# ACVM

Ministry for Primary Industries
Manatū Ahu Matua

# News and Views

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## Timeframes for applications

The ACVM Group is not currently able to meet timeframes relating to registration of ACVM veterinary medicine products (as specified under section 16 of the ACVM Act) because of significant resourcing constraints. This situation is due to:

- higher than normal application workload for this period (65 applications pending/in progress)
- two technical assessor vacancies that are not expected to be filled before October, and
- limited number of staff to manage all veterinary medicine-related work, such as the need for those staff to be involved as specialist technical experts in a number of emergent issues within ACVM and other groups across MPI.

Timeframes will depend on resolution of the resourcing issues as well as on how many non-BAU activities require input from the technical team. The situation is likely to continue for at least the next six months, including time needed to recruit and train at least one new member of the team.

Note: If you have more than one application in the system, you may swap their order in the processing queue. Let us know which one has top priority (approvals@mpi.govt.nz).

## Data assessor workshops

Planning for the "Becoming an ACVM Recognised Data Assessor" workshop is underway. It will likely be held on Thursday, 30th October. We have chosen Wellington as the venue to enable data assessors to meet all the ACVM technical team (and vice versa).

Tentatively, the morning will be devoted to general ACVM requirements, which affect all data assessors, including an explanation of how the recognition process will work. In the afternoon, we will split into groups for ag chems and vet meds (and VTAs if required) to go through the data assessment templates. The final agenda, venue and cost will be announced closer to the time.

If you have already notified us of your interest in attending one of these workshops, details will be emailed to you when they are available. If you have not notified us but would like to attend, contact Sarah Lester (sarah.lester@mpi.govt.nz).

# Adverse event reporting update

Since our last update two months ago, record numbers of adverse event reports have been submitted. The reports are following the expected product use pattern with an increase in reports relating to the changing seasonal animal health issues.

During this period there have also been several product recalls. This has prompted us to update the procedures for expectations regarding these events and to streamline the process internally. These changes will improve the registrant's ability to meet MPI expectations during these events and ensure they meet their regulatory obligations.

The general quality of reports submitted by registrants is adequate, but we would like you to consider some of the common deficiencies identified when these reports are reviewed so that the most useful information is provided and appropriate monitoring of the product in the marketplace is occurring. Common deficiencies are as follows:

- **Not providing adequate information regarding the incident in the narrative**. This information is important so that an adequate assessment can be made and reported. In some cases it is appropriate to provide clinic case records from the attending veterinarian and laboratory results.
- **Providing a causality ruling without discussion.** Causality needs to be specifically linked back to the information provided in the narrative and supported by case report investigation.
- **Failing to consider and adequately investigate the possibility of product quality defects**. This is a possibility, for example, when there is a lack of expected product efficacy or a different outcome such as an unexpected reaction at the site of application.
- **Stating "other causes possible" as a justification for a non-probable causality ruling without specifying what the "other causes" might be.**
- **Not providing the reporter's contact details and the geographic location where the adverse event occurred.** This information becomes very important when trending of data is required or when an adverse report in lodged through more than one avenue.

# Annual fees

In May letters were sent to registrants reminding you to view your list of registered products on the web register and advise us by 20 June 2014 if you did not wish to renew any of your product registrations. A good number of registrants de-registered via the electronic method and advised us well within the timeframe.

Unfortunately, when we posted out the invoices in late July, hard copy product lists were included with the invoices. On the lists was a box for ticking if you wanted to de-register your products. A number of registrants have used this list to de-register their products but after the cut-off date (20 June). This has caused us quite a bit of work in making credit adjustment requests and reissuing new invoices. From our perspective, it would be easier if you pay the invoice and then advise us to de-register the product accordingly. This avoids crediting the original invoice and reissuing another for all your remaining products. Please use this option if possible.

**Annual fees for registered products must be paid by 30 September**. If fees are not paid, products may be de-registered as per section 81J of the ACVM Act.

# Forms update

As advised in the last issue, we have revised the registration application form to make the requirements more obvious. Instead of one form for new registrations, renewals and variations, there are three separate, short forms:

- Registration of an ACVM trade name product (ACVM 1)
- Variation to registration of an ACVM trade name product (ACVM 1V) (still under construction)
- Renewal of registration of an ACVM trade name product (ACVM 1R).

The recent MPI restructuring (see June 2014 issue for details) meant that all ACVM forms and templates required updating to provide correct branch name/contact details. Updated forms have been sent to the website and will be available as soon as the web team is able to upload them. (We are only one of the affected groups, so the web team has a significant workload.)

# New Zealand Biosecurity Institute NETS Conference

**30 July -1 August, New Plymouth**

Teresa Robinson and Joy O'Connor attended the NETS conference. Their main focus was on learning about the new VTA research, animal welfare changes and alternative pest control methods, but they also took the opportunity to catch up with people using the products in the field and to hear any concerns.

Talks covered all weed and vertebrate pests (land and aquatic), as well as pathways and responses to dealing with incursions. There was a demonstration using drones and optional field trips to explore New Plymouth's beautiful scenery, and see the results of pest management in action.

For more information, contact Joy O'Connor (joy.o'connor@mpi.govt.nz).

# New Zealand Plant Protection Society Conference

**12-14 August, Taupo**

Sarah Lester and Bruce Nalder attended this conference on behalf of the ACVM Group. It was a great opportunity to find out about emerging research and technologies, meet new people and catch up with some of the researchers, data assessors and applicants that we deal with.

Resistance management and data protection were both hot topics and we look forward to seeing progression in these areas. Other topics included:

- biosecurity surveillance
- biological control
- statistics
- alternatives to methyl bromide
- effects of adjuvants
- spray technologies, and
- management techniques.

For more information, contact Sarah Lester (sarah.lester@mpi.govt.nz).