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ACVM News & Views

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MPI cost recovery and ACVM fees

Following the first major review of charges since 2008, ACVM fees will change on 1 July 2015.

Costs recovered

MPI recovers costs for the delivery of various ACVM services, including the authorisation of agricultural compounds and veterinary medicines, and monitoring their importation, manufacture, sale, and use. MPI also provides guidance on regulatory requirements to the sector and makes technical contributions to national and international forums in relation to this area.

Consultation on fees

Before making any changes to fees and charges, MPI held 21 meetings around the country to discuss proposals and potential impacts. We aimed to keep fees down while ensuring we charge businesses fairly and appropriately. We received 247 submissions on our proposals.

Key concern

The key concern of this industry sector was that registering trade name products was not happening quickly enough.

In response to this concern, and following consultation with industry, MPI agreed to put extra resources into this area. The cost of this has been factored into our new fees and charges for this service.

Ministry for Primary Industries
Manatū Ahu Matua



New Fees

Hourly rate:
\$155.00/hour exc GST
\$178.25/hour inc GST

Annual fee and Pre-screen fee:
\$540.00 exc GST
\$621.00 inc GST

Registration renewal:
Time taken charged at the hourly rate

Class determination:
\$178.25 inc GST

Disbursements:
Charged at actual cost

What will I be charged?

- If you have work with us that is currently underway, then this will continue to be charged at the old rates until the work is complete.
- Any work or applications received and accepted by us (i.e. the applications are assessed as complete) before 1 July will be charged at old rates until work is complete.
- All work and applications received and accepted by us on or after 1 July will be charged at the new rates.

For more details, see our [Fee Schedules](#) on the website on or after 1 July.

Annual Fees

In May we sent letters to registrants reminding you to view your list of registered products on the public register and advise us if you wished to cancel any of your product registrations. The deadline for notifying us has passed, so if you have not cancelled a registration you will be invoiced in July for its annual fee.

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

Essential animal welfare medications

MPI has recently adjusted its rules for approvals in special circumstances under section 8C of the ACVM Act. This adjustment has been made to approve the importation and use by veterinarians of essential animal welfare medications that are not registered under the ACVM Act or the Medicines Act.

Essential animal welfare medications are those products that MPI and the veterinary community consider:

1. are needed to avoid unnecessary or unreasonable pain or distress (i.e. animal is likely to die, have to be euthanized, or will suffer significant pain or distress without medication)
2. must be available for immediate use when cases arise
3. are products for which there is not likely to be any party prepared to register them as trade name products in New Zealand
4. no practical alternative registered veterinary medicine or consented human medicine is available in New Zealand.

“Section 29 medicines”

Until recently veterinarians purchased these products, commonly referred to as “section 29 medicines”, as unconsented human medicines under a misunderstood exemption in the Medicines Act 1981. They were used as veterinary medicines under an exemption in the ACVM (Exemptions and Prohibited Substances) Regulations 2011.

A review of the exemption to use unconsented medicines in the Medicines Act made it clear that the exemption did not apply to veterinarians, so the products could no longer be purchased. This created an immediate animal welfare problem. An approval in special circumstances under section 8C was possible, but the existing rules were case-specific and did not allow for importation in anticipation of use. To address the immediate animal welfare problem, the rules have been amended and veterinarians can now apply for an approval in special circumstances to import and hold any of the specific essential animal welfare medications listed

in the box below. The ACVM Group will also consider submissions from expert parties concerning other candidates for essential animal welfare medications. A medication will be listed if, in the opinion of MPI and the New Zealand veterinary community, it meets all of the criteria listed at left. The listing may be subject to conditions, and those conditions may change if the circumstances in which the medication is likely to be used change.

The responsible veterinarian must keep records of the amount of medication on site and use, and those records must be made available to MPI on request. The medication must not be supplied to any party outside of the practice. An exception may be made if a medication is supplied to another veterinarian in a specific animal welfare emergency as judged by the responsible veterinarian. In the event that medications are supplied

Essential Animal Welfare Medications

1. **Doxapram (Dopram) 20mg/ml, 5ml injection**
2. **Phenobarbital (Phenobarbitone) 200mg/ml injection**
3. **Piroxicam 10mg tablets**
4. **Prednisolone 5mg tablets (28s)**
5. **Selegiline (Apo Selegine) 5mg tablets**
6. **Trazadone tablets (Desyrel) 50mg and 150mg capsules**
7. **Zonisamide (Zonegran) 100mg capsules**

The approval will be granted to import an unconsented medicine as a veterinary medicine and to hold that medicine in anticipation of use. Approval will be site-specific (i.e. confined to a single veterinary practice and geographical location), and although applications will be individually assessed the approval will not be specific to individual clinical cases. The approval will be granted to the veterinarian requesting the approval. The animal(s) to be treated must be under the direct care of the applying veterinarian or another veterinarian in the same practice. The veterinarian granted the approval will be responsible for:

- importing the medication and controlling its storage and security;
- use of the medication in the practice (including use by any other veterinarian in the same practice and geographical location);
- reconciliation of use/stock; and
- disposal of medications after expiry.

to another veterinarian to manage an emergency, records of the transfer of that medication and the amount used must be kept by both parties.

A request for up to one year's supply of the product (based on a reasonable justification in the application) will be acceptable. A roll-over request can be considered for import and use of the medication for subsequent years without the submission of a new application. Applications can be submitted to import and hold more than one of the listed products if it is deemed necessary to hold multiple products in the responsible veterinarian's practice, but there must be a specific justification for each product and the quantity needed.

Veterinarians wanting to request an approval in special circumstances should contact us at approvals@mpi.govt.nz.

updates

Applications

We processed 929 applications from January to June 2015. The average processing time is 37 days with:

- 66% completed within the regulatory time frame
- 27% completed within 80 days
- 6% exceeding 80 days.

During the collation of data for this reporting period it was noted that the tracking for time waivers had not been triggered in all cases. This means that the figures for the period January to June include days with applicant. In addition to this it was identified that not all applicants are requesting time waivers when further information is required to complete an assessment. As we cannot initiate a time waiver without a request, a number of applications are showing as overdue even though they are with the applicant pending a response. We will be making improvements to our reporting systems to rectify this, but we remind all applicants that if there is insufficient information to conclude an assessment and a waiver is not requested the application will be declined.

Currently 189 applications are in the system, and figures for June indicate a move towards performance targets. Trials of initiatives from the Registration Review along with additional assessment resource applied in the past six weeks have had a significant impact on our ability to meet timeframes. This has resulted in a 50% reduction in the assessment queue.

MRL Standard

MPI is planning to issue a public consultation document on the next round of MRLs in the next 2-3 weeks. At this stage there are likely to be MRLs for six compounds, two exemptions and some minor tidy-ups to the MRL Standard.

Adverse Events Report

Although there have been delays, we are pleased to advise that the report is progressing well. We are reviewing trends and providing context on some figures of concern. The report will require the addition of sales figures in future to facilitate identification of negative trends. This will also help to inform the need for further investigation or targeted audits.

Introducing...

Francie Olliver |

Auditor - Regulatory Programmes, ACVM Programmes & Appraisals

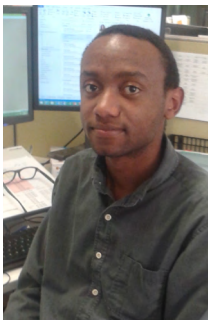


"I was raised on a dairy farm in Taranaki and then moved to Palmerston North to work at AgResearch while studying for the NZ Certificate in Science. In my five years there I worked in the Agronomy, Ecology and Genetics sections. During this time I graduated with a double major in Biology and Microbiology. I had time out doing voluntary work with my husband in NZ and overseas, then worked part time. Our three children born during this time are adults now, and we are blessed to have two grandchildren.

I returned to work full-time when we moved to the Wellington region in 1998, working at MSD Animal Health (then Schering-Plough). For most of my time there (11 years) I worked in Regulatory Affairs, most recently as Regulatory Manager, responsible for MSD's animal health products in NZ. The work also included some Quality Assurance and Auditing. In my spare time I enjoy creative crafts, gardening, reading, crosswords and time with our growing family."

Vuyisile Mpofo (Vu)

Adviser, Operations Team



"I was born in Bulawayo, Zimbabwe where I spent the first 15 years of my life before moving to Taupo. It was quite difficult adjusting to the school system and way of life at first but I managed to settle in and complete high school. I then attended the University of Otago, studying for a BSc in Botany.

I enjoy reading, making music and playing sport in my spare time and would like to complete a full marathon in the near future. I like to have a good laugh quite often and have

gained the nickname 'Chuckles' among some of my colleagues. I look forward to the rest of my time working at MPI."

Shaleen Narayan

Adviser, Operations Team

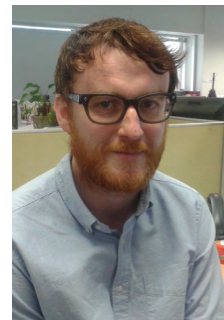


"I come from the beautiful Island of Fiji where I graduated from the University of the South Pacific in Economics and Banking & Finance in 2006. Later I did a post-graduate diploma in Tertiary Teaching. I was a Head of Department for Commerce for five years after graduation, and I taught Economics to final year students. I arrived in New Zealand in 2012 and worked at Inland Revenue as a Revenue Assessment Officer.

I joined MPI as Support Officer for Animal and Animal Products Directorate in July 2014. I am now part of the Approvals team and most of my work is ACVM related. Outside work, I have interest in painting and pottery. Love the New Zealand climate and outdoor activities despite the windy and cold days. I am pleased to be in a workplace such as MPI where people are valued for the work done."

Josh Leen

Adviser, Operations Team



Our man on the end of the phone...

Josh has lived in Japan and in France, and after a few years abroad, has returned to his hometown – Windy Wellington. His Japanese is better than his French, and his English is even better than his Japanese.

This is helpful because now, in his late twenties, Josh spends his time answering customer queries on the Approvals phone line and inbox. He loves communicating with the public and takes pride in helping solve their problems.

On a personal note, Josh likes to wrap up warm and read a book with a nice strong cup of coffee on a cold winter's day.

Simon Hoffmann

Graduate Development Programme



"I joined MPI in February as part of the Graduate Programme – ACVM is the first of three six month rotations I will complete before landing in a permanent position. I have had a long-time passion for all things food related. I worked as a chef

in Auckland for a couple of years, but became interested in the politics and science involved in food and agriculture on a broader scale and went to Otago University to study conjoint degrees in Law and Food Science.

I have found my rotation in ACVM to be a great introduction to MPI. My work has covered:

- day to day regulatory activities, such as handling applications for vet meds and agricultural chemicals
- data management for longer-term reporting, such as the antibiotic sales report, and
- assessing and gathering information for OIA requests.

It has been enjoyable working on a wide range of projects with both legal and scientific aspects and being able to draw on the experience of the team."

ACVM Registration Review

The review of the ACVM registration process is progressing well. We are currently working on four aspects of the registration process which will provide some immediate benefit to both the ACVM Group and our customers:

- The submission process and published guidance is undergoing an overhaul to remove unnecessary complexity and to make the process easier to understand and follow.
- Changes are being made to improve application visibility in particular how an application is progressing through the system, starting with the implementation of notifications to stakeholders at key points in the process.
- Management of the assessment process is being reviewed with a focus on interfaces between operations and technical activities. The aim here is to remove inefficiencies.
- We are considering whether certain types of assessment activity can be carried out by the operations team to reduce multiple handling and allow the technical team to focus on more complex assessment and ensuring the overall robustness of the process.

In addition to the above, we are close to rolling out a formalised process for requesting additional information under section 11 of the Act. This has been complicated due to confidentiality issues when dealing with multiple parties. For example, when confidential information is sought from the manufacturer of a trade name product a separate communication is required. We will trial the new system with a number of registrants before implementation.

Improvements have been made to assessment reports for minor variation applications. The new templates remove unnecessary information and have reduced reporting time significantly.

Animal Feeds Review

The review of the animal feeds regulatory framework resulted in the following recommendations:

- develop guidance documents
- undertake risk assessments on the animal feed chain
- develop better targeted ACVM Notices
- amend ACVM regulations.

We are identifying and prioritising work streams resulting from the review. Resourcing to support ongoing work in risk assessment and in the development of guidance and requirements is yet to be determined. This will occur once work streams are finalised.

Currently, we are:

- developing a notice outlining the requirements for documented systems
- drafting information requirements for animal feeds
- drafting general requirements for animal feeds under Schedule 2 of the ACVM (Exemptions and Prohibited Substances) Regulations.

These will be similar to the existing ACVM (Imported Feed Commodities) Notice 2014. We expect that draft notices will be available for consultation in August/September.

Glyphosate IARC Review

In March 2015, the International Agency for Research on Cancer (IARC, an intergovernmental agency forming part of the World Health Organization) released a brief summary of a review into several herbicides, including glyphosate. Its conclusion was that glyphosate was potentially “carcinogenic to humans”. This finding has created a great deal of interest as it is counter to previous findings.

Note that the finding was based on previously reviewed epidemiological data (meaning no new information was considered by IARC), which while showing an association between exposure and health, is rarely able to demonstrate cause and effect. Also note that IARC does not carry out risk assessments. Instead it undertakes hazard assessments to determine if a substance might cause cancer, but does not consider the likelihood that it would.

The IARC findings are at odds with previous conclusions made by significant regulators such as the EU and the USA. Regulators in New Zealand have previously reviewed all the data on glyphosate toxicity and found it to be safe to use as a herbicide.

The IARC full report, when available, will be evaluated by the Environmental Protection Authority (EPA) to see if there is information that would indicate a need to re-assess the safety evaluation of glyphosate.

Off-label use of vet meds in minor species

Recent discussions with industry have raised the need to review the standardised withholding periods (WHPs) in the maximum residue limit (MRL) standard. There is also general agreement that guidance in the establishment of WHPs needs to be improved.

The issue primarily lies in the requirement to seek veterinary advice when establishing WHPs for off-label use. This is especially important with respect to off-label use and multi-modal therapy. In addition to the need to provide better guidance to veterinarians on establishing WHPs, we are also considering:

- changing the conditions of registration
- applying an automatic default WHP for off-label use
- reclassifying products as appropriate.

Warren Hughes attended recent Organisation for Economic Co-operation and Development (OECD) meetings covering:

- Biopesticides Steering Group (BPSG) including a one day seminar on secondary metabolites
- Global Joint Reviews
- Working Group on Pesticides (WGP)
- Expert Group on Electronic Exchange of Pesticides Data (EGEPPD).

BPSG Meeting and Seminar

Speakers for the seminar on secondary metabolites ranged from manufacturers to regulators. The focus of the seminar was on data requirements as regulators are looking more closely at them from a toxicological and environmental perspective. Key points from the seminar were secondary metabolites are not well characterised, noting some produce antibiotic secondary metabolites. It was agreed further guidance on them was required and this was proposed to be in the BPSG work programme.

At the BPSG meeting, of particular interest to New Zealand was the first draft of a guidance document on stability data requirements for microbial pesticides. This is a problematic area for New Zealand and other regulators, so the development of the first draft is welcome.

Joint Review Meeting

This meeting discussed the current state and future direction of Joint Reviews (in these reviews Regulators from different countries work together on the same application for registration of a pesticide containing a new active ingredient).

The meeting reconfirmed that Joint Reviews are important and recognised that different regulators and pesticide manufacturers have different drivers for undertaking them, including:

- faster access to new chemistry
- harmonised end points, such as residue definitions
- predictability and efficiency, and
- timeline gains.

WGP

New Zealand chairs the Expert Group on Product Chemistry and provided an update on its activities to produce a guidance document.

There was a discussion on what regulators would require to support registration of double stranded RNA-based pesticides. This is new technology and has the potential to provide very targeted control of pests (without impacting on non-target animals), but manufacturers are being cautious about providing information on manufacture and delivery systems for

commercially sensitive reasons. This will be an ongoing discussion.

The next Registration Steering Group and Risk Reduction Steering Group meetings along with a one-day seminar will be held in Brisbane, Australia, in the first week of December 2015.

EGEPPD

A demonstration of the Global Harmonised Submission Transport Standard (GHSTS) Viewer was given. This Viewer allows a regulator to review the data package submitted by an applicant in a user friendly format. It only requires a web-based browser to view it.

Applicants will be required to compile their data packages using software and this is still to be designed. Once designed New Zealand will be in a better place to understand the implications for our registrants.

New Zealand noted that both Australian and New Zealand regulators also manage veterinary medicines and similar IT developments in this area need to be compatible with those in the pesticides area.

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

Adverse Events with Swedes

We have been working with industry since November 2014 to identify the cause of deaths of cattle in Southland after transitioning to swedes. Post-mortem analysis indicates the most likely cause of the deaths is high concentrations of glucosinolates (GSLs), naturally occurring toxins that can be toxic to cattle at high concentrations. Preliminary analysis of survey information indicates that there are several contributing factors rather than a single cause.

A survey identified that the increase in adverse health effects is likely due to changes in feeding practices, changes to climatic conditions that affected crop growth, and exposure of high risk animals (cows at calving) to higher concentrations of GSLs. We are continuing to work with industry on identifying the probable cause(s) and will consider regulatory intervention if findings indicate this is necessary.

We have posted the form [Adverse Event Report: Animal Feeds](#) on the website to facilitate reporting. The form covers a new area of AE reporting and we consider it an initial draft. Comments on the form are welcome.