



AgVetLink

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From the Director

Recent workshops in Auckland and Wellington provided good dialogue with the industry (pages 2-3). Similar workshops will be held in Australia in February.

Thanks to all those who took time to complete our client survey – a brief summary of results is provided on page 4.

The Group wishes to congratulate the animal health industry on its newly agreed initiative on self-regulation of standards for advertising veterinary medicines, FAIRad (Forum for Animal Health Industry Regulation of Advertising). Over the years, advertising has been a significant source of compliance complaints to the Group, and we are fully supportive of this plan (see page 8).

Details about our Christmas closure period are also on page 8.

We wish you all a happy and safe holiday season!

Debbie Morris
Director
Approvals and
ACVM Group



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.

GENERAL INTEREST

ACVM and ERMA Workshops

The ACVM Group, in conjunction with ERMA New Zealand, held registrant/consultant workshops in November in Wellington and Auckland.

In general, these were well received and the agenda items created some interesting dialogue. A number of the questions asked at the workshops are presented below. Some of our responses will require further in-depth discussion with all staff and other interested parties before complete answers can be provided.



Chris Boland presents information on the alignment with Australia workplan

1. Would the Group consider a special relabelling category for manufacturing that does not attract irrelevant manufacturing specifications?

This is likely to be revisited in the review of our information requirements, which is scheduled for early 2007.

2. Would Warren Hughes check with the US EPA on his upcoming visit about its view on release and expiry specifications?

AUSTRALIAN WORKSHOPS

The ACVM Group will hold workshops for registrants, consultants or interested parties in Sydney on the 13th of February and Melbourne on the 14th of February 2007. (Details of venues will be advised later.)

If you are interested in attending, please contact Helen Simpson by email helen.simpson@nzfsa.govt.nz or by fax 64 4 894 2501 by Friday, 17 January 2007.

We would appreciate any workshop agenda items that you may wish us to address. These can be emailed to maree.zinzley@nzfsa.govt.nz

Warren is overseas at present and will report on this in the next issue.

3. Would the Group consider how it updates and integrates new international standards and requirements to stay in line with the international community?

The Group regularly monitors changes in international standards and requirements. Changes are reviewed to see if they are relevant under New Zealand conditions or impose trade obligations that must be complied with. ACVM standards and requirements are modified at their next review unless immediate action must be taken. Affected parties are advised, but consultation may not occur because the change is obligatory. If options are possible, consultation will be carried out as part of the revision of standards.

4. Would the Group consider how it could address the nonylphenol issue to make it more transparent and

minimise disruption if change is necessary?

Nonylphenol is under review with ERMA. As far as the ACVM Group is concerned, if required, we would follow our reassessment process and this would be in sufficient time for companies to supply us appropriate information.

5. Would the Group consider a 'slice of life' review in regard to counterfeit and/or 'out of spec' products (e.g. products with higher impurities or lesser concentration of actives than they should have)?

We will consider adding this as we set up and decide on the programme for 2007.

6. Would the Group give some more thought to the cost implications re data assessors?

In the first instance, the ACVM Group will have training sessions to bring data assessors up to speed. The timeframe will be announced in the next *AgVetLink*.

ACVM Bill

The Agricultural Compounds and Veterinary Medicines Act Amendment Bill has had its first reading in Parliament and has been referred to the Primary Production Select Committee, which has called for submissions. For details, visit the Parliamentary website (www.parliament.nz). Closing date for submissions is Friday, 23 February 2007.

GENERAL INTEREST

7. Would the Group consider taking up a role of providing good operational practice guidance in regards to pest control products (fly sprays etc.)?

The rules around these types of products may change under the new definition of an agricultural compound in the ACVM Act Amendment. This will be included in the consultation on ACVM Act changes.

8. Would the Group make up a list of excipient trade name products (surfactants etc.) for which it already holds formulation information, so applicants would know that if they included them in their product they would not have to get the same information from the proprietors of those products?

The ACVM Group will look at what we can do to assist, but essentially the excipients are not associated with any products. We do have information but excipients change and this makes it quite difficult.

9. Is it always necessary to get agreement from a registrant to source information about an active ingredient from the AI manufacturer/proprietor? Sometimes requesting that information is, in itself, commercially sensitive.

This will be actioned in the new year and the question will be presented to the Operational Policy Committee.

10. Would the Group take into consideration the significance of a deviation from the expiry specifications before deciding what regulatory action should be taken in a non-compliance case?

The risks associated with the non-compliance would be the deciding factor.

11. Provisional registration: Can a formulation be changed but keep the same trade name?

The provisional registration requirements will be reviewed as we go about reviewing the overall registration requirements early next year. In regards to this question, we will look at the rules governing when a change in formulation triggers a new registration and discuss the issue with the Commerce Commission.

12. Provisional registration: Importation of trade name products for use in labs. ERMA's stance is that they do not give an approval for something that is being imported for lab use.

We acknowledge the issues and, again, this will be addressed in reviewing provisional registrations with a view to aligning with ERMA as far as possible.

13. Would the Group amend or review the list of silicants in the chemistry standard?

This is being actioned.

Data Protection

NZFSA Policy is working with ERMA New Zealand and the Ministries for the Environment, Economic Development and Health with a view to developing policy proposals for data protection.

Three broad areas are being looked at: the length of data protection, its application to reassessments, and application for new uses for existing protects.

LABELLING

Approved Label Information

During a recent visit to a wholesaler it was noted that a number of products were being distributed without all the approved label information. Even though labels are not technically approved in registrations, **all the approved label information must accompany the product.** In effect, this means that if approved information is not on the primary labels but is contained in leaflets, package inserts or outer packaging, this must be distributed with the product. If package inserts are not contained in outer packaging, care needs to be taken to ensure they do not become separated from the primary packaging during distribution.

Failure to provide the correct label information not only means the product does not comply with the ACVM registration but may also result in non-compliance with HSNO controls.

Labels of Exempt Products

The following statement, or something similar, can be placed on labels of products that have been deemed exempt from registration:

“This product is exempt from registration under the ACVM Regulations 2001”.

GENERAL INTEREST

Client Survey Response

As a result of the client survey included in the October *AgVetLink*, we are now in a position to give you a generalisation of our findings. For a more detailed synopsis of the survey please visit our website after the holidays.

Processes

The majority of applicants usually find that:

- our forms and instructions are easy to understand and complete
- we keep them sufficiently informed during the application process, and
- we meet the regulatory timelines.

Service

Responses show that we are always or usually polite and co-operative in our daily telephone and email communications and that we respond to messages approximately 90% of the time. The majority of applicants are content with the way in which we resolve their issues, although about 30% of applicants would like us to give more consideration to their issues.

Communication

The most preferred method of communication was email with telephone calls coming a rather distant second. In general, applicants found our overall written communication easy to understand.

Website

Our website was generally found to be user friendly. Many constructive comments have been taken on board for further development of our website tool, which is planned for early 2007.

Publications

AgVetLink is considered by our applicants to be a worthwhile publication.

The ACVM Group would like to thank everyone who took the time to participate in the survey. We received many valuable comments and we appreciate your suggestions for improvement and positive feedback.

Staff Update

While Jodie Trubshoe is on maternity leave for the next 12 months, Halina Smolski will take her place leading the Executive Management team.

Paulina Rodriguez Advisor (ACVM Standards - Animals)

Paulina, who comes from Mexico, completed her veterinary degree in Mexico City and worked as a companion animal vet for two years. She came to New Zealand four years ago for work experience, especially in large animal practice. Last year she passed the required examinations to obtain veterinary registration in New Zealand, and now she is learning about legislation and the pharmacology part of the profession. Paulina says, "I am interested in continuing my education and doing a diploma to open future opportunities. My hobbies are dancing flamenco, travelling, parties. I am a dog lover as well – I enjoy being around dogs and people".



GENERAL INTEREST

Animal Feeds

NZFSA is currently considering submissions received following recent public consultation on proposals* to change the regulatory requirements applying to certain manufacturers of animal feed. The proposals only relate to manufacturers involved in secondary processing of animal material resulting from the death of the source animal (red meat, offal, poultry, fish) for animal feed. NZFSA expects to provide advice on the proposals to Government early in 2007 and legislative changes, if agreed to, would be introduced later in 2007.

***Proposal 1** would require manufacturers of feed containing animal material resulting from the death of the source animal to list with NZFSA by supplying information such as manufacturer's name, address and type of feed being manufactured.

Proposal 2 would require manufacturers of petfood (cat/dog food) containing animal material resulting from the death of the source animal to procure material only from regulated sources and to maintain a documented system that demonstrates such things as source of process inputs, suitability for intended purpose, sufficient labelling to enable traceback, and inventory control to identify substitution and security during transportation.

Red Flags

As part of issuing a Prohibition Notice, the ACVM Group may apply an additional compliance tool to advise the public that a notice has been served prohibiting the manufacture, sale or use of a trade name product. The Group does this by adding a 'red flag' to the relevant trade name product on the public register, stating that the product is prohibited under section 55 of the ACVM Act.

PLANT COMPOUNDS

BCPC International Conference and Exhibition

Plants Advisor Bruce Nalder attended the British Crop Protection Council (BCPC) International Conference in Glasgow in October. As many of you will be aware, this conference is generally recognised as one of the leading international meetings for the crop protection industry.

This year's conference incorporated three main themes:

- global aspects of crop protection—what are the risks?
- factors affecting crop production
- global food supply—what is the problem?

Most of Bruce's time was spent in sessions relating to risk management, import/export, and communication.

Risk management

The risk management presentations largely focused on public perceptions in relation to pesticides, pesticide use and the associated risk management employed by regulators. The impact of public perceptions and some of the factors contributing to public opinion were also discussed.

Later presentations examined the difficulties of achieving global harmonisation in terms of pesticide risk management and included a presentation looking at the reduction of pesticide risks through the use of conservation agriculture.

Import/Export

Sessions attended on import/export issues explored the advantages and disadvantages of a global market as well as touching on the challenges associated with global harmonisation of MRLs and issues associated with natural toxins in terms of risk regulation and monitoring.

Exhibition

The exhibition attached to the conference appeared to be dominated by active and generic product manufacturers, with Indian and particularly Chinese companies having a strong presence. The Chinese manufacturers alone provided nearly half of the total exhibits.

Patent infringements have tended to be a problem at the exhibition in recent years and, despite repeated warnings by

organisers, this year was no different. Representatives from Bayer CropScience, Syngenta, DuPont and BASF were present to ensure compounds protected under UK patents where not being unlawfully promoted.

Most of the infringements were reported as being by first time offenders. In these cases, company representatives were served injunctions and required to remove advertising material relating to the infringements or, where appropriate (for example where it was only part of a poster or brochure), make the offending material unreadable. Three companies were repeat offenders and, as a result, had their exhibits closed.

Highlight

Although Bruce considered the whole conference to be a worthwhile experience, the highlight was the exhibition because it provided the opportunity to talk directly to active manufacturers.

For further details about the conference, contact Bruce by email (bruce.nalder@nzfsa.govt.nz).

VETERINARY MEDICINES

The Use of Veterinary Medicines in Research, Testing and Teaching Organisations in New Zealand

Background

The ACVM Group recently commissioned a 'slice of life' or 'reality check review' to assess the level of compliance to relevant conditions under the ACVM Act by research, testing and teaching organisations (RTTOs) when they are using veterinary medicines to manage experimental animals. This review also ascertained the level of awareness of relevant approved codes of practice and ACVM standards, and if these were being used to develop operational procedures to ensure compliance with the conditions of registration (or the conditions of exemption) for the veterinary medicines used.

Six randomly selected institutions involved in the purchase, storage, dispensing, training and use of registered veterinary medicines or unregistered veterinary and human medicines requiring veterinary overview in experimental animals were visited as part of this review.

Results

Only one major university RTTO and one commercial RTTO satisfied the reviewer regarding compliance with the requirements of the legislation. The review identified several areas where common best practice was not being achieved.

Staff

RTTOs need to ensure that the prescribing veterinarian is provided with adequate staff and resources (dependent on the size and complexity of the organisation) to ensure training of non-veterinary staff (and students if appropriate) in the legislation and the correct use of prescriptions.

Several RTTOs either employed a part-time local practicing veterinarian or had part-time permanent staff; two had unfilled vacancies for a permanent veterinary position.

Training

The RTTOs reviewed showed a large variation in the availability, standard and recording of training. Similarly, there was inconsistent recognition of staff competency.

Training must be available for new staff or students prior to them becoming involved in the use of drugs on animals. One location provided full-time 'online' training and competency assessment. At other locations training sessions were held infrequently.

Untrained or inadequately trained staff were found to be involved in the use or control of PAR Class II drugs at three locations.

At two locations there was evidence of the use of Twink and erasing in the drug control register. This meant that the register could not be audited as required.

At one location the procedure stated that the Drug Control Officer was to sight and verify the accuracy of each Principal Investigator's drug use registers prior to dispensing further PAR Class II drugs. This was not occurring and PAR Class II drugs were being re-dispensed without drug register checks.

At a second location drugs that had been prescribed by more than one veterinarian were stored together and there were no staff training records available. It was not possible to identify which veterinarian had prescribed which drugs because the drugs were not identified with the prescribing veterinarian's details. Therefore, it was impossible to trace which veterinarian was responsible for the instructions and training of non-veterinary staff for their particular use.

Audits

There was inconsistent adherence to the stated frequencies that each organisation stipulated for internal and external audits. This inconsistency and, in several

cases, lack of any audits compromises the RTTO's ability to be an efficient self regulator in the management of ACVM Act requirements.

At some locations drug stores had significant quantities of expired PAR Class II drugs. There was also inadequate security of PAR Class I and II drugs at two locations. In these instances, drugs were stored in open cupboards and were freely accessible.

There was also a lack of uniformity in the recording of drug usage. At several locations drug control registers were generic pocket notebooks, pages were not numbered and mandatory columns were either non-existent or, if partially present, were hand drawn.

Summary

This review highlighted several areas where compliance with the legislation was not being achieved. However, where deficiencies were highlighted and brought to the attention of the responsible personnel, there was a universal commitment to correct procedures and ensure compliance with the ACVM Act.

There are significant risks with the use of prescription veterinary medicines within the RTTO environment. The prescribing veterinarian must rely heavily on robust internal systems to provide assurance that use of prescription medicines is compliant. A prescribing veterinarian may have numerous RTTO staff and students, often at isolated sites, using PAR Class I and, more importantly, PAR II medicines without direct physical veterinary supervision.

Locations that did not have a full-time veterinarian or where there was a current vacancy were under-resourced for their relative size and complexity, resulting in non-compliance with the code of practice and the ACVM standard.

Milk Withholding Periods

Current policy for the setting of milk withholding periods assumes whole herd treatment and no dilution. It is recognised that this approach can be considered conservative, particularly for those products that are likely to be used in only a small percentage of cows at any one time.

NZFSA is being asked to consider allowing for dilution in the setting of withholding periods with two different scenarios:

- Drugs that are used infrequently and not likely to be used on a large percentage of a lactating herd. This could include antibiotics, particularly those with restrictions or use patterns that would not be likely to result in treatment of more than a few animals.
- Drugs that are routinely used on a whole herd but where a case can be made that treatment of part of a herd is still good practice (e.g. the use of anthelmintics in lactating cows).

No final decisions have been made as to how this will be managed. However, there is agreement within NZFSA to consider milk dilution as an option when setting withholding periods. The issues that need to be considered include:

- The current system may be compensating for the fact that residue data does not provide for all the possible variations (e.g. differences in diseased animals, higher doses, prolonged treatment and additive residues for different application routes).
- Users must be able to understand and practically follow label advice.
- Label advice has to provide for animals treated over a period of time. If a product is being used regularly, this issue may be difficult to manage and lead to error.
- In extreme circumstances, high percentages of lactating herds may be treated (e.g. at the start of calving).

In order to provide for consistency and to reduce the complexity, set herd percentages are likely to be established as thresholds providing a fixed number of options. It is likely that residue assessments will have an inbuilt degree of conservatism to allow for increased potential for error by the user.

The conditions of registration must be taken into account with products managed under conditions such as prescription providing for more control. Two label statements are currently being considered with one providing for dilution and the other giving the traditional withholding period assuming no dilution.

As indicated in the recent workshops (see page 2), we are happy to consider any comments, either negative or positive, on the proposed change. Email comments to Lucy Johnston (lucy.johnston@nzfsa.govt.nz).

Carbadox: Change in Conditions

Internationally there has been concern over the need for additional residue information for this compound because the parent compound and some metabolites are recognised as carcinogens.

A review of the withholding period and registration conditions for the single product registered in New Zealand has resulted in a change in the meat withholding period for pigs from 28 days to 35 days and a move to prescription PAR I status. The revised withholding period has been based on information that a 35 day period is the longest withholding period that can be applied in normal practice.

Products containing carbadox will have a condition restricting use in food-producing animals except pigs because residue information has not been assessed for other species. This also manages the risk to trade to countries that have banned the use in food-producing animals.

Information on the sales of carbadox will be collected annually and included in the report of prescription antimicrobials.

'Restricted Use' Category

The development of a new, 'restricted use' category of registration has been proposed to complement the existing over the counter and prescription options for veterinary medicines.

It has been recognised that the conditions on several veterinary medicine registrations effectively provide for use of products by people working under codes of practice or to other standards. In addition, a number of vertebrate toxic agents are managed in a similar manner. The category is also being considered as an option for new conditions on leptospirosis vaccines, which are currently under review.

A draft standard will be developed and made available for consultation. Once the details of the new conditions are finalised, there is likely to be some consideration given as to whether existing registrations would be better managed in the new category. One option that has been suggested would affect some or all poultry vaccines where codes of practice could be developed as an alternative to use under prescription.

VETERINARY MEDICINES

FAIRad

Animal health industry promotes fair advertising

The Group congratulates the animal health industry on its newly agreed initiative on self-regulation of standards for advertising veterinary medicines, FAIRad (Forum for Animal Health Industry Regulation of Advertising).

FAIRad, which is based on the Researched Medicines Industry Association's code of conduct and other overseas models, was launched on 30 November. It aims to ensure users that they can be confident in claims and information presented in promotional material such as advertising and sales materials. The initiative will encourage high standards and self-regulation of promotional activities of animal health companies, distributors, veterinary practices and other animal health retailers.

The FAIRad board has been established with representation from the three participating industry bodies: the New Zealand Veterinary Association, ARRPA and Agcarm. The board's role is to set and maintain the standards defined in the code, ensure it keeps pace with the promotional environment, process complaints through the complaints committee and ensure that all resolutions are communicated to the industry and the public.

GMP

Although GMP certificates are issued as being valid for a three year period, the frequency of GMP inspection is biennial unless there are specific reasons for a different frequency (e.g. MRA with EU for biological products).

Season's Greetings

Best wishes to you all for a happy and safe holiday season.

Remember the New Zealand Foodsafe Partnership message of the four 'Cs' –

- **clean** hands and food preparation surfaces
- **cook** food thoroughly
- **cover** food until ready to eat, and
- **chill** food correctly and quickly.

Christmas/New Year Holidays

The Approvals and ACVM Group will close for Christmas on Friday, 22 December 2006.

The office will reopen on 8 January 2007, but there will be minimal staff in the office over the January period.