client through inadequate advice or service.

Veterinary Evaluation

All the following steps are requirements of a veterinary evaluation which must be performed before discretionary use.

1. The veterinarian must obtain sufficient information about the animal or group of animals, being animals in the immediate care of that veterinarian, to enable that veterinarian to wisely judge that treatment with a veterinary medicine is justified.
2. The veterinarian must then first assess if there is a registered or exempted veterinary medicine available, which meets the treatment and welfare needs of the animal(s), within the general conditions imposed on that medicine. If such a veterinary medicine is available, then discretionary use is not justified.
3. If discretionary use is justified, the veterinarian must then assess if there is a registered or exempted veterinary medicine available, which can be expected with discretionary use, to meet the treatment and welfare needs of the animal(s), while reasonably ensuring that the risks identified in the ACVM Act can still be managed. If so, such medicine should be used in preference to the options in #4 below.
4. If no registered or exempt veterinary medicine is available which, even with discretionary use, meets the treatment and welfare needs of the animal(s) a veterinary medicine from the exempted groups “human medicines” or “preparations specially compounded by or for a veterinarian for animals under their immediate care” may be used, provided such use reasonably ensures that the risks identified in the ACVM Act can still be managed.

Requirements of registered veterinarians on each occasion of discretionary use of veterinary medicines or use of human medicines or specially compounded preparations.

A. Requirements relating to discretionary use in animals kept for production of food, fibre or other products used by man.

1. Ensure that there is no specific ban, by contacting the ACVM Group if there is doubt, precluding the medicine under consideration from being used on the intended species or in the intended way.
2. Assess the scientific data available so as to reasonably predict the efficacy of the intended use, and that unnecessary pain or suffering will not result from the discretionary use.
3. Maintain open communication channels with the animal’s owner or owner’s agent after treatment, and respond to any report of adverse reaction to the discretionary use, by examination of the treated animals, to prevent unnecessary pain and suffering.
4. Assess the information available, including the pharmacology of the medicine, that indicates the probability of residues of the medicine occurring in food, or other product derived from the animal to be treated, and establish withholding times which are sufficiently long to ensure that no violative residues result. Where it is not possible to establish a safe withholding time, a minimum withholding time of 60 days must be set.
5. Assess if there is significant risk to agricultural security, and if there is, do not proceed with the intended discretionary use. If there is doubt about the risk, enquire of the ACVM Group or MAF Regulatory Authority before discretionary use.
6. Ensure that the following information is conveyed to the animal’s owner or agent, in writing, and that a record is kept by the prescribing veterinarian for inspection for two years:
 - (i) Name of owner or owner’s agent;
 - (ii) The identity of the animal or group to be treated;
 - (iii) The established name of the drug, the active ingredient (if compounded for discretionary use) and the concentration;
 - (iv) The dose rate and frequency of treatment;

- (v) The route and method of administration;
 - (vi) The duration of treatment;
 - (vii) The withholding time;
 - (viii) The date of treatment;
 - (ix) The name of the prescribing veterinarian and the name, address and contact phone numbers of that veterinarian's practice.
7. Ensure that the following information is conveyed to the animal's owner or agent:
- (i) Any special considerations in regard to operator safety;
 - (ii) Specific advice that adverse reactions should be reported immediately to the prescribing veterinarian or in the absence of that veterinarian to other veterinarians in the practice;
 - (iii) Provide the information that this use is discretionary use;

B Requirements relating to discretionary use in animals not kept for production of food, fibre or other products used by man.

1. Ensure that there is no specific ban, by contacting the ACVM Group if there is doubt, precluding the medicine under consideration from being used on the intended species or in the intended way.
2. Assess the scientific data available so as to reasonably predict the efficacy of the intended use, and that unnecessary pain and suffering will not result from the discretionary use.
3. Maintain open communication channels with the animal owner or owner's agent after treatment and respond to any report of adverse reaction to the discretionary use by examination of the treated animals to prevent unnecessary pain and suffering.
4. Ensure that the following information is conveyed to the animal's owner or agent in writing and that a record is kept by the prescribing veterinarian for inspection for two years:
 - (i) Name of owner or owner's agent;
 - (ii) The identity of the animal or group to be treated;
 - (iii) The established name of the drug, the active ingredient and the concentration;
 - (iv) The dose rate and frequency of treatment;
 - (v) The route and method of administration;
 - (vi) The duration of treatment;
 - (vii) The date of treatment;
 - (viii) The name of the prescribing veterinarian and the name, address and contact phone numbers of that veterinarian's practice.
5. Ensure that the following information is conveyed to the animal's owner or agent:
 - (i) Any special considerations in regard to operator safety;
 - (ii) Specific advice that adverse reactions should be reported immediately to the prescribing veterinarian or in the absence of that veterinarian to other veterinarians in the practice
 - (iii) Provide the information that this use is discretionary use;

DEFINITIONS

Immediate care:

1. The veterinarian must have been given the responsibility for the care of the animal(s) by the owner or the owner's agent and must have accepted that responsibility to provide ongoing care which is real and not nominal.
2. The veterinarian must be sufficiently familiar with the animals either through physical examination or through frequent examinations in the previous 6 months to be aware of their current health status.
3. The veterinarian must be in a position to practically provide, or must make prior arrangements to ensure provision of, ongoing veterinary care of the animal in the event that adverse reaction threatens the animal's welfare.

Withholding time:

The time that must elapse between the last treatment and slaughter for human consumption or harvest of product for human consumption or use.

Discretionary use (one or more of the following):

1. The use by or on the authority of veterinarians of registered or exempt veterinary medicines in a manner not specified in the other conditions that apply to those veterinary medicines under the ACVM Act.
2. The use by or on the authority of veterinarians, of human medicines permitted under the Medicines Act 1981 and designated in the exempt group human medicines described in "MIMS" or "New Ethicals Catalogue" under the ACVM Act.

If a human medicine intended for discretionary use is not described in "MIMS" or "New Ethicals", it must be notified to the ACVM Group before it can be used

3. The use of preparations, by or on the authority of veterinarians, which have been specifically compounded, by or on the authority of that veterinarian, for use on animals in that veterinarian's immediate care.

This does not extend to veterinary medicines which have been compounded by veterinarians for sale for animals which are not in that veterinarian's immediate care or in respect of which all the requirements of a veterinary evaluation have not been carried out. Such veterinary medicines must be notified to the ACVM Group for registration or exemption.

Unnecessary pain and suffering:

This is a professional but subjective assessment by the veterinarian of what is unnecessary pain and suffering taking into account the veterinarian's knowledge of animal welfare and New Zealand society's current attitudes. In the face of uncertainty the discretionary use should be avoided or the veterinarian must monitor the animals post treatment and take appropriate steps to prevent unnecessary pain and suffering should adverse reaction occur.

Agricultural security:

Agricultural security is defined in the ACVM Act as follows: "means the exclusion, eradication, and effective pest management of

- (a) Pests
- (b) Unwanted organisms under the Biosecurity Act 1993".

APPENDIX F

ORAL ANTIBIOTICS AND COCCIDIOSTATS LICENSED FOR AGRICULTURAL AND VETERINARY USE IN NEW ZEALAND (JUNE 1999)

A MACROLIDES

Tylan AF 250 (A05804)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 250g/kg tylosin as tylosin phosphate

Approved species: Pigs, chickens, beef cattle

Approved claims: For increased rate of weight gain and improved feed efficiency in pigs. For the reduction in the incidence of liver abscess in beef cattle. As aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum* and/or *Mycoplasma synoviae* in chickens.

Dose: 40-400g per tonne feed, fed continuously (pigs). 44g per tonne feed, fed continuously (cattle). 88-220g per tonne feed, fed continuously (layer chickens). 3.6-4.0kg per tonne feed, fed for 5 days and then 2 additional days (broiler chickens and replacement layers).

Tylomix (A06775)

Licensed to Bomac Laboratories Ltd

Non ethical animal remedy

Active ingredient: 100g/kg tylosin as tylosin tartrate

Approved species: Pigs and chickens

Approved claims: For increasing weight gain and feed efficiency in pigs. To control chronic respiratory disease in chickens caused by mycoplasma species.

Dose: 0.1-1.0kg per tonne feed (pigs). 0.22-0.55kg per tonne feed, fed continuously (layers). 9.0-10.0kg per tonne feed for five days then an additional two days (broilers and layer replacements).

Tylasul G (A02233)

Licensed to Elanco Animal Health

Prescription Animal Remedy class 1

Active ingredient: 20g/kg tylosin as tylosin phosphate and 20g/kg sulfadimidine

Approved species: Pigs

Approved claims: For maintaining weight gains and feed efficiency in presence of swine enzootic pneumonia and atrophic rhinitis. Reduction of *Bordetella bronchiseptica* rhinitis. Prevention of dysentery and salmonella enteritis. Control of bacterial pneumonia and streptococcal lymphadenitis.

Dose: 5.0kg per tonne feed.

Tylasul G Concentrate (A04994)

Licensed to Elanco Animal Health

Prescription Animal Remedy class 1

Active ingredient: 100g/kg tylosin as tylosin phosphate and 100g/kg sulfadimidine

Approved species: Pigs

Approved claims: For maintaining weight gains and feed efficiency in presence of swine enzootic pneumonia and atrophic rhinitis. Reduction of *Bordetella bronchiseptica* rhinitis. Prevention of dysentery and salmonella enteritis. Control of bacterial pneumonia and streptococcal lymphadenitis.

Dose: 1.0kg per tonne feed.

Tylan 100 (A00080)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 100g/kg tylosin as tylosin phosphate

Approved species: Pigs, chickens, beef cattle

Approved claims: For increased rate of weight gain and improved feed efficiency in pigs. For reduction in the incidence of liver abscess in beef cattle. As an aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum* and/or *Mycoplasma synoviae*.

Dose: 0.1-1.0kg per tonne feed, fed continuously (pigs). 0.11kg per tonne feed, fed continuously (cattle). 0.22-0.55kg per tonne feed, fed continuously (layer chickens).

9.0-10.0kg per tonne feed, fed for five days then two additional days (broiler chickens and replacement layers).

Tylan Soluble (A00086)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: tylosin tartrate

Approved species: Chickens and turkeys

Approved claims: As an aid in the prevention and treatment of chronic respiratory disease.

Dose: 100g per 200 litres drinking water.

Tylosol (A05891)

Licensed to Bomac Laboratories Ltd

Non ethical animal remedy

Active ingredient: 500g/kg tylosin as tylosin tartrate

Approved species: Poultry

Approved claims: An aid in the prevention and treatment of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae*.

Dose: 1.5kg-2.0 per 1000kg of feed or 1.0kg per 1000litre drinking water, for 3-5 days.

Tetramutin (A07185)

Licensed to Sandoz Pharma Ltd

Prescription Animal Remedy class 1

Active ingredient: 33.3g/kg tiamulin hydrogen fumarate and 100g/kg chlortetracycline as chlortetracycline hydrochloride

Approved species: Pigs

Approved claims: To treat, prevent and control conditions of the respiratory and alimentary tracts associated with organisms sensitive to chlortetracycline/tiamulin combination.

Dose: 3.0-4.5kg per tonne feed, fed for 7-10 days or as required.

Dynamutlin Feed Premix (A04209)

Licensed to Technik Products Ltd

Non ethical animal remedy

Active ingredient: 25g/kg tiamulin hydrogen fumarate

Approved species: Pigs and poultry

Approved claims: For the treatment and control of chronic respiratory disease (CRD) in poultry. For swine enzootic pneumonia and swine dysentery in pigs, and for growth promotion in pigs.

Dose: 0.4-4.0kg per tonne feed (pigs). 0.5-2.0kg per tonne feed (poultry).

Tiamutin 2% premix (A03887)

Licensed to Sandoz Pharma Ltd

Non ethical animal remedy

Active ingredient: 20g/kg tiamulin hydrogen fumarate

Approved species: Pigs, poultry

Approved claims: For growth promotion in pigs. An aid in the control of mycoplasma in poultry.

Dose: 2.5kg per tonne feed, fed 7 days in every 28 days (poultry). 1.25kg per tonne feed, fed continuously (pigs).

Dynamutilin-S (A04721)

Licensed to Technik Products Ltd

Prescription Animal Remedy class 1

Active ingredient: 25g/kg tiamulin hydrogen fumarate and 100g/kg sulphadimidine

Approved species: Pigs

Approved claims: For the prevention of swine dysentery and control of swine enzootic pneumonia. For growth promotion and for the reduction in incidence and severity of atrophic rhinitis.

Dose: 1.0kg per tonne feed.

Erythrosol (A05893)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: 500g/kg erythromycin as erythromycin thiocyanate

Approved species: Poultry

Approved claims: For the treatment of respiratory diseases, multiple disease conditions and stress due to climatic environmental or management factors in poultry.

Dose: 200g per 1000 litres drinking water, for 5 days or as prescribed.

B BACITRACIN**Bomix Calf Milk Supplement (A04370)**

Licensed to Bomac Laboratories Ltd

Non ethical animal remedy

Active ingredient: Zinc bacitracin

Approved species: Calves

Approved claims: For supplementation of feed, including growth promotant.

Dose: 5.0kg per tonne milk powder, or 4g per 10litres liquid milk.

Bio-grow (A06466)

Licensed to Nutritech International Ltd

Non ethical animal remedy

Active ingredient: zinc bacitracin

Approved species: Pigs

Approved claims: For supplementation of feed including a growth promotant.

Dose: 2.5kg per tonne feed.

Vitastart (A07563)

Licensed to Vitec Nutrition Ltd

Non ethical animal remedy

Active ingredient: 3.3g/kg zinc bacitracin

Approved species: Pigs

Approved claims: For supplementation of feed including a growth promotant.

Dose: 3.0kg per tonne feed.

Supreme Calf (A04790)

Licensed to Rhone Merieux Animal Health

Prescription Animal Remedy class 1

Active ingredient: zinc bacitracin

Approved species: Calves

Approved claims: For supplementation and to improve growth rates.

Dose: 5g per 10 litres liquid milk, or 5g per kg milk powder or feed.

Vitablend (A06304)

Licensed to Unitech Industries Ltd

Prescription Animal Remedy class 1

Active ingredient: 11.4g/kg zinc bacitracin

Approved species: Calves

Approved claims: For supplementation of feed with growth promotant.

Dose: 7kg per tonne milk replacer.

Stressol (A04140)

Licensed to Technik Products Ltd

Non ethical animal remedy

Active ingredient: 13.3g/kg bacitracin

Approved species: Poultry, calves and pigs

Approved claims: Assists in maintaining health and growth, and combats stress.

Dose: 500g per 1250 litres drinking water, as required.

Danmix Pig Weaner Vitamin Mineral Premix (A04904)

Licensed to Nutritech International Ltd

Non ethical animal remedy

Active ingredient: zinc bacitracin

Approved species: Pigs

Approved claims: For supplementation with growth promotant.

Dose: 3.0kg per tonne feed.

Bio-wean (A06467)

Licensed to Nutritech International Ltd

Non ethical animal remedy

Active ingredient: zinc bacitracin

Approved species: Pigs

Approved claims: For supplementation with growth promotant.

Dose: 3.0kg per tonne feed.

Vitalean (A07562)

Licensed to Vitec Nutrition Ltd

Non ethical animal remedy

Active ingredient: 3.3g/kg zinc bacitracin

Approved species: Pigs

Approved claims: For feed supplementation and growth promotion.

Dose: 3.0kg per tonne feed.

Premium Calf Booster (A04010)

Licensed to Technik Products Ltd

Prescription Animal Remedy class 1

Active ingredient: 15g/kg zinc bacitracin

Approved species: Calves

Approved claims: For supplementation of feed with growth promotion

Dose: 4g per 10 litres liquid milk, or 4g per kg meal or milk powder.

Danmix Calf Food Supplement (A03396)

Licensed to Nutritech International Ltd

Non ethical animal remedy

Active ingredients: 100g/kg zinc bacitracin

Approved species: Calves

Approved claims: For supplementation of feed and to promote healthy, vigorous growth in animals up to 12 weeks of age.

Dose: 1.0-1.5g per calf per day, or 50g per 25kg meal or milk powder.

Calf Replacer Premix (A03861)

Licensed to Poultrymen's Co-op Ltd

Non ethical animal remedy

Active ingredient: zinc bacitracin

Approved species: Calves

Approved claims: For supplementation of feed.

Dose: 5.2kg per tonne feed.

Calfmax (A04533)

Licensed to Animal Nutrition Laboratories

Non ethical animal remedy

Active ingredient: zinc bacitracin

Approved species: Calves

Approved claims: For supplementation of diet and improved growth performance.

Dose: 4.0g per kg milk powder or 4.0g per 10 litres of liquid milk.

Danmix Pig Grower Finisher Vitamin Mineral Premix (A02194)

Licensed to Nutritech International

Non ethical animal remedy

Active ingredients: 40g/kg zinc bacitracin

Approved species: Pigs

Approved claims: For supplementation of feed with growth promotant

Dose: 2.5kg per tonne feed

Supreme Calf Plus Deccox (A06297)

Licensed to Rhone Poulenc Rural Australia Pty

Prescription Animal Remedy

Active ingredients: 25g/kg decoquinat and 0.12g/kg zinc bacitracin

Approved species: Calves

Approved claims: For growth promotion and coccidiosis.

Dose: 5g/kg milk powder or 5g per 10 litre liquid milk.

Albac G Feed Supplement (A06736)

Licensed to Asia Pacific Specialty Chemicals

Non ethical animal remedy

Active ingredients: 150g/kg zinc bacitracin

Approved species: Calves, pigs and poultry

Approved claims: For growth promotion. For increased egg production in chickens.

Dose: 30-100ppm in feed.

C AVOPARCIN

Broiler Starter Premix (A03466)

Licensed to Poultrymen's Co-operative Ltd

Non ethical animal remedy

Active ingredient: 4g/kg avoparcin

Approved species: Poultry

Approved claims: For optimum performance in broiler starters.

Dose: 8kg per tonne feed.

Avotan 100 Granular (A06152)

Licensed to Roche Products NZ Ltd

Non ethical animal remedy

Active ingredient: 100g/kg avoparcin

Approved species: Pigs and chickens

Approved claims: For the promotion of growth and the improvement of feed conversion efficiency in broiler chickens and growing pigs. An aid in the prevention of necrotic enteritis in broiler chickens.

Dose: 200g per tonne feed (pigs). 100-200g per tonne feed (chickens).

Avotan 100 Feed Supplement (A03452)

Licensed to Roche Products NZ Ltd

Non ethical animal remedy

Active ingredients: 105g/kg avoparcin

Approved species: Pigs and chickens

Approved claims: For growth promotion in pigs and broiler chickens. For enteritis in broiler chickens.

Dose: 200g per tonne feed (pigs). 100g per tonne feed (growth promotion in chickens).

200g per tonne feed (enteritis in chickens).

D VIRGINIAMYCIN

Founderguard Pelleted Feed Additive for Horses (A06863)

Licensed to Bomac Laboratories Ltd

Non ethical animal remedy

Active ingredient: 10g/kg virginiamycin

Approved species: Horses

Approved claims: To maintain low blood D lactate of gut origin and to reduce the risk of laminitis.

Dose: 4.0kg per tonne feed.

Stafac 500 (A02848)

Licensed to Pfizer Laboratories Ltd

Non ethical animal remedy

Active ingredients: 500g/kg virginiamycin

Approved species: Pigs, chickens and turkeys

Approved claims: For growth promotion

Dose: 40g per tonne feed (pigs and turkeys). Up to 40g per tonne feed (broiler chickens).

40-160g per tonne feed (layer chickens).

E FLAVOPHOSPHOLIPOL

Flavomycin 40g (A04673)

Licensed to Animal Health Advisory

Non ethical animal remedy

Active ingredients: 500g/kg bambermycins

Approved species: Calves, turkeys, pigs and chickens

Approved claims: For growth promotion.

Dose: 400g per tonne feed or up to 2g per 5 litre milk (calves). 100-500g per tonne feed (pigs). 65-100g per tonne feed (chickens). 100-200g per tonne feed (turkeys).

F IONOPHORES

Rumensin Technical (A07871)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 900g/kg monensin as monensin sodium

Approved species: Cattle

Approved claims: For increased feed efficiency and rate of weight gain in beef cattle. For increased milk protein production, as an aid in the control of ketosis and as an aid in the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*, in dairy cattle.

Dose: Up to 300mg monensin per day per animal, or 11-33ppm monensin in the ration of feedlots. For calves, use at the rate of 0.5-1.0mg/kg liveweight monensin in the final feed.

Elancoban (A02055)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 100g/kg monensin as monensin sodium

Approved species: Broilers, replacement chickens and growing turkeys

Approved claims: An aid in the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E.maxima*, *E. mivati*, *E. necatrix* and *E. tenella* in chickens, and *E. meleagrimitis*, *E. adenoides* and *E. gallopavonis* in turkeys.

Dose: 1.0-1.2kg per tonne feed (broiler and layer replacement chickens). 0.6-1.0kg per tonne feed (turkeys).

Rumensin Liquid (A07450)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 60g/litre monensin as monensin sodium

Approved species: Cattle

Approved claims: An aid in the reduction of bloat in pasture fed dairy cattle, for increased production of milk solids in pasture fed dairy cows and as an aid in the control of ketosis in cattle.

Dose: 5ml per animal per day.

Elancoban 200 (A07100)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 200g/kg monensin as monensin sodium

Approved species: Broiler and layer replacement chickens, turkeys

Approved claims: An aid in the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E.maxima*, *E. mivati*, *E. necatrix* and *E. tenella* in chickens, and *E. meleagrimitis*, *E. adenoides* and *E. gallopavonis* in turkeys.

Dose: 0.5-0.6kg per tonne feed, fed continuously (broiler chickens) or up to time of laying (layer replacement chickens). 0.3-0.5kg per tonne feed, fed up to 16 weeks of age (turkeys).

Rumensin Premix (A03553)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: Monensin sodium

Approved species: Sheep, goats, and cattle

Approved claims: For increased milk protein production, an aid in the control of ketosis and an aid in the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernni*, in dairy cattle. For improved feed efficiency and/or rate of weight gain, an aid in the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernni*, in beef cattle. For improved feed efficiency in beef cows as indicated by improvement in the relationship of feed to cow weight, calf weight and reproductive performance. For increased rate of weight gain and to promote early onset of first oestrus, and as an aid in the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernni*, in replacement heifers. As an aid in the control of coccidiosis caused by *Eimeria arloingi* in goats. As an aid in the control of coccidiosis caused by *Eimeria ninakohlyakimovae*, *E. ahsata*, *E. faurel*, *E. parva*, *E. intricata* and *E. pallida*, in sheep.

Bovatec 20 Liquid (A06956)

Licensed to Roche Products NZ Ltd

Non ethical animal remedy

Active ingredient: 200g/kg lasalocid sodium

Approved species: Cattle and goats

Approved claims: For improved feed efficiency and rate of weight gain in cattle. An aid in the control of coccidiosis caused by *Eimeria* species in cattle and goats.

Dose: Up to 0.450g per animal per day (goats). Up to 2.0g per animal per day (cattle).

Avatec Premix (A03390)

Licensed to Roche Products NZ Ltd

Non ethical animal remedy

Active ingredient: 150g/kg lasalocid as lasalocid sodium

Approved species: Broiler chickens, turkeys and layer birds

Approved claims: An aid in the prevention of coccidiosis caused by *Eimeria* species.

Dose: 0.5-0.833kg per tonne feed.

First Milk (A07537)

Licensed to Roche Products NZ Ltd

Non ethical animal remedy

Active ingredient: lasalocid sodium

Approved species: Calves

Approved claims: Aid in the control of coccidiosis and improvement of growth rates.

Dose: 25ml per animal per day, in whole milk.

Bovatec (A04395)

Licensed to Roche Products (NZ) Ltd

Non ethical animal remedy

Active ingredient: 150g/kg lasalocid sodium

Approved species: Goats and cattle

Approved claims: An aid in the control of coccidiosis in goats. Improvement of weight gain in goats and cattle.

Dose: Up to 0.6g per animal per day (goats). Up to 2.668g per animal per day (cattle).

Aviax (A06122)

Licensed to Pfizer Laboratories Ltd

Non ethical animal remedy

Active ingredient: 50g/kg semduramicin as semduramicin sodium

Approved species: Chickens

Approved claims: For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/mitis*, *E. necatrix* and *E. tenella* in broiler chickens.

Dose: 0.5kg per tonne feed.

Salocin (A07640)

Licensed to Animal Health Advisory

Non ethical animal remedy

Active ingredient: 120g/kg sodium salinomycin

Approved species: Poultry, pigs and cattle

Approved claims: For the prevention of coccidiosis caused by *Eimeria acervulina*, *E.brunetti*, *E.maxima*, *E.mivati*, *E.necatrix* and *E.tenella* in broiler chickens and replacement birds. For increasing rate of weight gain and feed efficiency of grower/finisher pigs and feedlot beef cattle.

Dose: 0.5kg per tonne feed (poultry). 0.125-0.5kg per tonne feed (pigs). 0.125kg per tonne feed (cattle).

Coxistac (A03932)

Licensed to Pfizer Laboratories Ltd

Non ethical animal remedy

Active ingredient: 60g/kg sodium salinomycin

Approved species: Chickens

Approved claims: For the prevention of coccidiosis caused by *Eimeria acervulina*, *E.brunetti*, *E.maxima*, *E.mivati*, *E.necatrix* and *E.tenella* in broiler chickens and in replacement birds intended for use as caged layers.

Dose: 1kg per tonne feed.

Coxistac 120 Anticoccidial Premix Feed Additive Premix (A07622)

Licensed to Pfizer Laboratories Ltd

Non ethical animal remedy

Active ingredient: 116.6g/kg salinomycin as sodium salinomycin

Approved species: Chickens, pigs and beef cattle

Approved claims: For the prevention of coccidiosis caused by *Eimeria acervulina*, *E.brunetti*, *E.maxima*, *E.mivati*, *E.necatrix* and *E.tenella* in broiler chickens and in replacement birds intended for use as caged layers. For increasing weight gain and improving feed efficiency of grower/finisher pigs and feedlot beef cattle.

Dose: 0.5kg per tonne feed, fed continuously (poultry). 0.21kg per tonne feed (pigs). 0.125kg per tonne feed (cattle).

Cygro (A05035)

Licensed to Roche Products NZ Ltd

Non ethical animal remedy

Active ingredient: 10g/kg maduramicin

Approved species: Chickens

Approved claims: For the prevention and control of coccidiosis caused by *Eimeria acervulina*, *E.brunetti*, *E.maxima*, *E.mivati*, *E.necatrix* and *E.tenella* in broiler chickens.

Dose: 0.5kg per tonne feed.

Monteban (A04309)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredients: 100g/kg narasin

Approved species: Chickens

Approved claims: An aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E.tenella*, *E.acervulina*, *E.brunetti*, *E.mivati* and *E.maxima*, in broiler chickens.

Dose: 0.6-0.8kg per tonne feed.

Maxiban (A05591)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 80g/kg nicarbazin and 80g/kg narasin

Approved species: Chickens

Approved claims: As an aid in the prevention of coccidiosis caused by *Eimeria acervulina*, *E.brunetti*, *E.maxima*, *E.mivati*, *E.necatrix* and *E.tenella* in broiler chickens.

Dose: 0.5-0.625kg per tonne of feed, fed continuously for at least 14-28 days.

Carbigran (A07039)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 250g/kg nicarbazin

Approved species: Chickens

Approved claims: As an aid in prevention of carcal (*Eimeria tenella*) and intestinal (*E.acervulina*, *E. brunetti*, *E.maxima*, and *E.necatrix*) coccidiosis in broiler chickens.

Dose: 0.5kg per tonne feed.

Cycarb 250 Anticoccidial Premix (A06048)

Licensed to Roche Products (NZ) Ltd

Non ethical animal remedy

Active ingredients: 250g/kg Nicarbazin

Approved species: Chickens

Approved claims: An aid in the prevention and control of coccidiosis caused by *Eimeria* spp, in broiler chickens.

Dose: 0.5kg per tonne feed.

G OTHER**Tylasul G (A02233)**

Licensed to Elanco Animal Health

Prescription Animal Remedy class 1

Active ingredient: 20g/kg tylosin as tylosin phosphate and 20g/kg sulfadimidine

Approved species: Pigs

Approved claims: For maintaining weight gains and feed efficiency in presence of swine enzootic pneumonia and atrophic rhinitis. Reduction of *Bordatella bronchiseptica* rhinitis. Prevention of dysentery and salmonella enteritis. Control of bacterial pneumonia and streptococcal lymphadenitis.

Dose: 5.0kg per tonne feed.

Tylasul G Concentrate (A04994)

Licensed to Elanco Animal Health

Prescription Animal Remedy class 1

Active ingredient: 100g/kg tylosin as tylosin phosphate and 100g/kg sulfadimidine

Approved species: Pigs

Approved claims: For maintaining weight gains and feed efficiency in presence of swine enzootic pneumonia and atrophic rhinitis. Reduction of *Bordatella bronchiseptica* rhinitis. Prevention of dysentery and salmonella enteritis. Control of bacterial pneumonia and streptococcal lymphadenitis.

Dose: 1.0kg per tonne feed.

Linco-Spectin Premix (A04032)

Licensed to Upjohn New Zealand

Prescription Animal Remedy class 1

Active ingredients: 22g/kg lincomycin as lincomycin hydrochloride and 22g/kg spectinomycin as spectinomycin sulphate

Approved species: Pigs

Approved claims: For treatment and control of enteritis, mycoplasmal pneumonia, swine dysentery and salmonellosis.

Dose: 1.0kg per tonne feed. Fed as sole diet in swine up to 57kg LWT.

Linco Spectin Soluble Powder (A02098)

Licensed to Pharmacia & Upjohn

Prescription Animal Remedy class 1

Active ingredients: 222g/kg lincomycin and 444.7g/kg spectinomycin

Approved species: Chickens and pigs

Approved claims: For proliferative enteritis in pigs. For chronic respiratory disease in chickens.

Dose: 10mg/kg LWT per day (pigs). 50-150mg/kg LWT per day for 5 days then 2 further days, in drinking water.

Lincomix Premix (A03661)

Licensed to Upjohn Inter-American Corporation

Prescription Animal Remedy class 1

Active ingredient: 110g/kg lincomycin as lincomycin hydrochloride

Approved species: Broiler chickens and pigs

Approved claims: Aids in the control of necrotic enteritis in chickens. Aids in the treatment of mycoplasma pneumonia and swine dysentery in pigs.

Dose: 20g per tonne feed (poultry). 0.4kg per tonne feed (pigs).

Lincomix S Premix (A04587)

Licensed to Upjohn New Zealand Ltd

Prescription Animal Remedy class 1

Active ingredient: 44g/kg lincomycin as lincomycin HCl and 110g/kg sulphamethazine

Approved species: Pigs

Approved claims: Aids in the treatment of mycoplasma pneumonia, swine dysentery and atrophic rhinitis.

Dose: 500g-1.0kg per tonne feed.

Neomix Concentrate (A01350)

Licensed to Upjohn InterAmerican Corporation

Prescription Animal Remedy class 1

Active ingredient: 500g/kg neomycin as neomycin sulphate

Approved species: Chickens, turkeys, pigs, and cattle

Approved claims: For treatment of bacterial enteritis.

Dose: 170g to 340g per tonne feed. Feed for 3 to 5 days.

Biosol M Pump (A01811)

Licensed to Upjohn Inter-American Corporation

Prescription Animal Remedy class 1

Active ingredients: 0.25g/litre methscopolamine and 35g/litre neomycin as neomycin sulphate

Approved species: Piglets

Approved claims: For the treatment of bacterial diarrhoea and gastro intestinal infections, especially when accompanied by hypermotility and hypersecretion.

Dose: 1-2ml per day.

Apralan 100 Premix (A04393)

Licensed to Elanco Animal Health

Prescription Animal Remedy class 1

Active ingredient: 100g/kg apramycin as apramycin sulphate

Approved species: Pigs

Approved claims: For the treatment and control of colibacillosis caused by susceptible strains of *Escherichia coli*.

Dose: 1kg per tonne feed.

Apralan (A04391)

Licensed to Elanco Animal Health

Prescription Animal Remedy class 1

Active ingredient: 333g/kg apramycin as apramycin sulphate

Approved species: Pigs and broiler poultry

Approved claims: For the treatment of colibacillosis caused by susceptible strains of *Escherichia coli* in pigs.

For the control and treatment of colibacillosis caused by susceptible strains of *Escherichia coli* and of other infections caused by either *Salmonella* species or susceptible gram negative organisms.

Dose: 25mg apramycin/kg LWT per day for 7 days, via drinking water (pigs). 40-80mg apramycin/kg LWT per day for 5 days, via drinking water (broilers).

Tetramutin (A07185)

Licensed to Sandoz Pharma Ltd

Prescription Animal Remedy class 1

Active ingredient: 33.3g/kg tiamulin hydrogen fumarate and 100g/kg chlortetracycline as chlortetracycline hydrochloride

Approved species: Pigs

Approved claims: To treat, prevent and control conditions of the respiratory and alimentary tracts associated with organisms sensitive to chlortetracycline/tiamulin combination.

Dose: 3.0-4.5kg per tonne feed, fed for 7-10 days or as required.

Aurofac D (A01938)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: 10g/kg chlortetracycline HCl

Approved species: Calves and pigs

Approved claims: For the treatment of diseases caused by micro-organisms susceptible to chlortetracycline

Dose: 50kg per tonne feed or 20.0g per litre drinking water, for 7 days.

Tetravet 200 Soluble Antibiotic Powder (A07137)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: 200g/kg oxytetracycline hydrochloride

Approved species: Pigs, poultry, calves

Approved claims: For the treatment and control of disease caused by or associated with oxytetracycline sensitive microorganisms.

Dose: 2.0-5.0kg per tonne feed, fed for 7-14 days (pigs). 1.25-2.0kg per tonne feed, fed for 5-10 days (poultry). 2.0kg per tonne feed, fed for 5-10 days (calves).

Tetravet 100 Soluble Antibiotic Powder (A01749)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: 100g/kg oxytetracycline HCl

Approved species: Calves, foals, pigs, lambs, poultry, cats, dogs and pigs

Approved claims: For the treatment of infections caused by micro-organisms susceptible to oxytetracycline, especially of the gastrointestinal and urogenital tracts

Dose: 2.5-5.0g per 50kg LWT per day (calves and foals). 2.5g per 10kg LWT per day (pigs and sheep). 200g per 90 litres of drinking water.

Tetravet Quat (A07714)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: 200g/kg oxytetracycline as the quaternary ammonium complex

Approved species: Poultry and pigs

Approved claims: For the treatment and control of diseases caused by or associated with oxytetracycline sensitive microorganisms e.g. enteritis, pneumonia, mastitis metritis agalactia, leptospirosis and septicaemia in pigs, and bacterial enteritis, pasteurellosis, infectious synovitis, fowl cholera, mycoplasma and chronic respiratory disease in poultry.

Dose: 5.0kg per tonne feed (poultry). 8.0-10.0kg per tonne feed (pigs).

Alphamycin (A04147)

Licensed to Technik Products Ltd

Prescription Animal Remedy class 1

Active ingredient: 100g/kg oxytetracycline HCl

Approved species: Calves, poultry, pigs

Approved claims: For treatment of disease due to or associated with oxytetracycline sensitive organisms

Dose: 3.0-10.0kg per tonne feed, for 5-14 days (pigs). 2.5-4.0kg per tonne feed, for 5-10 days (poultry). 3.0-4.0kg per tonne feed, for 5-10 days (calves).

Terasol (A04144)

Licensed to Technik Products Ltd

Prescription Animal Remedy class 1

Active ingredient: 100g/kg oxytetracycline HCl

Approved species: Pigs, poultry and calves

Approved claims: For the treatment and prevention of bacterial infections susceptible to oxytetracycline.

Dose: 2.5g per litre liquid feed or drinking water per day, as required (calves). 2.5-4.0g per litre drinking water per day, as required (pigs). 2.5g per litre drinking water per day for 5-10 days or as required.

Terramycin 200 (A06294)

Licensed to Pfizer Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: Oxytetracycline HCl

Approved species: Poultry, pigs, cattle

Approved claims: For the treatment and prevention of diseases associated with oxytetracycline sensitive organisms.

Surmax (A05217)

Licensed to Elanco Animal Health

Non ethical animal remedy

Active ingredient: 100g/kg avilamycin

Approved species: Pigs and chickens

Approved claims: For increased rate of weight gain and improved feed efficiency in broiler chickens and pigs.

Dose: 0.1-0.4kg per tonne feed (pigs). 25-150g per tonne feed (poultry).

Baytril 2.5% Oral Solution (A05579)

Licensed to Bayer NZ Ltd

Prescription Animal Remedy class 1

Active ingredient: enrofloxacin

Approved species: Calves

Approved claims: For therapy of diseases in unweaned calves caused by bacteria.

Dose: 5.0-10.0ml per 50kg LWT per day for 3 days, either undiluted or with liquids.

Toltro (A00970)

Licensed to Westwood Products Ltd

Non ethical animal remedy

Active ingredient: 63g/kg diaveridine and 145g/kg sodium sulphaquinoxaline

Approved species: Poultry and rabbits

Approved claims: For the treatment and prevention of caecal and intestinal coccidiosis

Dose: 15-25g per 45kg feed (poultry). 35g per 45kg feed (rabbits). 5.0-10.0g per 18 litres drinking water for treatment.

Trisulfin Suspension (A07555)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: 25.0mg/ml sulphadiazine and 5.0mg/ml trimethoprim.

Approved species: Horses, pigs, preruminant calves, lambs, cats, dogs and kids

Approved claims: For the treatment and control of bacterial infections sensitive to trimethoprim and sulphadiazine.

Dose: 30ml per 25kg LWT daily, for 3-5 days.

Paracillin SP (A06847)

Licensed to Chemavet Division, Pharmaco (NZ) Ltd

Prescription Animal Remedy class 1

Active ingredient: 800g/kg amoxicillin trihydrate

Approved species: Poultry

Approved claims: For the treatment of infections caused by bacteria sensitive to amoxicillin.

Dose: 6-20g per 100litre drinking water, for 3-5 days.

Pulmotil 200 (A07515)

Licensed to Elanco Animal Health

Prescription Animal Remedy class 1

Active ingredient: 200g/kg tilmicosin

Approved species: Pigs

Approved claims: For the control of pneumonia caused by *Actinobacillus pleuropneumoniae*, *Pasteurella multocida* and other organisms sensitive to tilmicosin. For improved weight gain and an aid in improving feed conversion in pigs with pneumonia.

Dose: 1.0-2.0kg per tonne feed, for 21 days.

Dimetramix (A07340)

Licensed to Technik Products

Non ethical animal remedy

Active ingredient: 225g/kg dimetridazole

Approved species: Pigs, turkeys, chickens, game birds

Approved claims: For the treatment and prevention of swine dysentery and post weaning scours. For the prevention of blackhead in turkeys, chickens and gamebirds.

Dose: 900g per tonne feed, fed continuously (pigs – prevention). 2.25kg per tonne feed, for 7-14 days (pigs and poultry – treatment). 560g-670g per tonne feed, fed continuously (poultry – prevention).

Dimetrasol (A07341)

Licensed to Technik Products

Non ethical animal remedy

Active ingredient: 400g/kg dimetridazole

Approved species: Pigs, turkeys, chickens, game birds, pigeons

Approved claims: For the treatment of swine dysentery and post weaning scours in pigs. For the treatment of blackhead in turkeys, chickens and game birds. For the treatment of canker in pigeons.

Coccidiosol (A05894)

Licensed to Bomac Laboratories Ltd

Non ethical animal remedy

Active ingredient: 200g/kg amprolium as amprolium HCl and 200g/kg sulphaquinoxaline

Approved species: Poultry

Approved claims: For the treatment and prevention of coccidiosis.

Dose: Up to 1.0kg per tonne feed, fed continuously in broiler and replacement feed and for 3 days in layer feed.

For drinking water treatment, use up to 1.0kg per 1000 litre water, for 3-5 days.

Baycox (A05390)

Licensed to Bayer NZ Ltd

Non ethical animal remedy

Active ingredient: 25g/litre toltrazuril

Approved species: Poultry

Approved claims: For the treatment of coccidiosis.

Dose: 1.0 litre per 1000 litres drinking water, for 2 days.

Roxolin 6% (A03209)

Licensed to Technik Products Ltd

Non ethical animal remedy

Active ingredient: 60g/kg halquinol

Approved species: Poultry and pigs

Approved claims: For growth promotion in pigs and broilers. For the control of organisms sensitive to halquinol in enteric disease syndromes in poultry.

Dose: 2.0kg per tonne feed (pigs). 250g-2.0kg per tonne feed (poultry).

Rabbit Premix (A04499)

Licensed to Poultrymen's Co-op Ltd

Non ethical animal remedy

Active ingredient: amprolium HCl

Approved species: Rabbits

Approved claims: For feed supplementation.

Dose: 2.5kg per tonne feed.

Coxiprol (A05275)

Licensed to Technik Products Ltd

Non ethical animal remedy

Active ingredient: 120g/litre amprolium

Approved species: Poultry and turkeys

Approved claims: For the treatment and prevention of coccidiosis.

Dose: 10-40ml per 20 litres drinking water, for 12-21 days.

Kaomide D (A02303)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredient: 200g/kg sulphadimidine

Approved species: Cattle

Approved claims: For the treatment of enteritis and diarrhoea.

Dose: 25-50g per 50kg LWT, twice daily, in water or milk.

Cycostat 66 Coccidiostat (A01557)

Licensed to Roche Products NZ Ltd

Non ethical animal remedy

Active ingredient: 66g/kg robenidine HCl

Approved species: Chickens, turkeys and rabbits

Approved claims: For prevention and control of intestinal coccidiosis caused by Eimeria species

Dose: 0.5-1.0kg per tonne feed.

Hi-Performance Creep Premix (A02224)

Licensed to Technik Products

Non ethical animal remedy

Active ingredient: dinitro-o-toluamide

Approved species: Pigs

Approved claims: For supplementation of feed.

Dose: 4.0 kg per tonne feed.

Premstat (A02942)

Licensed to Poultrymen's Co-op Ltd

Non ethical animal remedy

Active ingredient: 250g/kg dinitro-o-toluamide

Approved species: Broiler chickens

Approved claims: An aid in the prevention and control of coccidiosis.

Dose: 160g-500g per tonne feed.

Wespak (A02854)

Licensed to Westwood Products Ltd

Non ethical animal remedy

Active ingredient: dinitro-o-toluamide

Approved species: Poultry

Approved claims: For prevention and treatment of coccidiosis.

Dynamutilin-S (A04721)

Licensed to Technik Products Ltd

Prescription Animal Remedy class 1

Active ingredient: 25g/kg tiamulin hydrogen fumarate and 100g/kg sulphadimidine

Approved species: Pigs

Approved claims: For the prevention of swine dysentery and control of swine enzootic pneumonia. For growth promotion and for the reduction in incidence and severity of atrophic rhinitis.

Dose: 1.0kg per tonne feed.

Mecadox Plus (A04571)

Licensed to Pfizer Laboratories Ltd

Non ethical animal remedy

Active ingredient: 50g/kg carbadox and 30g/kg morantel citrate

Approved species: Pigs

Approved claims: Growth promotant, scour preventative and wormer.

Dose: 1kg per tonne of feed.

Virbac Scour Mixture (A04526)

Licensed to Virbac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredients: 10g/litre neomycin, 21.3g/litre sulphadiazine, 21.3g/litre sulphaquanidine and 21.3g/litre sulphamethazine

Approved species: Goats, cattle and sheep

Approved claims: For scours.

Dose: 30-60ml per 25kg LWT, twice daily.

Supreme Calf Plus Deccox (A06297) Licensed to Rhone Poulenc Rural Australia Pty
Prescription Animal Remedy
Active ingredients: 25g/kg decoquinatate and 0.12g/kg zinc bacitracin
Approved species: Calves
Approved claims: For growth promotion and coccidiosis.
Dose: 5g/kg milk powder or 5g per 10 litre liquid milk.

Deccox Premix (A06001)
Licensed to Asia Pacific Specialty Chemicals NZ Ltd
Non ethical animal remedy
Active ingredient: 100g/kg decoquinatate
Approved species: Cattle, sheep and goats
Approved claims: For the treatment and prevention of coccidiosis.
Dose: 1g per 100kg LWT per day, for at least 28 days.

Baytril 2.5% Oral Solution (A05579)
Licensed to Bayer NZ Ltd
Prescription Animal Remedy
Active ingredients: 25g/ litre enrofloxacin
Approved species: Calves
Approved claims: For osteitis and pneumonia.
Dose: 5ml per 50kg LWT per day (osteitis). 5-10ml per 50kg LWT per day (pneumonia).

Tribactral 80mg tablets (A07359)
Licensed to Mallinckrodt Veterinary Ltd
Prescription Animal Remedy class 1
Active ingredients: 611g/kg sulphadiazine and 122g/kg trimethoprim
Approved species: Cattle, pigs, horses and large dogs
Approved claims: For the treatment of bacterial infections.
Dose: 1 tablet per 32 kg LWT twice daily for 5 days.

Sulphadimidine sodium (A07164)
Licensed to Bomac Laboratories Ltd
Prescription Animal Remedy class 1
Active ingredients: 1000g/kg sulphadimidine sodium
Approved species: Cattle, sheep, horses, cats and dogs
Approved claims: For the treatment of bacterial infections caused by organisms sensitive to sulphadimidine
Dose: 10-20g per 100kg LWT, twice daily. Treat for 3-5 days or as prescribed.

Doxycycline 5% Soluble Powder (A07149)
Licensed to Phoenix Pharm Distributors Ltd
Prescription Animal Remedy class 1
Active ingredients: 60g/kg doxycycline
Approved species: Calves
Approved claims: For bronchitis, pneumonia, pasteurellosis and mycoplasmosis.
Dose: 10mg/kg daily, for 2-3 days.

Trisulfin Antibacterial Bolus (A07066)
Licensed to Bomac Laboratories Ltd
Prescription Animal Remedy class 1
Active ingredients: 588g/kg sulphadiazine and 117g/kg trimethoprim
Approved species: Calves, foals and pigs
Approved claims: For the treatment and control of infections of the respiratory tract, urogenital tract and alimentary tract.
Dose: 1 bolus per 40kg LWT per day, for 5 days or as prescribed.

Phoenix Pink Scour Tablets (A06478)

Licensed to Phoenix Pharm Distributors Ltd

Prescription Animal Remedy class 1

Active ingredients: 244g/kg sulphadiazine, 48.4g/kg streptomycin, 244g/kg sulphamerazine and 246g/kg sulphapyridine

Approved species: Sheep, goats and calves

Approved claims: For the treatment of bacterial enteritis

Dose: 6.5g per 35kg LWT as initial dose, then 3.25g per 35kg LWT every 12 hours. Treatment period is 2-3 days or as prescribed.

Clavulox Palatable Tablets Broad Spectrum Antibiotic 500mg (A05785)

Licensed to Pfizer Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredients: 229g/kg amoxicillin as amoxicillin trihydrate and 60g/kg clavulanic acid as potassium clavulanate

Approved species: Calves and dogs

Approved claims: For the treatment of bacterial infections sensitive to clavulanic acid and amoxicillin.

Dose: 6-12.5mg/kg LWT, twice daily (calves). 12.5-25mg/kg LWT twice daily (dogs). Treatment period for 5-7 days or as prescribed.

Scourban Plus (A03622)

Licensed to Bomac Laboratories Ltd

Prescription Animal Remedy class 1

Active ingredients: 1.8g/litre neomycin, 7g/litre streptomycin, 28g/litre sulphadiazine, 21g/litre sulphaquanidine and 21g/litre sulphadimidine

Approved species: Horses, cattle, goats, sheep, pigs, dogs and cats

Approved claims: For the prevention and treatment of intestinal infections.

Dose: 4-32ml per 8-10kg LWT, twice daily (dogs and cats). 30-60ml per 25kg LWT, twice daily (calves, pigs, sheep, goats, cattle and horses). 2-4ml, twice daily (piglets). 5-10ml, twice daily (lambs).

Albipen 500mg (A02994)

Licensed to Chemavet Division, Pharmaco NZ Ltd

Prescription Animal Remedy class 1

Active ingredients: 500g/kg ampicillin

Approved species: Horses, cattle, pigs, cats and dogs

Approved claims: Treatment of infections caused by micro-organisms sensitive to ampicillin.

Dose: 10-20mg/kg LWT per animal per day for 3-5 days, or as prescribed.

Albipen 125mg (A02993)

Licensed to Chemavet Division, Pharmaco NZ Ltd

Prescription Animal Remedy class 1

Active ingredients: 364g/kg ampicillin

Approved species: Horses, cattle, pigs, cats and dogs

Approved claims: Treatment of infections caused by micro-organisms sensitive to ampicillin.

Dose: 10-20mg/kg LWT per animal per day for 3-5 days, or as prescribed.

Albipen 50mg (A02992)

Licensed to Chemavet Division, Pharmaco NZ Ltd

Prescription Animal Remedy class 1

Active ingredients: 614g/kg ampicillin

Approved species: Horses, cattle, pigs, cats and dogs

Approved claims: Treatment of infections caused by micro-organisms sensitive to ampicillin.

Dose: 10-20mg/kg LWT per animal per day for 3-5 days, or as prescribed.

Strinacin (A01105)

Licensed to Rhone-Poulenc NZ Ltd

Prescription Animal Remedy class 1

Active ingredients: 52g/kg streptomycin, 249g/kg sulphadiazine, 249g/kg sulphamerazine and 249g/kg sulphapyridine.

Approved species: Cattle, pigs, horses, sheep, goats and deer

Approved claims: For the treatment of bacterial enteritis.

Dose: 5g per 35kg LWT as initial dose, followed by 2.5g per 35kg LWT every 12 hours (cattle, sheep, goats, deer, horses). 5g per 35kg LWT as initial dose, followed by 1.7g per 35kg LWT every 8 hours (pigs). Treatment period is 2-3 days, or as prescribed.

APPENDIX G:

EXPERT PANEL

The expert panel was made of experts with expertise and experience in a broad cross-section of scientific, veterinary and medical disciplines. The panel included:

Michael Bates, BSc (Hons), MSc, MPH, PhD
Epidemiologist
Kenepuru Science Centre
Institute of Environmental Science and Research Ltd (ESR)
Porirua

Tim Blackmore, MBChB, FRACP, FRCPA, PhD
Infectious diseases physician and microbiologist
Capital Coast Health
Wellington

Paul Chambers, BVSc, PhD, DVA, MRCVS, MRCA
Veterinary clinical pharmacologist
IVABS
Massey University
Palmerston North

Bill Manktelow, CNZM, BVSc, PhD, Dip Microbiol, MACVSc, MRCVS
(Chairperson)
Emeritus Professor of Veterinary Pathology
Massey University
Palmerston North

Roger Marshall, BVSc, MS, PhD, Dip Microbiol, MACVSc
Veterinary microbiologist
Palmerston North

Julian Waters, BSc (Hons), MSc, PhD, C Biol, MI Biol, Accredited Nutritionist
Livestock nutritionist
Nuritech International Ltd
Auckland

Rod Ellis-Pegler, MB, ChB, FRACP, FRCPA, DTM&H (London)
Associate Professor
Clinical Director of the Infectious Diseases Department, Auckland Hospital, Auckland Healthcare Services Ltd.
also participated, by electronic means, throughout the panel's deliberations in order to maintain appropriate liaison with parallel work on antibiotic resistance under the auspices of the Ministry of Health.