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Manatū Ahu Matua

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Theileriosis and Buparvaquone

Background

In August 2013, the ACVM Group received a request for Approval in Special Circumstances (ref: section 8C of the ACVM Act) to import a product containing buparvaquone for the treatment of theileriosis in cattle. (Carried by cattle ticks, the Ikeda strain of *Theileria orientalis* causes anaemia in affected cattle and can lead to death in severe cases.)

Over the following days as more import requests were received, it became clear that this was the beginning of a serious outbreak affecting both dairy and beef cattle. We were called in to be part of a wider response group comprised of different groups within MPI (including Response and Market Assurance), representatives of the dairy and beef industries, and New Zealand Veterinary Association (NZVA) veterinarians to manage the outbreak and associated controls. Treatment with buparvaquone containing drugs, and managing the risks associated with that treatment, became central to the response.

Need to minimise distribution delays

The need for buparvaquone was greater than could effectively be managed by individual veterinarians and the usual approval process used to import non-New Zealand registered products. Despite the ability to issue approvals within hours of receipt, it was quickly discovered that delays associated with importing individual consignments of product could jeopardise animal welfare. To manage this, we granted a strictly controlled import approval to the New Zealand registrant company that owned one of the overseas products. This approval, which required veterinarians to make an application for distribution of product much like the Approval in Special Circumstances pathway, allowed for product to be imported to New Zealand and held by the company to expedite the distribution of treatment to veterinarians who needed it.

Strict controls required

Wider use of an unregistered product requires very strict controls on its use. This was especially important because the animals on which the product was being used were food-producing species, and because there are no Maximum Residue Limits (MRLs) set for buparvaquone in any of our major trading partners. To set these controls, a series of risk

assessments were undertaken with all available data on toxicology and residues to ensure all food safety and trade risks were appropriately managed.

The controls were, and continue to be, adjusted as more information becomes available. They include strict requirements on record keeping, tagging and tracking treated animals, and detailed controls on how meat and milk from treated animals can be processed under the Animal Products Act. MPI has been working with industry and the veterinarians dealing with this disease in the field to ensure these controls are understood, requirements are sufficiently communicated to farmers with affected animals and those that may be affected, and that all record keeping and processing requirements are met.

Plan for future

Because it is likely that theileriosis will continue to be a problem, we have had discussions with registrant companies about getting a buparvaquone product registered in New Zealand. A *Theileria* Working Group is also being formed to ensure the cooperative approach between MPI and industry continues. The experience with this response will provide a template for working with stakeholders and veterinarians in outbreak and emergency situations in the future, and will inform policies on how to manage the need for unregistered products in production animals in future outbreaks should they occur.

Annual fees and registration cancellations

Annual fees for product registrations should have been paid by 30 September. To date, 36 companies have not paid their fees. We remind you that registrations may be cancelled if fees are not paid within 20 working days after the written demand for payment has been sent (ref: section 32A(4) of the ACVM Act).

This year some companies are sending us requests to cancel registrations of products with annual fee payments for other products. This causes problems for the financial team.

Each year registrants are sent a list of their products and asked to notify us if they want to cancel any products. Notification of cancellations should be made by mid-July, **before** invoicing of fees occurs. Once an invoice is raised, the process of cancellation needs to be handled differently so that the financial records are correct.

If you wish to cancel a product registration after you have been invoiced for its annual fee, please notify us as soon as possible with the necessary information. We will then either reissue your invoice or a credit will be raised.

Workloads and timeframes

Team members have been receiving many queries about application processing times. This year with applications for agricultural chemicals and vertebrate toxic agents reaching record peaks and staff numbers at reduced levels, ‘business as usual’ has been anything but usual.

We are working to process applications as quickly as possible, but it is obvious from the numbers that any applications received from 1 November will not be through the system before the holiday closure period, which is 20 December to 15 January (ref: “working day” in section 2(1) of the ACVM Act). This effectively means February (or longer if a *Gazette* notice is required).

OECD pesticide meetings

7-12 October 2013, Paris

Warren Hughes attended various OECD pesticide meetings along with Global Joint Review meetings. In addition to the two usual OECD meetings (Risk Reduction and Registration

Steering Groups), there were three OECD expert group meetings covering pollinators, pesticide risk indicators and minor use.

Of interest from the various OECD meetings:

- Work is progressing well on the Globally Harmonised Submission and Transport System. This will allow applicants to submit a single electronic format of data packages to all regulators. New Zealand has provided input into the New Zealand specification requirements.
- The refresh of the Vision and Work Programme for the OECD Pesticide Programme is near completion and is likely to be finalised at the OECD Working Group on Pesticides meeting in April 2014.
- A system to alert regulators of bee incidents in other countries is under development.
- Web-based hubs for activities on pollinators and Integrated Pest Management are also under development.
- We had an update on activities on illegal trade of pesticides by the network of government officials including finalisation of their terms of reference and the development of a Rapid Alert System.
- The Expert Group on Minor Uses discussed priorities as it has a significant work programme. One of the priorities has been exploring the possibility of a database giving information on data packages available for minor uses.
- The next Risk Reduction Steering Group seminar will be on amateur pesticide users. It is proposed to have the seminar in 2014 -- probably with the Risk Reduction and Registration Steering Group meetings.

In the Global Joint Review meetings, five companies presented either new chemistry for consideration for joint reviews or updates on preparing their dossiers for submission of a Global Joint Review. Regulators and companies continue to see value in these Global Joint Reviews. As noted by the US, previous Global Joint Reviews have led to alignment of around 70% of established MRLs among partner regulators.

For more information, contact Warren Hughes (warren.hughes@mpi.govt.nz)

Career opportunity

We are looking for an experienced technical adviser with a strong scientific background to join our ACVM team.

As a technical adviser, you will undertake risk assessments on new and innovative compounds. You will also play an important part in establishment and implementation of policy and standards as needed to administer the ACVM Act.

This is a chance to use your technical knowledge and experience in agricultural science, chemistry, manufacturing (or related fields) and make a real difference to all of New Zealand. Experience in industry would be advantageous. The role also provides an opportunity to further develop your skills within a large and dynamic organisation.

To apply, you must be immediately available for interview in New Zealand and must hold a current New Zealand work permit or be a New Zealand resident.

For more information, contact Glen Bradbury (glen.bradbury@mpi.govt.nz)

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