



AgVetLink

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SPECIAL ISSUE FOR VETERINARIANS

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From the Director

A lot has happened in the year since our last AgVetLink for veterinarians. NZFSA has restructured and the ACVM Group has been expanded to cover all approvals issued under the legislation administered by NZFSA. However, the Group's 'business as usual' goes on.

Reviews

Of interest to veterinarians, at present this business as usual involves reviews in the areas of PAR trading (page 2) and animal feeds (page 3).

Trans-Tasman

Work on an agreement with our Australian counterpart to align registration procedures (as much as practical) should lead to access to a wider range of veterinary medicines that might not be available in New Zealand because the cost of registration would be prohibitive, given the size of the market in this country (page 6).

Residues

We receive many queries about residues, particularly relating to bobby calves, and some answers are provided on page 4. Information on restricted substances is also included in this issue. An investigation into the use of a plant pesticide as an animal spray, which resulted in residues in a shipment of beef to Korea, highlights the need to use agricultural compounds and veterinary medicines correctly.

Consultation

Several discussion documents are mentioned in this issue of AgVetlink. We hope you will help us by commenting on those that are relevant to your work. Your feedback is appreciated.

Debbie Morris
Director
Approvals and
ACVM Group



AgVetLink is provided free of charge. To be added to the mailing list, send your contact details to Mary Alexander (address below). AgVetLink is also available on the ACVM website (www.nzfsa.govt.nz/acvm).

AgVetLink is produced at least six times annually by the New Zealand Food Safety Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of agricultural compounds and veterinary medicines. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

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

Reviews

PAR Traders:

A look at their understanding of and compliance with the *ACVM Standard for Prescription Animal Remedy Veterinary Medicines*

A review of prescription animal remedy (PAR) traders will be carried out this year to ascertain the level of understanding of and compliance with the *ACVM Standard for Prescription Animal Remedy Veterinary Medicines* and *ACVM Expectations for Approved Traders of PAR Products*.

Review

The review will examine the following areas:

Quality system

Is there a person responsible for the operation of the quality system? Is the system documented? Is there training for staff operating under the system? Are internal reviews of the quality system carried out at regular intervals?

Transportation

An assessment will be made on transportation arrangements for all PAR products. Are they transported in an appropriate manner for their PAR classification? Are they protected from the weather with appropriate temperature maintained? Are Class II and Class III products transported securely locked? Is the procedure documented?

Receipt and storage

An assessment will be made on the documented receipt of PAR products and the arrangements in place for their storage.

Dispensing

If dispensing is carried out, is there an appropriate designated area set aside? Is documentation and record keeping appropriate?

Training

Where the trader is neither a registered veterinarian nor pharmacist, the trader must be able to demonstrate (through training records) competence to operate within the quality system and carry out specific dispensing activities.

Documentation

Documentation includes electronic and hard copy versions of current regulatory standards and guidelines, standard operating procedures, and records of activities including transactions.

Sample

The Approvals and ACVM Group has consulted with the New Zealand

Veterinary Association (NZVA) and the Veterinary Council of New Zealand (VCNZ) to decide how the sample of PAR traders will be chosen this year. It has been agreed to focus on veterinary practices because non-veterinary traders are audited upon entry to the list of approved traders of PARs, and registrants and manufacturers wishing to sell PARs to end users will be audited as part of their Good Manufacturing Practice (GMP) audits.

The veterinary practices to be reviewed will be selected to give a range of the various practice types in New Zealand but will be weighted to emphasise the areas with the greatest volume of PAR trading, where issues relating to food safety and risk to trade will occur. Therefore, this year five dairy practices, three sheep and beef practices, two equine and two small animal practices will be randomly selected. Upon selection the practice will be contacted to confirm it fits into the appropriate category and to arrange a time for the inspection to take place. In the case of mixed practices, only the area in the selection category will be inspected.

Analysis

Following the visits an analysis will be made and reviewed with VCNZ and NZVA. A public report will then be made available.

It is anticipated that such reviews will be conducted annually because they play an important part of giving assurance to international trading partners that we are managing risks associated with trading in PARs.

A similar procedure for practice selection will be used in subsequent years unless the findings indicate there is a poor understanding or non-compliance with the ACVM standard.

The *ACVM Standard for Unregistered Veterinary Medicines Requiring Veterinary Overview* will be available on the website this month.

Thanks to:

- **veterinarians and VCNZ for your input into this document**
- **the working party on specifications for compounding.**

(www.nzfsa.govt.nz/acvm)

Reviews

Animal Feeds

For several months now the ACVM Group has been working with the New Zealand Standards and Policy Groups of NZFSA to prepare a public discussion document covering the regulatory control of animal feeds. It should be noted that 'animal feeds' include all oral nutritional compounds for all kinds and classes of animals, including dog and cat foods as well as stock feeds.

Schedule 4 requirements

As you will already know, animal feeds and feed supplements are exempt from registration under the ACVM Act, but the products and their manufacture must comply with the minimum standards set out in Schedule 4 of the ACVM Regulations 2001. This means that they must comply with:

- minimum labelling requirements;
- 'fit for purpose' criteria;
- restriction to general health claims related to a nutritional benefit only; and
- restrictions on the inclusion of therapeutic or pharmacological substances and only feed additives that are 'generally regarded as safe' (GRAS).

Codes of practice

The ACVM Group has not been prescriptive about what in detail must be complied with or how compliance must be achieved. In addition, we have not imposed verification requirements, leaving the industry to establish best practices in their own codes of practice (one already approved for the New Zealand Feed Manufacturers Association and one being developed by the New Zealand Petfood Manufacturers Association).

Compliance

The ACVM Group investigates suspicions and allegation of non-compliance, and expects to see evidence of taking due care to comply with the Regulations or prosecutions may be taken. The Group's experience is that, in general, there is a high level of compliance

and very few 'adverse events' related to non-compliant animal feeds. This has given the Group a reasonable level of confidence that risks are being managed adequately.

Different regulatory control

One main reason for the review is that the dog and cat food sector of the industry is regulated under the Animal Products Act 1999, which sets quite different regulatory obligations with a higher level of regulatory intervention because of the animal products content (meat and offal) in their products.

This difference in regulatory control has raised questions such as:

- What is the appropriate level of regulatory control and intervention for animal feeds?
- Are there grounds for different levels of control for different kinds of animal feeds or should they all be regulated in the same way?

The ACVM Group (and NZFSA as a whole) considers that there are grounds for variable levels of control based on the potential risks posed by different kinds of products. However, it also considers that the level of control should be no more than what is necessary and sufficient to manage the relevant risks.

Discussion document

The public discussion document, which should be released for comment soon, will be available on the website (www.nzfsa.govt.nz/acvm). It proposes a regulatory scheme that tries to strike a balance between assuring adequate mitigation of risks and the inevitable cost of complying with any regulatory requirements. It considers the relative risk profiles of different kinds of products and suggests the kind of regulatory intervention that would be appropriate.

It is hoped that veterinarians will provide comment on the proposals based on their experience.

Default Withholding Periods

The following is a list of default withholding periods applied to the registration of veterinary medicines where no residue data are provided. The figures have been arrived at following consideration of all residue data provided to the Group and can be considered conservative.

These withholding periods do not apply to sustained release formulations because the withholding period must apply to the time after the release period, not after administration.

AVIANS

Meat 63 days
Eggs 10 days

RUMINANTS (including deer)

Meat 91 days
Milk 35 days

CAMELIDS

Meat 63 days

LAGOMORPHA (e.g. rabbits)

Meat 63 days

MONOGASTRICS (e.g. pigs, horses)

Meat 63 days

FISH, CRUSTACEA, MOLLUSCS

Meat 35 days

Residues

Residues and Bobby Calves

Residue management in bobby calves is an area that frequently results in questions because residues may be from direct treatment, the diet (milk and colostrum) or from treatment of the cow prior to birth.

The ACVM Group is developing a comprehensive policy on the use of withholding periods to manage risks of residues. In the meantime, this article focuses on the issue of withholding periods for neonatal calves, which are commonly called 'bobby calves' when they are sent for slaughter.

Withholding time information

In general, residues and withholding time information will relate only to the treated animal as there is no requirement to produce data for calves born to treated cows. Although there are examples of situations where registrants have produced data on calves for products that are likely to be used near calving, this is not common because the trials are relatively complex and expensive. To date, one injectable

penicillin and one pour-on ivermectin have produced separate withholding periods for calves born to treated dams. They also take into account residues the calf might receive from the dam's milk.

Default

The ACVM Group considers that, unless there is information to say otherwise, the following rule should be used as a 'default':

If a cow calves within the meat withholding time of a veterinary medicine with which she has been treated, the calf is eligible for slaughter only when the cow is eligible for slaughter.

There are obvious exceptions to this rule where alternative advice may be considered by a veterinarian. The most common examples are where the meat withholding period is dependant on a prolonged depot effect or controlled release formulations such as boluses.

The advice from NZFSA is that calves born to cows treated with long-acting dexamethasone ester products can be sent for slaughter as bobby calves. This advice is based on the low but prolonged residue profile in the dam's meat and milk as a result of a depot effect at the injection site. After birth residues in the calf are metabolised relatively quickly and, because there are no high peaks in milk, it is unlikely the total dexamethasone residues will exceed regulatory limits in the calf at four days of age.

Milk

Labels of registered products will not normally contain advice on withholding periods for calves fed milk containing residues unless the registrant has produced specific data.

In the past, advice was given that a calf exposed to contaminated milk should be fed residue-free milk for seven days. This advice is not based on actual data and must be treated with a degree of caution. It assumes the level of residues in the milk will be relatively low and the calf will be able to eliminate this residue if it is absorbed. Situations where calves are allowed to suckle cows directly after administration of intramammary products or where a large percentage of a herd is treated could make these assumptions irrelevant.

Antimicrobials

In general, cattle meat withholding periods applied to products also apply to calves with the exception of antimicrobials where the current policy is for labels to carry the statement "Not for use in bobby calves".

This phrase is not very precise and it will be one of the matters to be addressed in the withholding period policy that is being developed. In the meantime, a calf must not be treated with or directly exposed to antibiotics and then sent for slaughter as a bobby.

Residue Investigation

Endosulfan, a horticultural pesticide, was found in a sample of New Zealand beef shipped to South Korea in late 2005. Korea, along with the meat company, provided valuable assistance that allowed rapid and conclusive traceback to determine the source of the residue.

Only one farm was implicated. The residue was from the non-approved use of a plant pesticide as an animal spray. Although detected at levels below those internationally allowed in a variety of fruit and vegetables for which the spray is approved (and not considered in itself to present a health risk to consumers), its use in such a way is a breach of regulations. Legal action has been taken.

The ACVM Group requests the help of veterinarians in reminding their clients of their obligations to adhere to all regulations, and their responsibility to ensure that food is both safe and suitable. This incident illustrates that alleged careless action by just one individual can have severe consequences not just for neighbours but for a whole food production and export industry.

Residues

Restricted Substances

The restricted substances list is included below as a reference. The presence of residues of these substances in exported product can have significant impacts on trade.

Veterinarians need to be particularly careful when considering off-label use of these drugs, compounding or sourcing products used in human medicine.

Chloramphenicol is an example of a drug that is frequently reported as a residue in internationally traded produce. Registered products containing this active have not been available in New Zealand for 20 years. Injectable and ophthalmic human preparations containing chloramphenicol must not be used in food-producing animals.

Topical products containing **nitrofurazone** were commonly used to treat teat lesions in dairy cows. Nitrofurazone was removed from these products in 2002. Because products are still available for treating small animals and horses, it is critical that people using these drugs understand they are not to be used for other than the prescribed reason. Remind clients to dispose of any product remaining in dairy sheds.

Restricted Substances

Our major overseas trading partners have banned the substances listed below. In consequence, these substances may not be used at any time during the life of an animal from which any product may be taken and exported from New Zealand for human consumption.

- All compounds of the nitrofurazone class of compound, including but not limited to nitrofurazone, furaltadone, ninhydrone, furazolidone
- All compounds that exert a thyreostatic action: methyl thiouracil, phenyl thiouracil, propyl thiouracil
- Beta sympathomimetic agents: cimetarol, salbutamol
- All compounds of the nitroimidazole class of compound, including but not limited to metronidazole or ronidazole
- Arsenilic acid
- Chloramphenicol
- Chloroform
- Chlorpromazine
- Colchicine
- Dapsone
- Diethylstilbestrol
- Nandrolone
- Phenylbutazone

Antibiotics

Antibiotic Sales 2004/2005

The antibiotic sales for the April 2004 to March 2005 year indicate a 12.7% drop in sales from the previous year. As this data only reflects sales and not use, overinterpreting variation from year to year should be treated with some caution (see tables at right).

When putting this information together no assumptions are made about use on- or off-label and, as a result, the actives are simply categorised on the registered indications. Where products are approved for use in a range of species such as cats, dogs, horses and cattle they are simply classified as 'unknown'. Use classified as 'others' include topical, ophthalmic and intrauterine routes. We make no assumptions from

the information we hold as to how any of these products are used. Feedback from the various agricultural sectors and veterinarians in particular is important in understanding any apparent trends. Individual veterinarians can comment on this data as it relates to the actual use of antibiotics either by directly contacting the ACVM Group or via industry groups and the New Zealand Veterinary Association.

The changes in sales of note are:

- A decrease of zinc bacitracin by 33%.
- Furazolidone sales decreased by over 60%.
- Oxytetracycline and sulphonamide sales continue to show increased sales.

- Tylosin and macrolides in general increased slightly following a large drop the previous year.
- Injectable amoxicillin quantities have nearly trebled.
- Ampicillin, Cloxacillin and Cephalonium sales in intramammary products show a significant increase. Approximately 70% of the total antibiotic actives used in intramammary products is for dry cow therapy.
- Aminoglycosides sales show no clear trend in recent years. The largest component is streptomycin/dihydrostreptomycin, which increased substantially from 2003 to 2004 only to show a moderate decrease in the latest figures.

Trans-Tasman Co-operation Project

The ACVM Group recently met with the Australian Pesticides and Veterinary Medicines Authority (APVMA) to progress the development of a memorandum of understanding (MoU) that will align (as far as practical) the registration processes in both countries. The intention is to facilitate access to a wider range of veterinary medicines by:

- ensuring that registration requirements are only what are necessary and sufficient to assess the safety and appropriateness of trade name products; and
- making the requirements in both countries as close to the same as is practical, given the differences in circumstances.

As part of the memorandum, the ACVM Group and APVMA are developing a five year workplan to progress the alignment of particular standards or processes. Already the Authorities have established an understanding in regard to recognition of each other's approvals for manufacturers of veterinary medicines. This in itself simplifies the registration process in some cases in regard to manufacturing dossiers required for an application.

Another exercise that has commenced is a side-by-side comparison of the assessments of registrations. Five representative veterinary medicine products that have been registered in both countries in the last two years will be selected, and the registration processes will be compared to identify similarities and differences. The outcome of the comparison will be used to assist alignment of both standards/requirements and processes.

The scope of the alignment is comprehensive and is intended to lead to access to a wider range of veterinary medicines that might not be available in New Zealand because the cost of registration would be prohibitive, given the size of the market in this country.

Antibiotics

Antibiotic sales by species (Apr04-Mar05)

(Kilograms of active)

	COMPANION	CATTLE	PIGS/POULTRY	UNKNOWN	OTHER	Total
Aminoglycosides	45.55	467.73	77.30	1324.76	4.66	1919.99
Bacitracin	0.49	0.00	18056.25	0.31	0.00	18057.05
Cephalosporins	268.25	805.42	0.00	127.97	0.00	1201.63
Clavulanic Acid	85.16	31.00	0.00	4.36	0.00	120.52
Fluoroquinolones	16.44	3.26	0.00	7.09	0.00	26.79
Fusidic Acid	2.36	0.00	0.00	0.00	0.00	2.36
Macrolides/Lincosamides	10.23	74.38	440.08	5142.80	0.00	5667.49
Nitrofurans	0.00	0.00	41.00	0.50	0.37	41.86
Nitro-imidazoles	11.91	0.00	48.77	0.00	0.00	60.69
Novobiocin	0.00	4.47	0.00	0.00	0.00	4.47
Other	0.20	3.63	0.00	78.98	0.00	82.80
Penicillins	449.64	5793.30	17.70	7557.96	0.00	13818.60
Sulphonamides/Trimethoprim	0.00	84.12	119.50	3654.03	1481.64	5339.28
Tetracyclines	23.22	7.76	0.00	3851.38	0.12	3882.49
Virginiamycin	16.08	0.00	0.00	0.00	0.00	16.08
Total	929.52	7275.06	18800.61	21750.12	1486.78	50242.10

Antibiotic sales by application route (Apr04-Mar05)

(Kilograms of active)

	ORAL	INJECTABLE	FEED	WATER	INTRA MAMMARY	OTHER	Total
Aminoglycosides	354.10	864.32	11.77	128.70	550.63	10.46	1919.99
Bacitracin	0.00	0.00	18056.25	0.00	0.00	0.80	18057.05
Cephalosporins	268.25	127.97	0.00	0.00	755.12	50.30	1201.63
Clavulanic Acid	85.16	6.48	0.00	0.00	28.89	0.00	120.52
Fluoroquinolones	14.62	12.17	0.00	0.00	0.00	0.00	26.79
Fusidic Acid	0.00	0.00	0.00	0.00	0.00	2.36	2.36
Macrolides/Lincosamides	10.23	1020.52	4483.57	80.72	72.46	0.00	5667.49
Nitrofurans	0.00	0.00	41.00	0.00	0.00	0.86	41.86
Nitro-imidazoles	11.91	0.00	42.77	6.00	0.00	0.00	60.69
Novobiocin	0.00	0.00	0.00	0.00	4.47	0.00	4.47
Other	0.00	8.70	0.00	0.00	73.86	0.25	82.80
Penicillins	542.40	7774.59	0.00	17.70	5454.80	29.11	13818.60
Sulphonamides/Trimethoprim	4979.26	183.89	119.50	0.27	0.00	56.36	5339.28
Tetracyclines	23.22	1446.37	1391.00	218.66	115.39	687.85	3882.49
Virginiamycin	0.00	0.00	16.08	0.00	0.00	0.00	16.08
Total	6289.15	11445.00	24161.94	452.05	7055.61	838.35	50242.10

Animal Welfare

Code of Welfare for Painful Husbandry Procedures

A new code of welfare for painful husbandry procedures carried out on farm animals was issued on 23 December 2005 by the Minister of Agriculture, Jim Anderton.

Recommended by NAWAC

The code was recommended to the Minister by the National Animal Welfare Advisory Committee (NAWAC). NAWAC is a ministerial committee whose role is to provide advice to the Minister on the welfare of all animals except those animals used in science. The role also includes developing codes of welfare, which set out the minimum standards of care for animals in New Zealand.

The code covers all procedures that involve physical interference with sensitive tissues that are carried out for reasons other than the treatment of injuries or diseases. As such it covers all procedures (as defined above) undertaken as part of normal farm husbandry that cause significant pain and distress.

Specific information

While the code covers all painful husbandry procedures, specific information is provided for castration, tail docking, and disbudding and dehorning only. The new provisions for castration and dehorning, which reduce the ages when these procedures can be carried out without pain relief, will replace requirements that have been in place since 1960. Tail docking of dairy cattle is discouraged, but farmers will be permitted to remove the last two-three vertebrae of the tail. Other procedures referred to in the code are covered in other codes of welfare, e.g. beak trimming of poultry, castration and tail docking of piglets.

Further procedures, such as mulesing, will be added to the code in the future. NAWAC is still reviewing this procedure and has yet to reach its final conclusions and recommendations.

NAWAC has not just given a big tick to procedures that are carried out now. The Committee recognises that the

avoidance, alleviation or minimisation of pain is vital to animal welfare, and to enhancing the biology of the animal, especially growth and the immune system. On the other hand, failure to undertake some of these procedures can, in some but not all circumstances, lead to an increased risk of compromises to animal health and welfare.

NAWAC accepts that the farming community is responsible and diligent regarding animal welfare, and that such procedures are not undertaken lightly but regarded as necessary for efficient livestock management. However, NAWAC is encouraging farmers to review the reasons for carrying out painful husbandry procedures by developing management systems and breeding programmes that do not require them to be performed routinely. Breeding programmes, management systems, and technologies (e.g. polled cattle, short-tailed sheep) should be developed and used so that painful husbandry procedures can be phased out in the future.

Pain relief

NAWAC wants to see the use of pain relief become routine where animals experience significant pain and therefore supports a move to the wider use of pain relief. However, at present NAWAC is not confident that local anaesthetics and pain relief are available for all painful husbandry procedures, that they are safe, that the necessary regulatory and veterinary supports exists and that it is always economically viable.

NAWAC proposes gathering a number of parties together to discuss the wider use of pain relieving drugs within agriculture. The Committee will liaise with farming industries and producer groups, veterinarians, drug companies and regulators in order to review the code in five years' time. The Committee's extensive report that backs up its recommendations can be viewed at: www.biosecurity.govt.nz/animal-welfare.

Special Provisions for Vet Med Imports

Occasionally the ACVM Group receives requests from registrants to import products that do not have the correct approved labelling. This would not normally be possible because the labels provide the link with the New Zealand registered product and provide information specific to our regulatory requirements.

However, there is now a formal process for registrants to apply to import and sell product where:

- it is the result of unforeseen circumstances (e.g. demand outstripping ability to supply) and where there will be significant issues for animals or users if the product is not supplied; or
- it is the result of limited product sales where it is not viable to maintain New Zealand labeled stock on-hand and where otherwise the registered product would be withdrawn from the market.

Under the conditions of these approvals the registrant has to sell directly to veterinarians and provide any additional label information with the product. The registrant will not normally be allowed to advertise the product for sale or to distribute it for wholesalers to hold in stock.