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### Recent events

#### ■ ACVM workshops

Workshops covering the ACVM Act application process were held in Christchurch, Auckland and Wellington in February. Thanks to all of those who attended and provided feedback.

A summary of the most frequently asked questions appears on page 4.

#### ■ AVCPC

ACVM Group Director Debbie Morris attended the recent planning meeting of the Australian Agricultural and Veterinary Chemicals Policy Coordination Group. A workplan for the next 12 months has been agreed.

#### ■ AVMAC/ILG meetings

Notes from the February AVMAC and ILG meetings will be available soon.

### What's coming up

#### ■ ACVM Act Amendment Bill

This discussion paper is expected to be released by MAF Policy in the next week or so. It will be available on the ACVM part of the MAF website. Make sure you use the 'Notify me when this site is updated' box (on the right of the ACVM home page: [www.maf.govt.nz/acvm](http://www.maf.govt.nz/acvm)).

#### ■ Mystery Creek

The ACVM Group will be part of the MAF Food stand at the 34th Mystery Creek Fieldays (12-15 June 2002). It will be an opportunity to meet some of the ACVM team face to face.

#### ■ VICH 2 Conference

This conference will be held in Tokyo, Japan, 11-12 October 2002. VICH is harmonising data requirements for the registration of veterinary medicines. It is composed of regulatory and industry representatives from New Zealand, Australia, USA, EU and Japan. See the 'Forums' section of the ACVM website.

*AgVetLink* is produced at least six times annually by the MAF Food Assurance Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of animal remedies and pesticides. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

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## Code of practice for own use

The ACVM Group has finalised the code of practice that must be followed when using compounds that are not trade name products as agricultural compounds or veterinary medicines (see page 2, *AgVetLink* 30).

The Group received written comments only from the Department of Conservation. In light of those comments some minor adjustments were made to the proposal presented in the *AgVetLink* article.

The code was approved under section 28 of the ACVM Act and can be viewed on the ACVM Group website or you can request a copy from the ACVM Group.

It must be noted that it is now an offence under the ACVM Act not to comply with the code if you are using generic compounds (substances that are not trade name products) as agricultural compounds or veterinary medicines on your own animals and plants.

If convicted of an offence, the penalty can be a fine up to \$30,000 for individuals and \$150,000 for corporations.

While the ACVM Group cannot proactively monitor own use situations, it will investigate any suspicions or allegations of non-compliance and will take action accordingly.

## Exemption from registration for veterinary medicines compounded by veterinarians

The ACVM Regulations 2001 provide an exemption from registration for preparations compounded and used by veterinarians. This exemption applies only if:

- the veterinarian uses the preparation in accordance with the code of practice that has been approved under section 28 of the Act; and
- the preparation is not used on animals except under the direct care, authority, or prescription of the veterinarian.

In effect, such a preparation becomes a prescription animal remedy that can be used only by or under the prescription of the veterinarian who compounded it or directed that it be compounded. The preparation cannot be offered for sale or use except to the person responsible for the animals that are under the direct care of the veterinarian or under his or her prescription.

The exemption does allow for a veterinarian to contract a second party, such as a chemist, to compound the preparation for the veterinarian's use or to fill the veterinarian's prescription. However, all parties must be careful not to market or be associated with the marketing of a compounded preparation as a trade name product, except under the circumstances prescribed in the regulations.

## Clarification of Good Laboratory Practice (GLP) expectations

A clarification of the GLP requirements for residue data was provided in the December issue of *AgVetLink*. It stated that data from the laboratory component of residue trials submitted after 1 January 2003 must be GLP compliant, i.e. all analytical laboratory trial studies must be carried out by a GLP accredited laboratory.

Some parties have interpreted this requirement to mean that the work had to be done in a GLP accredited laboratory but the work did not have to be GLP compliant. **This is not an acceptable interpretation.** The ACVM Group expects the work done in a GLP accredited laboratory to be GLP compliant.

Data from trials that are not GLP compliant will not be accepted after 1 January 2003, even if the work was done in what appears to be a GLP accredited laboratory. If you are making an application with non-GLP data after this date, you will need to use the 'information waiver' process and provide an argument as to why the data being provided should be considered equivalent to that from a GLP accredited facility.

Parties are advised to ensure that, when contracting services from a laboratory, the studies will actually be GLP compliant.

## Transfer to ACVM registration

### Change in plan to transfer individual trade name products to the ACVM Act by cancelling an animal remedy licence/pesticide registration and reissuing as an ACVM registration

As you are probably aware, under section 21(5) of the ACVM Act 1997, the ACVM Group cannot issue a registration for a trade name product containing a hazardous substance 'unless an approval for that substance has been issued under the Hazardous Substances and New Organisms Act 1996'.

#### Agreement with ERMA NZ

In September 2001, the ACVM Group sought agreement with ERMA NZ to show flexibility in the interpretation of an approval issued under the HSNO Act as referred to in section 21(5). It was recognised that the effect of taking a narrow interpretation of the word 'approval' was to require licensed animal remedies and registered pesticides to undergo a full HSNO approval process (or be transferred to the HSNO Act) before MAF could issue a registration for applications made under the ACVM Act. This was of particular importance to applicants who wished to make a B1 (identical product) application under the new legislation.

An agreement was reached whereby identical trade name products could be registered under the ACVM Act with reference to the existing registered or licensed product. The agreement was:

where the new product is the same as the referenced product (i.e. a dual label product with the same formulation, uses, manufacturer and registrant/licensee as was previously covered by a single registration or licence), then the existing registration or licence (which is retained under the HSNO provisions) will be regarded as fulfilling the HSNO approval referred to in section 21(5) of the ACVM Act.

Essentially, the agreement was that the trade name product had to be identical to the original product registered under the Pesticides Act or licensed under the Animal Remedies Act and cause no change in risk profile, particularly for human health or environmental risks.

#### Use of mechanism

Following this agreement, the ACVM Group sought a further understanding with ERMA NZ to use this mechanism to register products under the ACVM Act that already existed as registered/licensed products under the Pesticides Act 1979 or the Animal Remedies Act. Under the ACVM proposal, trade name products would be registered under the ACVM Act at the request of the registrant/licensee provided that they were identical in every way.

The ACVM Group believed that this mechanism was appropriate because conditions applied to current licences or registrations were considered sufficient to maintain adequate regulatory control, provided the product information and labels for each product were updated within a fixed period (before the end of the proposed ERMA NZ transition period). The products were identical in every way, so there would be no new risks associated with this mechanism.

After discussions with ERMA NZ, the ACVM Group was under the impression that agreement had been reached and details of the scheme were therefore outlined in the October 2001 *AgVetLink* (pathway three of the insert), and discussed at AGCARM and other public forums.

On 17 December 2001, however, the ACVM Group was informed that

ERMA NZ could not support this proposal under the HSNO Act. For this reason, we are unable to register products by this route, and we regret any inconvenience caused.

#### Legislative development

However, the ACVM Group currently has a legislative development process in place that will permit us to transfer all agricultural compounds to the ACVM Act by means of a regulation made under section 88 of the Act.

The date for transfer of all of these trade name products to the ACVM Act is proposed as 1 July 2002 (see box below).

## Update on transfer regulations

**The making of regulations to transfer all animal remedy licences and pesticide registrations to ACVM registrations has been recommended to Cabinet. MAF is awaiting Cabinet's direction.**

**It is anticipated that if Cabinet approves the recommendation, the transfer will take effect as at 1 July 2002. At that stage all agricultural compounds will be regulated under the ACVM Act and animal remedy licences and pesticide registrations will no longer apply except where products are not covered by the ACVM Act.**

## FYI: Workshop questions

The most frequently asked questions during the recent registration workshops were the following.

### ■ *Could we please have acknowledgement of when our application is formally accepted into the ACVM registration system?*

We have updated our notification letter to inform applicants of formal acceptance. This will be operational immediately.

### ■ *What applications must be publicly notified?*

Sections 13 and 14 of the ACVM Act 1997 state:

#### **13. Notification of application to Minister and departments**

- (1) The Director-General must, upon receipt of an application, notify the nature and proposed use of the trade name product or the proposed variation of conditions to –
  - (a) The Minister; and
  - (b) The Environmental Risk Management Authority; and
  - (c) Those Departments listed in Schedule 1 of the State Sector Act 1988 that have notified the Director-General that they have an interest in applications made under this Act.
- (2) The Director-General must supply further information to any person notified under this section, if requested to do so by that person, unless that information is protected in accordance with sections 73, 109, or 121.

#### **14 Notification of application**

- (1) The Director-General must, upon receipt of an application, publish a notice in the *Gazette* and give such

further notice of the application as the Director-General thinks fit having regard to the nature of the application and the persons likely to have an interest in the application.

- (2) The notice must include –
  - (a) A statement that an application has been made to register a trade name product or to vary a condition on a registered trade name product; and
  - (b) A brief summary of the relevant information on the trade name product; and
  - (c) Information on the proposed use of the trade name product or the variation proposed to a condition on a registered trade name product; and
  - (d) A statement that any person may make a written submission; and
  - (e) A closing date for receipt of the submissions by the Director-General, being no later than 30 working days after the date of public notification; and
  - (f) The place where the application and the accompanying information, other than information protected in accordance with sections 73, 109, or 121, may be viewed and the address for service of the Director-General and the applicant.

### ■ *Will ERMA NZ give data protection for a new active ingredient if the toxicology package is not submitted with the application to the ACVM Group? What is ERMA's stance on this?*

It is the ACVM Group's understanding that the data protection provisions of the HSNO Act are relevant only if an application for registration of a trade name product containing a new active ingredient is first lodged under the ACVM Act with the ACVM Group.

### ■ *Why do we have to complete an application form for the change in packaging when there are no additional risks existing?*

This is currently being discussed within the ACVM Group and the policy outcome will be notified in the next *AgVetlink*.

## Advertising

Several companies are using advertising material with claims that have not been approved. These companies have been contacted individually to come into compliance with governing legislation.

Please refer to the following advertising sections:

- ACVM Act 1997 – section 102
- Pesticides Act 1979 – section 40
- Animal Remedies Act 1967 – section 41.

These documents are available from our website: [www.maf.govt.nz/acvm/](http://www.maf.govt.nz/acvm/). The ACVM Group recommends that companies understand these sections of the relevant legislation and ensure they are compliant. Copies of the ACVM Act 1997 and ACVM Regulations 2001 are available from the ACVM Group website and also from Bennetts Government Bookshop, Bowen House, corner Bowen St & Lambton Quay, phone 04 499 3433.

## Compliance issues update

The ACVM Group has had a number of compliance incidents reported recently. The following issues currently under investigation are summarised to help readers understand compliance requirements.

### ■ **Incorrect/unregistered claims on labelling and advertising**

Claims published in advertisements must not exceed those that have been approved during the licensing of the trade name product.

### ■ **Products being sold/advertised that are not approved under the ACVM Act 1997**

No advertisement may be published for a trade name product that is not approved, or that is subject to a provisional licence or experimental use permit.

### ■ **The requirement to register glucosamine products**

All products that contain glucosamine must be registered if they are intended for use as a veterinary medicine.

### ■ **Incorrect packaging**

At present, all pack sizes must be approved before they can be sold/advertised. Should an applicant wish to include an additional pack size under their registration, a Type C3 – Additional Pack Size application should be lodged with the ACVM Group.

### ■ **Illegal manufacture**

A compliance investigation has recently been undertaken regarding bulk product being used to fill empty containers. It is illegal to tamper with and re-pack sealed trade name products as approved by the ACVM Group. The practice of re-filling containers has implications on the stability as well as efficacy of the product. It also limits traceability – if there is no batch number on the container, recalling containers affected would be impossible.

It should be noted by companies that, in relation to any agricultural compound, 'manufacture' includes all the following aspects: acquiring materials, making up, preparing, producing or processing, filling, and assessing the trade name product for release. It also includes the packing and labelling of an agricultural compound in a container for the purposes of sale.

Such manufacturers should be advised to, and are subject to approval by, the ACVM Group. Approval of a new manufacturer can be gained through a type C2 – Additional Manufacturer application. The forms and data requirements for this type of application are available from the ACVM Group website: [www.maf.govt.nz/acvm/](http://www.maf.govt.nz/acvm/).

## Illegal sale of unregistered or non-compliant agricultural compounds

The ACVM Group advises all parties (in particular retailers) that, among other things, it is an offence to knowingly:

- sell any agricultural compound in contravention of the ACVM Act; or
- contravene any conditions (including labelling specifications and promotion of products) that apply to any registered trade name product; or
- contravene any conditions that apply to any agricultural compound exempt from registration by regulations.

Similar offences are specified in the Animal Remedies and Pesticides Acts.

The ACVM Group is in the process of investigating the sale and use of unlicensed or unregistered products and products that are being promoted in a manner that is not consistent with the licence or registration of the products. Prosecution may be taken if the products are being sold in contravention to the relevant Acts or the licences/registrations issued under the Acts. Retailers may be liable even if they are selling products that are being inappropriately promoted by some other party.

In the first instance the ACVM Group will advise people who are inadvertently selling unregistered products or products that are being promoted inappropriately to advise them that the products should not be sold. (The ACVM Act also allows for prohibition notices covering manufacture, sale or use.) If, after being advised, a person continues to sell the products, then they may be prosecuted.

## VICH update

### Food Safety Working Group

In December 2001, the VICH Food Safety Working Group met in Tokyo to further the establishment of harmonised toxicology data requirements for supporting veterinary medicines used in food producing animals.

#### Step 3 sign offs

Draft guidelines for repeat-dose (90-day) and developmental toxicity studies, plus the general approach to testing, were signed off at step 3.

When approval to consult formally on these documents has been received from the VICH Steering Group, the drafts will be circulated and responses collated so that formal New Zealand and Australian comments can be made.

#### Repeat-dose (chronic) studies

The draft guideline for repeat-dose (chronic) studies has not yet reached an agreed draft. The discussions continue as to the appropriate length of these studies. Europe and the US believe that all should be known about a substance being tested after no more than one year (and maybe an even shorter period), while Australia and Japan require convincing that studies shorter than two years would give the required level of assurance to a regulatory authority.

New Zealand is neutral in this debate – while we also believe that studies shorter than two years should give proper assurance as to long-term toxicity of a substance, we are required to represent both New Zealand and Australia at the meeting.

### Pharmacovigilance

The VICH Pharmacovigilance topic is in a critical state and its continuation is in doubt. A recent phone conference was held by MAF, the NRA, Peter Scott (Merial) as the Australia/New Zealand topic expert, Sarah Weston (Bayer) for AGCARM and ARPPA, and Peter Holdsworth for AVCARE to determine the Australia/New Zealand position. Peter Scott provided background.

#### Expedited global reporting issue

One main issue of dissension concerns the global distribution of expedited reports of critical adverse events. This is a European regulatory requirement and the EMEA position is that harmonisation must be based on the EC process because the European legislation will not be changed.

The US (AHI) and EC (FEDESA) industries' position on expedited global reporting is that the EMEA requirements are excessive, will entail greatly increased costs, and that harmonisation should involve the willingness of all parties to accommodate a mutually acceptable outcome, not just the adoption of the highest standard of a particular party.

AHI and FEDESA have requested the VICH Steering Committee to intercede with the EMEA to modify its position on expedited global reporting, and that, if that does not occur, require the closure of this harmonisation topic.

The FDA position is understood to be that it believes it has the flexibility to accommodate a harmonised pharmacovigilance process under its legislation.

The Japanese response has been to request cancellation of the next working group meeting scheduled for April 2002, and the assumption is being made that Japan will seek closure of the topic at the next VICH meeting in Japan in October 2002.

The Australia/New Zealand position is that while MAF and the NRA are considering changes to improve the reporting of adverse events, the EMEA requirement for global distribution of expedited adverse event reports is excessive.

#### Periodic summary updates

A second, and lesser issue, of industry concern relates to the provision of periodic summary updates (PSU), and the complexity and frequency of reporting that may be required.

With regard to the issue of the PSU, the guideline has been signed off at VICH step 4. Both MAF and the NRA believe improvements to adverse event reporting can be introduced regionally under existing legislation that will be compatible with the guideline, but will be less demanding than the EC prescriptive requirements.

### Biologicals Quality Monitoring

The VICH Working Group on Biologicals Quality Monitoring is progressing its assignments on schedule and has just completed a guideline at step 2 on 'Test for the Detection of Mycoplasma Contamination'. (Copies are available from the ACVM Group. Please contact Brian Pidford: pidfordb@maf.govt.nz).

## VICH guidelines to be used for antibiotic resistance information requirements

As an outcome of the review of antibiotics, the ACVM Group has altered its information requirements for antibiotic products. Rather than create a separate standard or detail the requirements in *Registration Requirements for Veterinary Medicines in New Zealand*, the Group has examined the VICH guidelines for providing information on antibiotic resistance to support the registration of antibiotic trade name products. They are considered appropriate and have been adopted as the minimum information required for registration of such products in New Zealand.

The reference to the VICH guideline will be inserted at the next revision of the *Registration Requirements for Veterinary Medicines in New Zealand*. The VICH guidelines themselves can be viewed on the ACVM Group website through the 'links' pathway.

## Good Manufacturing Practice update

Progress towards completion of the mutual recognition agreement for GMP with the EC has been provided in *AgVetLink* issues 29 and 30. We are now waiting for notification by the Agreement Sub-Committee that the Veterinary Pharmaceuticals Annex has been signed.

Meanwhile the ACVM Group is continuing with its review of the GMP assessment process and implementing revisions as outlined in *AgVetLink* 30 (Feb 2002).

- AgriQuality New Zealand, the organisation contracted to provide inspection services to MAF, is recruiting staff with the competencies and experience required by the ACVM Group to carry out GMP inspections that fulfil the requirements for inspections of manufacturers of products exported to the EC under the mutual recognition agreement.
- Closer working arrangements have been agreed with Medsafe, Ministry of Health, for the provision of pharmaceutical expertise into the training of GMP inspectors and the conduct of inspections of veterinary pharmaceutical manufacturing premises.
- One collaborative inspection has been carried out by Medsafe and AgriQuality inspectors.
- AgriQuality inspectors will be provided with the opportunity to observe Medsafe inspections of human pharmaceutical manufacturing operations, to align the inspections more closely where it is relevant and appropriate to do so.
- The ACVM Group is reviewing its processes to provide more information to manufacturers that will make regulatory interventions, corrective action steps and time frames clearer for all parties.
- New GMP certificates in the form agreed under the mutual recognition agreement are being provided as inspections proceed.
- The ACVM Group has implemented the definition of deficiencies noted during inspections agreed under the mutual recognition agreement. This can be found attached to the *ACVM Standard and Guidelines for GMP* on the ACVM website and attached to inspection reports.

Further information will be provided as the ACVM Group works through its ACVM GMP Certification Project, which has been established to review processes, associated documentation, and its communications with regulated parties.

## NRA workshop: 27 February - 1 March

Two ACVM Group representatives attended a workshop run by the National Registration Authority (NRA) Australia for organisations/ persons who make applications to register agricultural chemicals and veterinary medicines under the Agricultural and Veterinary Chemicals Act 1994. The two-day workshop to assist applicants in preparing registration

applications covered various aspects, including administrative and technical screening, and what makes a good application.

The workshop provided a good insight into how the NRA processes worked.

This visit also gave the ACVM Group representatives the opportunity to visit the NRA to meet personnel and to discuss a range of topics.

During this visit, informal enquiries were made to the ACVM Group as to whether the Group, in conjunction with ERMA NZ, would hold a similar workshop in Australia.

The ACVM Group will consider this for the future and would welcome comment from Australian companies as to the merits of such a workshop.

## Standards review project

The ACVM Group is initiating a review of its standards. The intention is to have them all reviewed and revised by December 2002.

The review of some of the standards is not urgent and they require very little revision, while other standards require immediate and extensive attention. In some cases new standards will have to be written to replace sections that have been removed from existing standards. For example, the chemistry standard has been revised recently and all references to biological products have been removed, prompting a need for a specific standard for the identification and characterisation of biological products.

References to good laboratory and field practices in other standards have caused some confusion. This is most noticeable in the standards for residue data. Consequently, the ACVM Group intends to consolidate these references into the research standard.

In subsequent issues of *AgVetLink* information will be provided about which standards are being reviewed and the related submission process.

The *ACVM Standard and Guidelines for Good Manufacturing Practice* and the *Research Standard* will be the first to be reviewed and revised. The documents can be examined on the ACVM Group website through the 'publications' pathway. If you have any comments on the standards (concerns, additions, deletions, clarifications or recommendations) please send them to:

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## Standing Order

The ACVM Group is working on a standard for the required content of a Standing Order, to be included in the *Code of Practice for the Use of Veterinary and Human Medicines in Research, Testing and Teaching Organisations*. The code, which is in the latter stage of development, is being sponsored and co-ordinated by the Royal Society of New Zealand.

The Standing Order is a veterinary authorised set of directions to be followed by non-veterinary personnel when using veterinary and human medicines within such organisations. The intention is for the Order to be concise enough to provide a level of control over medicine use on animals that is equivalent to the control achieved when the veterinarian is supervising in person. The ACVM document will provide a framework for each of the organisations to 'fill in' according to their own circumstances.

It is possible that the concept of the Standing Order may be included in future MAF-related codes.

For further information regarding the code and its progress, contact the Royal Society c/o Ms Gill Sutherland, phone 04 472 7421 or fax 04 473 1841.