June 2019

News & Views

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New Chemical and Microbiological Assurance Manager

We are very pleased to welcome our new manager, Natalie Collins. Natalie has been with MPI for almost 14 years and comes to us from the Food Regulation directorate where she managed the dairy products team. Some of you may remember Natalie from her previous time in the CMA team when she led the food monitoring programmes.

Prior to starting her career at MPI, Natalie graduated with a food technology degree and worked in food safety and quality roles with various food manufacturers including Goodman Fielder and Foodstuffs.

Natalie is looking forward to working with her highly skilled CMA team and continuing the team's high level of delivery reputation.

Cost Recovery Update

The proposed changes to MPI's cost recovery policy, which were outlined in the March issue, have been approved.

Amended regulations to provide for the new fees have also been approved and Gazetted.

Changes will take effect from 1 July 2019.

New Zealand Food Safety
Haumaru Kai Aotearoa

Ministry for Primary Industries
Manatū Ahu Matua

Vertebrate toxic agent (VTA)reassessment

VTAs are regulated under the Agricultural Compounds and Veterinary Medicines Act 1997 (the Act). As part of the registration process, there is a thorough assessment of manufacturing, efficacy, target animal welfare, residues and proposed use patterns in relation to the risk areas under the Act. One of the risks with the use of VTAs is the potential for residues to occur in food-producing animals.

As noted in the last edition of *News and Views*, MPI is planning to reassess / review the conditions of registration and label requirements for all VTAs because MPI considers that the current controls and labelling of VTAs need strengthening.

The purpose of the reassessment is to review conditions of registration and label directions in relation to:

1. who can use VTAs
2. containing the VTA within the treatment area following application
3. ensuring label directions:
   - are sufficient to manage the ACVM risk areas, and
   - are sufficiently clear to end users
4. minimising exposure to non-target food-producing animals.

The initial reassessment will focus on brodifacoum based products, followed by other anti-coagulant VTAs, and then all the remaining VTA products. The reassessment process requires MPI to consult with registrants before the decision is made whether or not to proceed with the reassessment. Other key stakeholders will also be consulted. If it is decided to proceed with reassessment, then the applications are processed as for a new product registration.

ACVM Winter Workshop

The ACVM team is planning a workshop for registrants, New Zealand agents, consultants and data assessors. We invite you to submit topics for the agenda (by 29 June) to approvals@mpi.govt.nz.

Date: 24 July 2019 (prior to Agcarm Conference on the 25th)
Time: 8.30am - 4.30pm
Venue: Te Papa Museum, 55 Cable Street, Wellington
Cost: $100 (covers registration, morning/afternoon tea and lunch)

Registration closes on Friday, 12 July.
No-one will be admitted without prior registration.

For more information and to register, go to https://www.eventbrite.com.au/e/acvm-workshop-winter-2019-tickets-61402665024

Compliance Update

Online Sales of Unregistered Products

Oxalic acid is being sold as varroa miticide to bee keepers through Trademe and from several suppliers online. However, there is only one company with a registration for oxalic acid for use as a veterinary medicine. We are working with Trademe to advise all of the unregistered sellers that they are in breach of the ACVM Act and must remove their products from sale until they are registered.

Products with Mycotoxin Binder Claims

Any product making a claim as a mycotoxin binder requires registration under the ACVM Act. MPI is aware of unregistered products being marketed in New Zealand with these claims. This is a breach under the Act, and MPI will take action in these cases.

Advertising of Exempt Products

MPI has received complaints regarding advertising of unauthorised claims for certain exempt product types. We remind owners of exempt products of their legal obligations under the ACVM (Exemptions and Prohibited Substances) Regulations 2011. Marketing exempt products with therapeutic claims invalidates the exemption status and is a breach under the Act. MPI will take action in these cases.

FYI

Reminder to registrants: annual fees

The annual fee, defined as the levy in the ACVM (Fees, Charges, and Levies) Regulations, is a fixed fee payable in advance by registrants for the year starting 1 October. The annual fee, which is $621.00 (inc GST) per registered trade name product, has not changed as a result of the current Cost Recovery project (see page 1).

Because the annual fee is per registered product, it is important for you to review your products on the public register NOW and advise us **by 30 June** if you wish to de-register any of them before invoices are raised. It is also your responsibility to ensure that your contact details are current and to advise us of any change.

Reporting supply issues to MPI

Over the last year, MPI has been notified of stock-outs of various trade name products, often after the supply shortage has impacted the market. We encourage all registrants to report known or foreseen supply problems to MPI, particularly if these are dependent on processing of applications in the registration system. These can be reported either to your account manager or approvals@mpi.govt.nz

Guidance documents update

Chemistry and manufacturing guides

Internal consultation on the final draft of the **Veterinary Medicine Chemistry and Manufacturing (Chemical) Guidance** is now finished. Industry consultation has been set to coincide with the July workshop (see information on page 2), which will provide an opportunity to discuss the changes before final submissions are due.

The updated **Agricultural Chemicals Chemistry and Manufacturing Guidance** draft is undergoing internal consultation and will be ready for industry review as soon as possible.

Labelling guides

Consultation on the updated veterinary medicine and agricultural chemical labelling guides will take place in July-August so that any questions arising can be discussed at the July workshop.

Method of reporting adverse events

The causality assessment algorithm that product registrants are required to use when reporting adverse events (AERs) and that is applied by MPI to veterinary medicine adverse event assessments is currently based on the Kramer assessment model. The same model is also used by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Kramer assessment model
The algorithm is simple to follow but does not facilitate detailed consideration of the event as it has occurred. Rather, it requires the user to have already drawn general conclusions about aspects of the event before it can be applied. There are no in-depth prompts provided with respect to the sorts of information that should have been considered when reaching the conclusion.

ABON method
The majority of AERs now received by MPI include causality assessments based on the ABON method utilised by the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency (EMA).

The ABON method is also simple to use and facilitates consideration of the event in a systematic, structured and consistent fashion by asking specific questions relating to many relevant aspects of an event. It requires the user to draw conclusions on these specific aspects.

The causality rulings generated are similar to Kramer in that probable (A), possible (B) and unlikely (N) conclusion categories apply. However, the Kramer "unknown" category is replaced with category O that is further split into:

- category O1 – inconclusive (factors prevent a conclusion from being drawn, but product association cannot be discounted) and
- category O2 – unclassified (unreliable information does not allow a conclusion to be drawn).

The ABON method is revealed in more detail in the CVMP Guideline on Harmonising the Approach to Causality Assessment for Adverse Reactions to Veterinary Medicinal Products (EMEA/CVMP/552/03-FINAL).

Proposal to adopt ABON method
Although both methods are likely to reach similar conclusions if the event is uncomplicated due to the more in-depth consideration required, the ABON method is considered the better assessment tool for more complex events.

In consequence, and given the majority of cases received by MPI already include causality rulings based on the ABON assessment algorithm, MPI proposes to adopt the ABON assessment algorithm as the preferred causality assessment tool.

Feedback requested
We are seeking stakeholder feedback in relation to this proposal. If there is general support for the change to occur, the formal process of amending MPI policy and documentation will follow.

Please send any comments regarding the proposed change to: ACVM-adverseevents@mpi.govt.nz

deadline for submissions: 19 July 2019

Now, where is that???

When you submit applications, providing PDF files that are indexed/bookmarked in accordance with our e-files guidance is a great help during the appraisal process.

It would be even more helpful if you also ensure PDF files provided are searchable by keywords.

Remember: Saving our time saves you money.

Introducing...

Kaea Smiler
Approvals Operations Adviser

"I have worked for MPI since I left Victoria University in July 2018. I started in a support officer role in science and risk assessment progressing into approvals adviser in April 2019.

I graduated with a Bachelor of Science in marine biology and psychology. I currently work across the ACVM and Animal Products Acts and I will start training for the Food and Wine Acts in the next few weeks.

In my spare time I am a keen sports person and enjoy adventuring through the bush trails with my dog."

Shixi Wu
Adviser Agricultural Compounds
ACVM Programmes & Appraisals

"I received my Honour Bachelor of Science degree from Lincoln University in 2017. My research project was on biological control of plant pathogens.

After graduation, I worked as a field trialist in Hawke's Bay for a year before I joined the ACVM team. I am now based in Wellington, working as a regulator on registration of agricultural chemicals.

In my spare time, as a typical Chinese, I enjoy home time and cooking. And with almost five years in NewZealand, hiking and enjoying the great views also have become favourite activities."

Training events

Upcoming public industry training events that you and your staff may find useful

Please note that these training events are not accredited by MPI nor are they mandatory. However, due to the limited public training opportunities available in New Zealand, MPI is regularly asked for suggestions and these events are publically searchable and available.

If your company is providing public training in New Zealand that is applicable to ACVM related topics (particularly in the areas of Good Manufacturing Practice GMP) and would like to be added to the next *News and Views* newsletter please email ACVM.manufacturingandassurance@mpi.govt.nz

If you have questions about any training below, please contact the company providing the training event.

Pharmout:

- CAPA (Corrective and Preventive Action) Training Auckland, 10 October 2019 https://www.pharmout.net/events/auckland-capa-training/

SeerPharma:

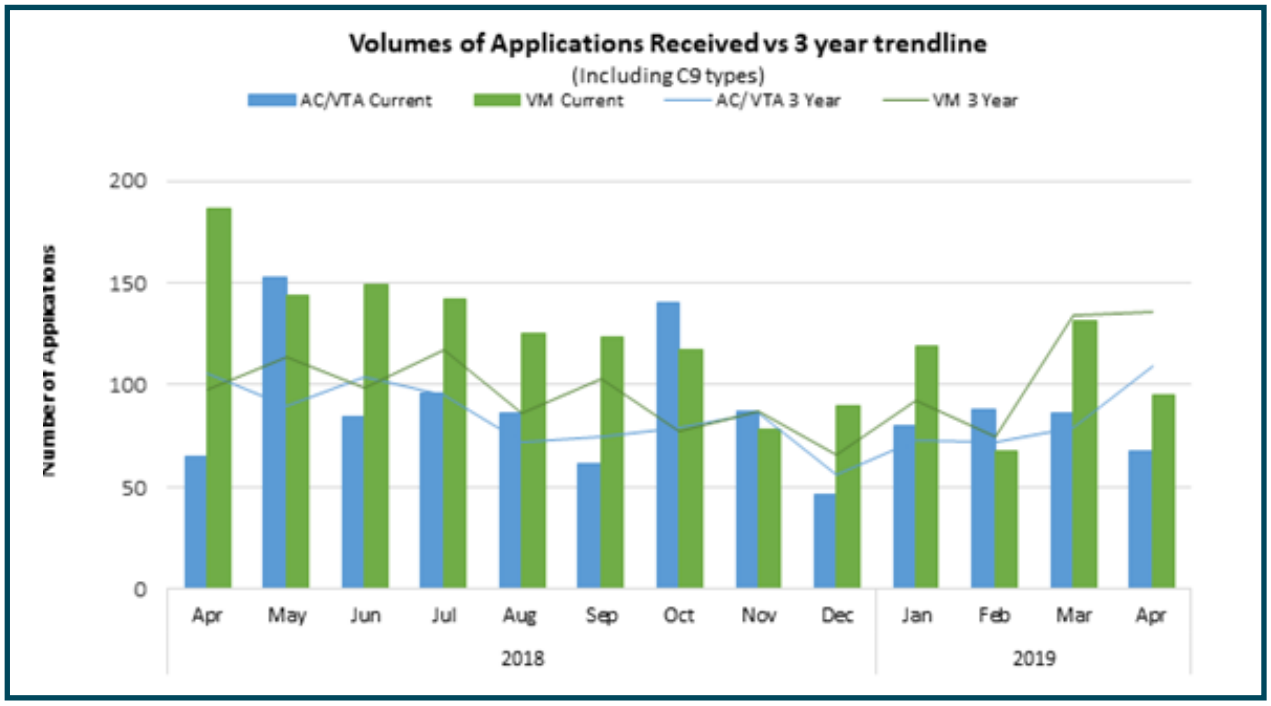
https://www.seerpharma.com/services/qa-and-gmp-training/public

Have a look at the public training available. Upcoming courses are:

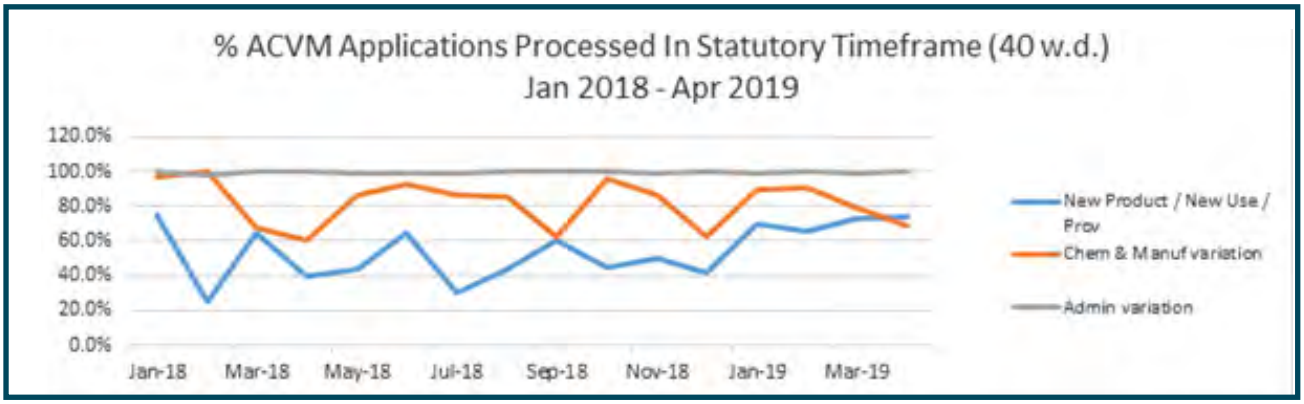
- Root Cause Analysis and CAPA
  Contact SeerPharma for date
- Supplier Quality Assurance
  Contact SeerPharma for date
- GMP – What you Need to Know
  Contact SeerPharma for date
- Good Writing Practices
- Contact SeerPharma for date
- Data Integrity – 15 October 2019

Performance Statistics (Jan-April 2019)

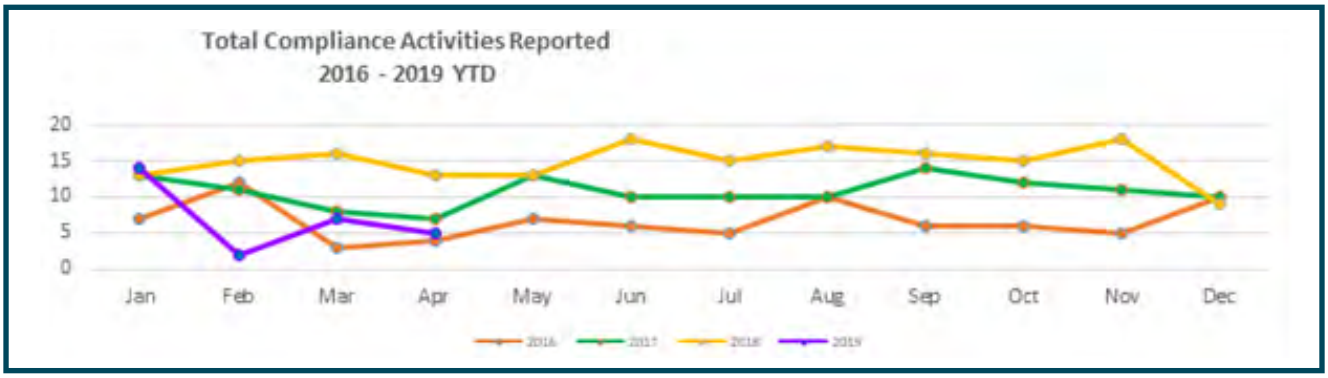
Veterinary medicine application volumes have been consistently higher than average over the last 12 months. The resulting backlog is likely to remain for the next quarter, as the new Adviser Veterinary Medicines settles in.



Overall, there has been an improvement in the processing of new product and new use applications. This is due mainly to improved performance of the ag chem team, which is now at full strength with the appointment of Shixi Wu in March.



There was a substantial increase in reported compliance events in 2017 and 2018. ACVM now has additional resource in this area, to assist in the management of these events.



Food & Live Animal Assurance Team Update

Inwards Certification

MPI has developed software (known as Tahora) to receive export certificates electronically for goods imported into New Zealand. The application receives data directly from the Competent Authority from the exporting country, which ensures the authenticity of the information.

Receipt of data electronically will increase efficiencies for border clearance and protects the biosecurity of New Zealand as it eliminates issues with fraudulent paper certificates.

Certificates
The solution is used now for phytosanitary certificate data from Australia, the USA, and Argentina but MPI is rolling out the functionality to accept electronic data from additional countries and for additional commodities. Currently MPI is working with Indonesia and Australia for sanitary certificate data.

Information to help importers to understand where electronic certificates can be used for border clearance will be posted on the MPI website.