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News & Views

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Cost recovery update

From 14 November 2018 to 16 January 2019, MPI consulted on eleven proposals for changes to cost recovery in the food system. (The 'food system' refers to services provided under the Animal Products Act 1999, Agricultural Compounds and Veterinary Medicines Act 1997, Food Act 2014, and Wine Act 2003.)

The Discussion Document covers seven proposals to change how much MPI recovers and four proposals to simplify, improve transparency and make charges more equitable. MPI sent 28,000 emails to fee payers seeking feedback on the document and met with nine industry organisations, including Agcarm and ARPPA.

Proposals

The first proposal, which applies to all four of the food system Acts listed above, is to reduce the rates of 127 charges that are based on a common hourly rate. The current hourly rate of $155 would decrease to $135 (GST exclusive). For 51 of these charges, variable rates would be replaced with a fixed charge because the time taken to perform these services is highly standardised.

Proposals that relate to the ACVM Act include:

- decreasing fees for ACVM product pre-screening and registration
- simplifying the process for amending ACVM levy rates
- clarifying ACVM levy provisions.

Proposals that relate to the Animal Products Act include:

- introducing cost recovery for approvals of manufacturers or suppliers of Official Devices
- aligning Official Assurance (animal materials and non-live animals) fees
- aligning charges for Official Assurances for live animals or germplasm
- updating unit charges for export of live animals and animal germplasm
- updating circuit verification charges
- modifying dairy levies for small processors and exporters
- minor updating to cost recovery provisions.

(For details, see Discussion Document.)

Cabinet will consider policy changes this month and, if approved, draft regulations will be considered through April and May. MPI expects to be able to confirm any changes in late May. **Any changes will take effect from 1 July 2019.**

New Zealand Food Safety
Haumaru Kai Aotearoa

Ministry for Primary Industries
Manatū Ahu Matua

On the road again... ACVM February workshop

ACVM workshop team (from left): Karen Booth, Shaleen Narayan, Teresa Robinson, Awilda Baoumgren, Warren Hughes, Jenni Doyle, Alfredo Caicedo, and Bruce Nalder (behind the camera: Maree Zinzley)

The annual February ACVM workshop was held at Jet Park in Auckland. With 90 participants, numbers were similar to last year.

Presentations covered a variety of topics including:

- updates on staff, the work programme, performance, projects and priorities
- proposed changes to cost recovery (see article on page 1)
- common problems with applications
- ACVM reassessments, and
- manufacturing expectations.

Copies of the full ACVM presentations can be found on the ACVM Resources page on our website.

EPA update

The ACVM presentations in the morning were followed by presentations from the Environmental Protection Authority (EPA) covering their reassessment process and priorities for the coming year (i.e. paraquat and the synthetic pyrethroids). We would like to take this opportunity to express our thanks again to the EPA for taking the time to be involved in our workshop.

Break-out sessions

The last part of the day involved separate break-out sessions for agricultural chemicals and veterinary medicines. These sessions covered topics of interest to each group and questions raised earlier in the day.

Discussions were useful and identified some aspects for further ACVM consideration. Some comments also reinforced the need for good communication between regulators, registrants and industry groups to ensure that all parties understand expectations and that approaches align.

From our perspective the day was a big success, once again providing a valuable opportunity to connect with registrants, consultants and data assessors face-to-face. Feedback has also been generally positive.

Workshop in Wellington

As indicated during the workshop, this year is the last year we will run the February workshop in Auckland. The main ACVM workshop will move to Wellington during July (either immediately before or after the annual Agcarm conference). This will allow more ACVM staff to be involved and, hopefully, avoid the typical disruptions experienced early in the year, which complicate organising a workshop during this period.

Review of Vertebrate Toxic Agents (VTAs)

The ACVM team is currently undertaking a review of the registration conditions and label requirements that apply to VTAs. The first products to be considered in this process are those containing Brodifacoum. The process for the review will be outlined in the June *News and Views* and will be discussed at the July 2019 Wellington Workshop.

FYI

Chemistry and Manufacturing: Agricultural Chemicals

A draft of a new guidance document for Chemistry and Manufacturing of Agricultural Chemicals is underway. The document has increased focus on harmonising our requirements with those of the Australian Pesticides and Veterinary Medicines Authority (APVMA). Once internal consultation is completed, a draft will be circulated to stakeholders for feedback.

Chemistry and Manufacturing: Veterinary Medicines

The final draft of the Veterinary Medicine Chemistry and Manufacturing (Chemical) Guidance is being completed after reviewing the feedback received on the last draft. We had feedback from 15 registrants and a group submission from ARPPA, which have allowed us to refine the previous draft and provide more examples and guidance where needed. When completed, the final draft will be sent to registrants with a document summarising the differences between the current standard and the new guidance, as well as a draft product data sheet (PDS) reflecting the new guidance. These documents will be sent out for comment in the next few weeks. The ACVM July workshop in Wellington will provide an opportunity to discuss the changes.

Once the Chemical Veterinary Medicine guidance has been completed, work will begin on the Biological Veterinary Medicine guidance.

Labelling guides

- Revision of the veterinary medicine labelling guide is nearly complete. It is in its final round of comments from the veterinary medicine technical team and is likely to be published in April. Changes are being made to clarify requirements, and to correct an error ('of' should be 'for') in the mandatory label statement regarding residues: "It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels of Agricultural Compounds." This should read: "It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds."

- The agricultural chemical labelling guide revision has begun. Collating comments from the agricultural chemical technical team is the first step.

Antibiotic reassessments

As registrants will be aware, we are currently in the process of reviewing all registrations for registered veterinary and horticultural antibiotics as part of work being conducted under the Antimicrobial Resistance (AMR) National Action Plan.

Timeframe: first tranche
When confirming that the first tranche of antibiotics (that is, veterinary products containing macrolide, penicillin, and later-generation cephalosporin active ingredients) would progress to formal reassessment, the registrants of the affected products were asked to provide an estimate of the time they would need to submit applications. The responses indicated a variable time frame -- the longest estimate was four years. The majority of registrants, however, stated they would be able to submit applications at or before July 2019 if they had additional guidance as to what the submission needed to contain.

The feedback received has led us to reconsider our approach to this reassessment to ensure work progresses in a timely manner without negatively impacting registrants.

ACVM review
The reassessment will now be pre-empted by an ACVM review that will first evaluate all available information on AMR risk and current good agricultural practice for each compound and antibiotic family relative to their use as veterinary medicines. The outcome of this evaluation will then inform a review of all approved use patterns, label claims, other label information, MRLs and withholding periods for each affected product to determine whether the current product-specific approvals and controls are still fit for purpose.

While this is not our preferred approach, it will provide more specific guidance for each product and registrant, and limit the amount of general information required for each application. This approach will also provide registrants with an opportunity to amend the product-specific proposals as they consider appropriate, supported by confidential information and data they may hold.

The ACVM antibiotic compound and family review has already commenced, with the completion of both the overall and product-specific reviews by March/April 2019. When completed, the outcomes of the overall evaluation will be made available to all registrants. They will also receive registrant-specific lists of products and proposed changes to align registrations with the outcomes of the review.

Registrants will then be expected to submit variation applications on all affected products by 1 July 2019 to either progress changes as proposed or provide information and data to support an alternative proposal relative to that individual product. Public notification will follow, with the assessment commencing when the public notification period closes. The time to completion of individual product assessments will be dependent on what and how much additional information the registrants choose to provide for evaluation at the time of submission.

Second tranche
The second tranche of antibiotic reassessments will be proposed before the end of the year.

Introducing Barry Meade, Auditor (Regulatory Programmes) ACVM Programmes & Appraisals

Barry (pictured here at Castlepoint) has more than 15 years' experience in medical devices, pharmaceutical and biotechnology sectors.

"I received my MSc. Industrial Pharmaceutical Science from the Royal College of Surgeons in Ireland and am a graduate of Limerick Institute of Technology with BSc (Hons) in Chemical Instrumentation and Analytical Methods. I founded Pharmed Bioserve Limited in Limerick City, Ireland, specialising in supplying, hiring and validating of medical devices. Before that, I was an independent contractor in various companies in Ireland and other parts of Europe.

Prior to joining MPI, I was a Validation Engineer in Auckland, and a Quality Engineer with ManukaMed Limited Partnership (Masterton). I am dedicated and committed to working diligently to meet the highest standards of product safety and quality. I am of Irish descent and a proud Munster Rugby supporter. Outside of work I enjoy recreational sporting activities involving proficiency tests of accuracy, precision and speed in shooting, and trying to get better at cooking."

Introducing... our new Approvals Operations Advisers

Phillippa Skeet

"I have lived in Wellington since my family's move from England when I was three. In 2017 I graduated from Victoria University of Wellington with a Bachelor of Commerce, majoring in Information Systems and Management.

In my last year of University I worked in a full-time role at Datacom as a Schemes Administrator for the Government Superannuation Fund. I started with MPI in January 2019. My main role here is approvals under the ACVM Act, but I am also learning and training in other parts of the team with the Animal Products Act, Food Importers, Warrants, Appointments and more.

In my spare time I enjoy nature and big walks, the gym, reading, drawing, and spending time with family and friends. I look forward to working with and meeting you all in due course."

Jillian Edwards

"I started with MPI in February in the Approvals Operations team. I have initially begun working under the ACVM Act. I look forward to expanding my skill set to also include the Food Act.

I studied Food Science at the University of Otago, and Finance and Economics at Victoria University of Wellington. After graduating with my Bachelors degree in Science, I worked in microbiology for Heinz Watties. After a few years in this role I left New Zealand to explore the world. I travelled for five years and lived in Canada, Australia and England, before returning home with a new found appreciation for Aotearoa.

In my spare time I like to go on walks with my two dogs, read, ski and cook."

Grace Aislabie

"I joined Approvals in January and have been answering queries on ACVM (along with Food Act, Animal Products Act, and Wine Act) ever since. In addition, I process Special Circumstance and Class Determination applications.

I'm from Tauranga, where I was working with Bidfood managing accounts until this year. I have a Bachelor of Arts degree, majoring in English. And in my spare time, I am a photographer who has exhibited in a few galleries and had my own solo show."

Jed Aubrey

"After graduating from Waikato University with a degree in Business Management, majoring in Strategic Management and Finance, I decided it was time to move out of the Tron (Hamilton) and I found myself a job in Wellington.

I have been at MPI now since July 2018 and I work across a multitude of Acts -- ACVM, Animal Products Act, Food Act and Wine Act. My role varies with managing my client base and processing/assessing applications and responding to queries around these four Acts.

During my time out of work I am a keen sprint kayaker and spend my weekends and some weekdays training in Porirua. I also enjoy skateboard, GOT and exploring more of Wellington as my new home."

Time Waiver Update

If additional information is required before technical appraisal can be completed, the ACVM team will request a response within five working days from you to either:

- supply the additional information requested, or
- advise us if you are unable to supply the information within the five working day timeframe.

As the application is unable to progress at this time, a time waiver stopping the clock will be applied to the statutory time period from the date request for additional information was sent. The clock will remain stopped until the information is supplied or the matter is resolved. If you do not wish a time waiver to be applied, you will need to inform us in writing. Note that without a time waiver the application will continue to be processed without the requested information, which could lead to the application being refused.

Four other situations (if applicable) can also delay progress:

1. Environmental Protection Authority (EPA)
A decision on the application cannot be made until EPA provides an approval on the product under the HSNO Act.

2. Ministry of Health (MoH)
A decision on an application containing medicines under the Medicines Act cannot be made until MoH provides consent.

3. MPI Biosecurity
A decision on the application cannot be made until MPI Biosecurity provides biosecurity approval.

4. Maximum residue level (MRL) pending promulgation
A decision on the application cannot be made until an MRL is promulgated under the Food Act.

Food & Live Animal Assurance Team Update

Brands and Security Devices

The Food and Live Animal Assurance team has reviewed the requirements around Brands and Security Devices (e.g. container seals) for export of Animal Products, with the view to issue an updated Notice to consolidate and clarify requirements.

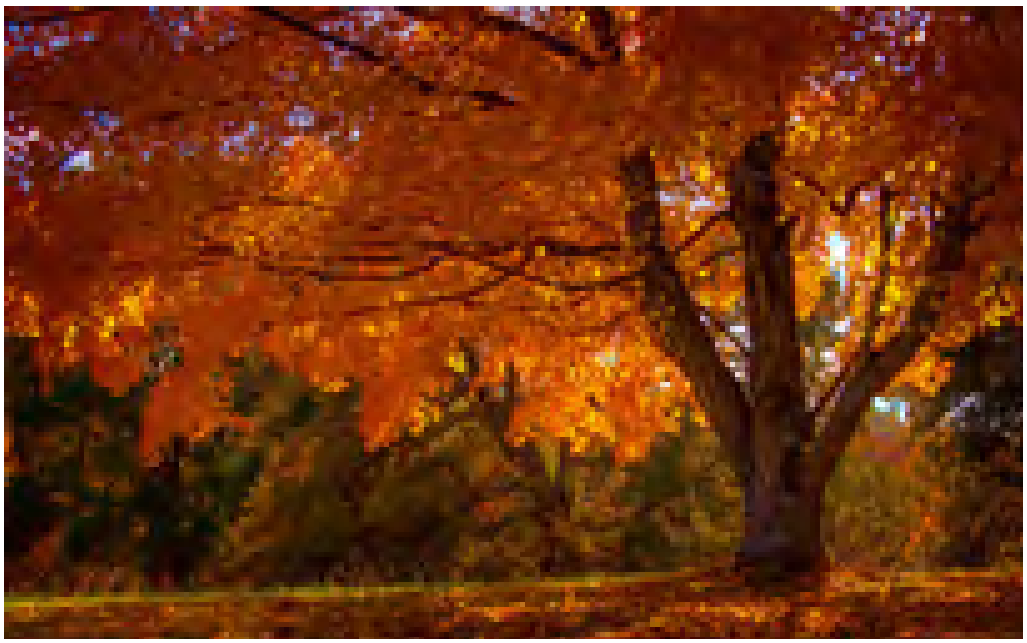
A paper proposing options to address any concerns has been circulated via industry bodies for initial feedback. MPI anticipates that public consultation on a draft Notice will take place later this year.

Dairy Verifier's Workshop

A Verifier calibration workshop for Animal Products Act dairy verifiers was held in MPI's Auckland office on 26 February.

Two of the key topics for discussions were:

- processes for China listing of export dairy premises, and
- identification and early management of poor performing RMP (risk management programme) premises.



Happy Autumn!