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ACVM News & Views

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Biosecurity Clearance of ACVM Products

When registering a product or getting a class determination done under the ACVM Act, the Ministry for Primary Industries (MPI) also assesses whether there are any biosecurity risks associated with the product under the Biosecurity Act. This is separate from the ACVM assessment, and is handled by the Animal Imports Group.

When registration comes up for renewal, MPI needs assurance that the product still carries no biosecurity risks. Production systems, suppliers, ingredients and manufacturing processes might have changed in the meantime, possibly impacting on the biosecurity risks. At time of registration renewal, MPI will ask you for either a signed declaration on company letterhead stating that there have been no changes in the manufacturing process since the last assessment was done, or an outline of the changes that have taken place so we can update the biosecurity clearance.

For some products, an initial assessment has been done when the product was first registered, but the biosecurity risks have not been evaluated since. A change in MPI processes means that in some cases you will be asked to provide the most current manufacturing information so we can align the biosecurity clearance with the registration renewal. For simplicity, the validity of the biosecurity clearance has been extended from 2 to 3 years.

The biosecurity assessment will be invoiced as part of the ACVM fee, and charged at an hourly rate. Depending on the complexity of the manufacturing process and the information required, assessments can take between 2 weeks and 2 months. Animal Imports endeavour to complete biosecurity assessment within the time frames outlined in the various ACVM application forms. We will contact you if the biosecurity application is incomplete (e.g. missing documents) or we require more information. From experience we know that Section 16 of the form is most often overlooked or incomplete!

Download the Application Form for Biosecurity Clearance of Agricultural Compounds or Veterinary Medicines. Completed forms should be sent to animalimports@mpi.govt.nz.

Annual Fees Reminder

All annual fees must be paid by 1 October.

At time of writing, 264 annual fee accounts are still unpaid. The amounts owed range from $621.00 to $172,638.00.

We remind you that product registrations may be cancelled if fees are not paid (ACVM Act, section 32A).

Ministry for Primary Industries
Manatū Ahu Matua

Purchase and use of RVMs

MPI has amended the conditions of registration of restricted veterinary medicines (RVMs) to give effect to the recognition of veterinarians (now under section 44G of the ACVM Act) to authorise the purchase and use of RVMs.

Restricted access
MPI imposes restrictions on who can sell*, buy or use certain veterinary medicines because the potential negative effects associated with their use are too significant and too likely to occur to allow uncontrolled access to them. In addition, many of these restricted veterinary medicines (RVMs) are also prescription medicines under the Medicines Act 1981, and restricted access to them helps prevent indirect and undesirable access to them for illegal use on humans.

Veterinarians as risk managers
Professional oversight is required to manage the risks of negative effects of RVMs, and MPI sees veterinarians as the main risk managers in this regard. MPI depends on the professional and expert oversight of veterinarians to make sure that RVMs are used only when they are justifiably needed.

Recognition of veterinarians
In August MPI re-issued its recognition (now under section 44G of the ACVM Act) of veterinarians to authorise the purchase and use of RVMs. To give effect to the recognition, the conditions of registration for all RVMs have been amended to expressly refer to it. The change in conditions is just a consequential change to the reference and does not alter any other matter relating to RVM registrations.

MPI has issued the *ACVM Notice: Requirements for Authorising Veterinarians.* This notice is a restatement (without material change) of the performance and technical standards issued under the now repealed section 62 of the ACVM Act. It restates the authorisation requirements that must be followed by veterinarians. An associated guidance document, *Veterinary Operating Instructions,* has also been published.

Expectations
MPI expects that veterinarians will always keep a close link between the examination of the animal, the judgement that a particular RVM is justifiable, and the supply of that RVM. This is relatively straightforward when it involves a single animal that requires treatment at the time the veterinarian examines it. It is also relatively simple when the situation is so routine and repeatable that all the variables are managed and veterinary inspection of the animal before use of the RVM is unnecessary to manage the risks, and the justification for use is always the same.

However, in herd/flock health, reproduction management or disease control situations, decisions to treat individual animals may have to be based on herd/flock data. At times, individual animals must be treated as soon as possible after onset of certain signs, whether or not the veterinarian can be present to inspect those animals. In such cases, the justification for the use of a particular RVM is always based on the predictive value of epidemiological analysis and regular monitoring of the herd.

Veterinarians manage all these situations to make sure that RVMs are used only when they are justifiably needed and only in a manner that will not jeopardise the welfare of the animals treated, the environment (spread of unwanted organisms), the general public, or trade in animal produce.

* Requirements for sellers of RVMs are currently being updated.

Introducing...
Jenni Doyle

We are pleased to welcome Jenni Doyle who has recently joined our team of veterinary medicine assessors. By way of introduction, Jenni says, "I have a varied background which includes farming, building, fine furniture making, and veterinary work. I enjoyed spending several years in small animal practice where I pursued an interest in soft tissue surgery. Most recently, I joined MPI and spent time working at a local meat export premises as a veterinarian. My out of office interests include home renovation, walking, travel, wine drinking, and spending time with family and friends."

FYI

DA workshops - residue assessments

We plan to hold two data assessor workshops to focus on residue data assessments in November.

- Veterinary medicines will be on Tuesday,10 November
- Agricultural chemicals will be on Thursday, 19 November.

Both will be held in Wellington, 9.30am – 4.30pm, at Pastoral House on The Terrace.
The cost is yet to be determined.
Please contact Sarah Lester (sarah.lester@mpi.govt.nz) if you are interested in attending.

Variations to registration applications

When you apply for a variation to your registration, be sure to DATE and SIGN the relevant page/s of your Product Data Sheet (PDS) that you submit with the application. The new page supersedes the previous version and we must have a clear record of what is currently approved.

Class determinations

We have revised our class determination process and no longer require FULL formulations to be supplied with applications. However, we do require that active ingredient and other details are on the label as per Regulation 12 of the ACVM (Exemptions and Prohibited Substances) Regulations 2011. For more information and a copy of the updated form, go to the Class Determination page on our website.

We require a copy of the product label and a completed request form--information on intended use is particularly important. Payment should accompany applications as they will not be processed until payment has been received.

MRL Standard

Consultation on the latest discussion document of proposed amendments to the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2015* closed on 26 August. Four submissions were received.