ACVM

Ministry for Primary Industries
Manatū Ahu Matua

News and Views

Nov 2014

ISSN 2230-4630

In this issue...

Data assessor workshop

We were pleased to welcome participants to the ACVM one-day workshop for data assessors, held Thursday, 30 October, at the Wellington SPCA Centre. From our perspective the day was a great success.

The morning covered general ACVM requirements. In the afternoon, the group was split into two (ag chems and VTAs in one group, vet meds in the other) to go over data assessment reports and information requirements for chemistry and manufacturing. By the end of the day, participants had everything they needed to make an application to be a listed data assessor, as well as a good understanding of what is expected of a listed data assessor, and how to approach Chemistry and Manufacturing and Overall Data Assessment Reports.

Workshop organisers appreciate industry's interest and help in the development of this new program. Contact Sarah Lester (sarah.lester@mpi.govt.nz) for more information.

We are now accepting applications to become a listed data assessor. The form is available on our website: Data Assessor Application

Adverse event reporting update

Summary report

The ACVM compliance team has nearly completed a year of data capture that will enable the generation of the first Adverse Events Summary Report. This is still on track to be published in December 2014.

The original draft summary report was circulated to industry by ARPPA and Agcarm. Some minor changes have been made to the format of this document because of feedback received from industry. However, it is important that MPI presents this document in a transparent manner and the adverse events that have been captured for all possible and probable reports will be reported based on the individual active. This also means that an adverse event reported for a multiple active product will be reported under all of the actives listed for that product. We consider this to be the most appropriate way to capture the data based on the restricted information that is collected during the reporting process.

MPI intends that this summary report will be available to a wider public audience so many clinical signs and other technical jargon have been simplified, and a strong emphasis on the purpose of the report has been captured in the summary.

Reports for 2014

Year to date figures for adverse event reports received by the ACVM Group have continued to trend upwards. These demonstrate a 150% increase in reports received for the same time period in 2013. This is considered to reflect better alignment from industry on what actually should be reported and also an overall increase in awareness of the reporting system.

Variations to registrations

Smart Track variations were introduced several years ago for MINOR changes to registrations. (Essentially, a change is MINOR if the information can be summarised in the application and it requires minimal supporting data.) However, each year sees an increase in the number of Smart Track applications we receive for changes that are MAJOR. This significantly adds to processing time and creates a backlog of pending applications as we wait for applicants to provide the additional information needed.

We examined our variation process and concluded that a new approach is needed. From 1 December 2014, apply for variations using our new variation form, which completes the set of registration application forms advised in the last issue:

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

This short form provides a table (shown below) to identify the type of variation you want. Notice that the table also has a column called ‘Form to use’. Use these new forms to provide information about the change you are requesting. The new forms are more explicit about information required for MINOR changes and about additional information required for MAJOR changes.

When a variation application is received, it will be screened. You will be informed via email if the information provided is complete or not. If more information is required, your application will be returned to you for re-submitting when you have all the information.

Variation to registration of an ACVM trade name product: section 3 table

Variation Application Type (Indicate type by highlighting in BOLD.)	**Form to use**
C1 Change in formulation	ACVM 6
C2 Change in active ingredient manufacturer	ACVM 7
C2 Change in formulation manufacturer	ACVM 8
C2 Change in manufacturing process, including changes in AI or formulated product specifications	ACVM 9
C3 Change in packaging	ACVM 10
C3 Change in shelf life	ACVM 11
C4 Extension of use to include additional target host or species C5 Extension of use to include control of additional pests, weeds, species, diseases or conditions	ACVM 12
C6 Change in dose regime or application rate or timing C7 Change in method of administration/application	ACVM 13
C8 Change in withholding period	ACVM 14
C9 Administrative change, such as phone number, postal/email address.	Provide details in section 4 below. No additional form required.
Registration renewal in addition to the variation	Provide relevant C1-C8 variation form as listed above and documents specified in section 4 below. Renewal form (ACVM 1R) is not required.

Applications

Application update

We are working through the application backlog (see August 2014 issue) as quickly as possible but there is no light at the end of the tunnel yet. Please also keep in mind when submitting applications that the days from 20 December to 15 January are non-working days in regard to the timeframe for processing applications. Any applications for which the regulatory timeframe ends within these dates have the remaining days added to their time after 15 January (i.e. if an application was supposed to be due on 25 December, the amended end of the regulatory timeframe becomes 20 January).

Outdated forms

Many applicants are using forms they downloaded years ago. We are still receiving applications on NZFSA and MAF branded forms. As above, this adds to the time needed to process an application as advisers must check to see if the current version of the form requires additional or different information.

From 1 December 2014, we will only accept applications on the latest version of forms. These are all MPI-branded and are the only versions currently on the website. Applications submitted on old forms will not be processed.

All ACVM forms can be accessed by clicking on "Documents-forms & templates" in the Quick Links box on our homepage (http://www.foodsafety.govt.nz/industry/acvm/).

To protect or not to protect

In response to requests from applicants, we 'unprotected' our forms during our last round of rebranding. This is causing some unexpected problems for our team. Some applications are arriving with answers put in the wrong place and/or questions in the form deleted. When this happens, it significantly adds to the time needed to process an application. If these problems continue, we will have to consider 'protecting' the forms again.

Please note:

- Questions in our forms are in shaded boxes and answers are to be put in white boxes.
- If you delete a question from the form, your application will not be processed.

Sign up to be notified when the next issue of *ACVM News and Views i*s out.
Send us your suggestions.