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ACVM News & Views

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ACVM Registration Review

The Registration Review Project is in the design phase, with some initiatives now near implementation.

The Business Technology and Information Services (BT&IS) review of current IT applications against ACVM needs has been completed. The solution options and costings component of the project is well underway, and will inform the senior management team regarding possible BT solutions and options going forward.

In parallel with the BT&IS work, the following process initiatives are being developed and tested internally.

Alternate pathways for a range of variation applications

The desire is to create regulatory effort to risk proportionate pathways for the management of these applications. This has led to work on how product and manufacturing specifications are defined and captured as part of the registration process.

We are proposing to strengthen the product identity characteristics, and manufacturing and quality characteristics that define a trade name product and are approved as part of the registration approval documentation. Better information approved in the product and manufacturing specifications will act as a more effective point of reference when variations are made, and for purposes of auditing and compliance.

Importantly, this will also inform development of guidance to applicants and pathways for the management of C1 (formulation), C2 (manufacturing) and C3 (packaging/shelf life) applications.

Transparency

Subsequent to the review of the information provided in the Delegate's Decision, we are looking at cost effective ways to improve transparency around applications received as well as applications approved. The intent is to provide more information for interested and affected parties while preserving protection of commercially sensitive information.

Registration renewal process

Review of the registration renewal process has been completed, and we propose to change the default registration expiry period from 3 years to 5 years (see page 2).

Data protection

A side project has been initiated with MPI BT&IS in preparation for the new data protection provisions (see page 3). The purpose is to have systems in place, and tested, prior to the new provisions coming into force.

Annual Fees Reminder

Annual fees, which are not the same as product registrations, were due by 1 October.

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

Registration Renewal Revisited

The registration review project (see page 1) is focused on maximising benefits to the registrant and eliminating pressure points in the existing process while optimising internal efficiency and effectiveness. In order to free up capacity and reduce administrative burden on both registrants and ACVM assessors, the first of several changes to the registration process has been finalised.

Current renewal policy

The requirements for registrants to submit a renewal every 3 years was put in place for the purposes of managing product drift over time. While MPI still needs assurances that product registrations are maintained to ensure compliance, 6 years of the 3-year renewal period and an average of 2 cycles of renewals per product has shown that the current policy is creating an unnecessary burden on industry and MPI.

The current process requires a renewal application, including an updated product data sheet (PDS) and label, to enable us to confirm that no changes have occurred. Once confirmed, registration certificates are re-issued with a revised expiration date.

The registration review has identified that a large proportion of these renewal applications are submitted either with applications to vary the registration, or changes to the PDS and/or label that require evaluation.

New process for renewal

Registration renewal will be limited solely to renewing the time frame for which the registration is valid. Any change to the registration itself (e.g. changes to the product, manufacture, or labelling of the product) will require a variation application prior to renewal.

On confirmation that there have been no changes to the product registration, the expiration period will be extended. Registrations will require renewal every 5 years from the date of registration or the date of the previous renewal or variation approval.

If in that 5 year period, there have been no variations made to the registration a renewal application must be made. This application will include:

1. the current PDS
2. the current marketed label
3. completed registration renewal application form, and
4. a declaration that no changes have occurred since the last approval date.

The application will be processed and a revised certificate with a 5 year expiry will be issued, along with approval of the submitted PDS and label.

key points

Registration expiry period will be 5 years.

Registrations will be renewed for 5 years from approval of each variation or renewal application.

Simultaneous renewal and variation applications will no longer be accepted.

There will be greater focus on post-authorisation monitoring.

Variations

When we receive an application for renewal, if we identify any variations to the current product registration we will advise the registrant to make an application for a variation. The renewal application will not proceed.

If an applicant identifies a change in their product, PDS or label at the time of renewal, then a variation application will be required instead of a renewal. This variation must also include the current market label, regardless of whether or not label changes are requested, to ensure the most recent label is always on file.

Similarly, if the variation is limited to a change in the label content, a PDS must be provided whether or not there are changes to its contents. The appropriate variation application form should be used.

If a variation has been submitted within the 5 year period, the registration will be granted for a further 5 years when that variation is approved. A new certificate will be issued with a revised expiration date, along with approval of the submitted PDS and label. A renewal application will not be required until that 5 year period expires.

Product drift

Under the registration review, post authorisation activities such as pharmacovigilance and monitoring programmes will be enhanced to ensure that any product drift as a result of the 5 year extension will be identified and addressed.

Commencement

The commencement date for the new process will be advised to registrants once the implementation plan has been finalised.

FYI

Research, Testing and Teaching Operating Plans

The first of these RTT Operating Plans are now starting to come up for renewal. To ensure that the RTT OP is identifying and managing risks, when you apply for a renewal please provide a master list of all the trials you have undertaken as part of your Operating Plan. During the renewal assessment we will select one trial and request the associated documentation for review.

Listed data assessor workshop

The next data assessor workshop is proposed for March 2017. We plan to cover general assessment expectations and requirements, and updated information requirements for chemistry and manufacturing. More information will be available early next year.

Data protection

The ACVM Amendment Bill 2015 (2016 54-2) has passed its second reading. This will be followed by the Committee of Whole House debate on it prior to its third reading before being enacted. Information about the Bill is available on the New Zealand Parliament website.

Labels and GHS

MPI does not require labels that are amended to meet globally harmonised system (GHS) requirements to be submitted to us for approval prior to either the next label change (if ACVM content is changed) or the date of registration renewal.

We are not concerned about receiving updated labels unless ACVM content is impacted, and we are happy to discuss with registrants on a case by case basis if issues resulting from GHS changes arise.

MRLs

Consultation on the latest maximum residue level (MRL) round has recently completed. MPI received 6 submissions and we are currently considering these submissions.

EU MUTUAL RECOGNITION AGREEMENT (MRA) ACVM INDUSTRY SURVEY

MPI's ACVM Group recently surveyed New Zealand veterinary medicine manufacturers and registrants with New Zealand contract manufacturers. Thank you to all who participated in the survey. The responses are extremely valuable as we work through the first stages of our Good Manufacturing Practice (GMP) review. We have summarised some of the responses below and would like to take the opportunity to reiterate what the EU MRA is and how it works. We have also addressed two important themes that will help clarify the scope of the EU MRA.

Executive summary

The response rate of 42% was successful with the responses valued and insightful. A range of large and small companies were represented, of which 49% provide product to both the domestic and international markets.

Is the EU MRA important for your business?

74% of respondents consider the EU MRA important for their business, 13% do not think it is important, and 13% do not know.

Is the EU MRA important for the veterinary medicine industry and New Zealand as a whole?

95% of respondents consider the EU MRA important for the veterinary medicine industry and New Zealand as a whole (2.5% did not know and 2.5% believed it was not important).

Impact on business if no EU MRA

60% of respondents indicated that their business would be impacted if there was no EU MRA. Responses included that there would be significant expense from audits required by international authorities, it would make it harder for small companies to access overseas markets, and it would take additional time and cause delays in registering products overseas.

Awareness of EU MRA

74% of respondents were familiar with/had heard of the EU MRA. Comments made by a small number of respondents indicated that there still might be some confusion about the MRA, what it involves, and what it is intended to do. We have put together a short summary of the current EU MRA to clarify its purpose and scope, and how it works.

Purpose of the EU MRA

The EU MRA provides assurance to our trading partners that a New Zealand veterinary medicine manufacturer complies with equivalent international standards and manages the risks associated with manufacturing.

New Zealand exporters can use MPI-issued GMP certificates to support market authorisation (registration) applications in Europe without having a GMP audit by an EU regulatory authority. The MRA also allows products to be exported to the EU without additional import batch testing, thereby reducing lead time, costs, and the need for additional laboratory animals.

The MRA is not an agreement to enable mutual acceptance of registrations and data packages. The EU has specific data and information requirements to meet their needs, as does New Zealand. If a product is registered in the EU, it does not necessarily mean that the data meets requirements for New Zealand registration. Additional New Zealand-relevant data may be required to support a New Zealand registration.

Current GMP Programme

We would like to address the following themes to clarify some responses from the survey.

Accepting GMP certificates from a wider range of regulatory authorities internationally

MPI currently recognises a wide range of GMP certifications from regulatory authorities that are PIC/S members and are part of the EU MRA, as well as those from the APVMA in Australia, with whom we have a separate agreement. Accepting certification from regulatory authorities with whom we have no formal agreement or are

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Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

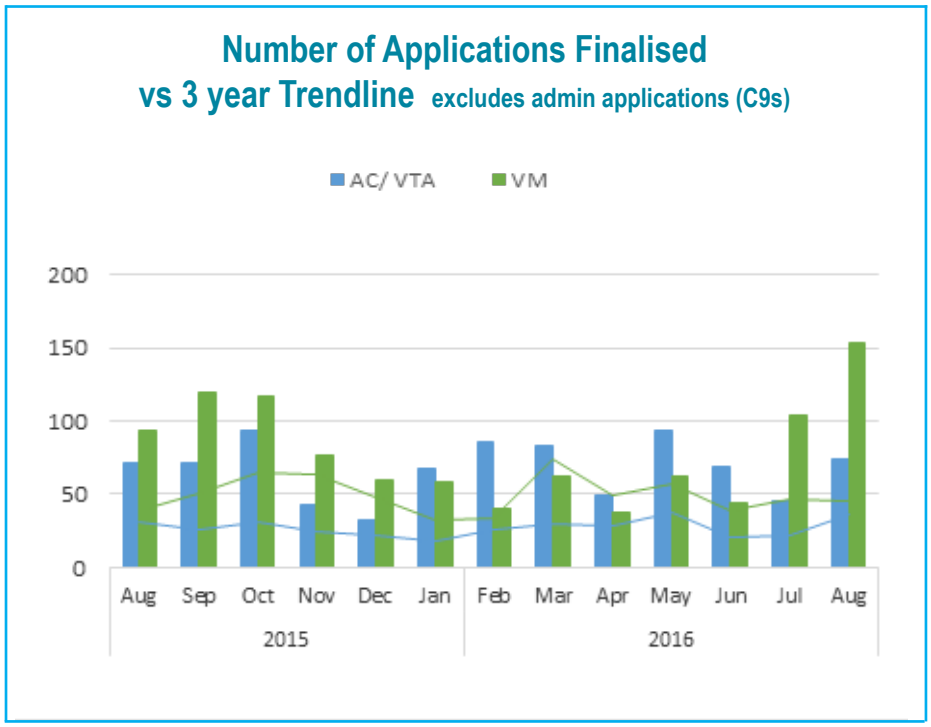
Warren Hughes and Bill Jolly will attend the 23rd session of CCRVDF in Houston, USA, from 16-21 October 2016.

Agenda items of interest include New Zealand's proposal for Codex MRLs for monepantel on cattle, the risk management recommendation for gentian violet, and carryover of veterinary drugs in feeds.

applications update

Although application numbers have been lower this year, the application queue has been relatively constant (approximately 200 at any point in time). Due to the consistent backlog over the last 12 months, numbers of applications being finalised are well above the 3 year average (see graph).

For the past 2 months, the number of applications processed within the regulatory timeframe of 40 working days has risen from 24% to 42%. Applications completed within 41-79 days have fallen from 52% to 35%. About 20% of applications have taken longer than 80 working days. This is expected to improve as new processes from the registration review project are adopted.



MRA survey concluded

not in these programmes poses risks to New Zealand because their GMP programmes have not been evaluated as being at the required standard.

Allowing products to be imported from a manufacturer who may not meet an appropriate level of GMP could pose risks to New Zealand biosecurity, animal welfare, food safety, and trade. In line with international authorities, MPI would need to conduct an inspection of the overseas facility if appropriate GMP certification is not provided.

If MPI is requested to recognise another agency's GMP certification, consideration can be given to forming an agreement with that authority. This would involve joint inspections, plus a full assessment of GMP programmes of both authorities. If several manufacturers are from the same country, this approach may be cost effective. If, however, only one veterinary medicine is sourced from that country (or if all other manufacturers have provided certification from a recognised agency), then in most cases it would be more cost effective for MPI to audit the sole manufacturer to ensure the relevant risks are managed.

The value of exporting to European countries under the EU MRA

Ensuring that MPI's GMP Programme continues to manage the risks associated with the manufacture of veterinary medicines while maintaining compliance with EU requirements does carry a cost.

However, we need to ensure our system is robust and fit for purpose, and that our auditors have continuous training and upskilling to be on top of industry developments and scientific advances. This would be expected whether we had the EU MRA or not. If EU authorities were to discontinue recognising MPI-ssued GMP certificates, then they would need to conduct their own inspections of New Zealand manufacturers.

Next steps

The findings from the survey will be used to assist MPI in preparing advice for the initial stage of our GMP review.

The first initiative in the review has been the amendment of our GMP Certificate. The new format better documents the scope of activities carried out at an approved manufacturer, and more closely aligns with internationally recognised formats. The new version will be adopted following the next inspection and successful audit closure at each manufacturer.

Send questions about the survey or GMP review to: ACVM.ManufacturingandAssurance@mpi.govt.nz

STAFF-STAFF-STAFF

We are pleased to introduce our three new advisers in the Approvals Operations team. Philippa is our new 'front line' phone contact. Gina and Emma deal with applications.

Philippa Vruink

"A little about me: Born and bred here in Wellington, my passion for animals was clear from a young age. After exploring various other career options it was this passion that took me to Palmerston North to study Veterinary Nursing at Massey University. Upon completing my studies I began my career in a small animal practice where I took a special interest in animal behavior and client relations. After a number of years in that line of work it was time for a new challenge, so I jumped at the opportunity to apply for a position within MPI.

In my spare time I enjoy being active and spending time outdoors."

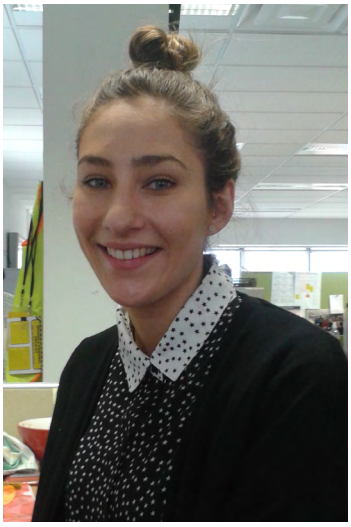
Gina Armstrong

"I was born in Wellington and went to school in the Hutt Valley. Not knowing what to do with myself after school, I somehow ended up at Victoria University studying Cell and Molecular Bioscience and I recently completed my Master's Degree in the same discipline, with a reproductive biology focus.

I joined MPI in May of this year -- first as the adviser for Statutory Appointments and then I moved into an Approvals Operations adviser role, with a focus on ACVM.

In my spare time I enjoy salsa dancing and watching horror movies."

Emma Forbes



"I grew up on a sheep and beef farm near Oamaru, and in 2015 I graduated from the University of Otago with a Bachelor of Applied Science in Consumer Food Science. During my degree I became more interested in the food safety and quality assurance side of things and thought MPI would be a great place to begin my career in this area.

I've been in the Approvals Operations team for two months now, and am enjoying the diversity of work from RMPs, Exporters and Food Control Plans -- no day is the same. I am looking forward to my upcoming training for ACVM applications."

fertilisers

To progress the Fertiliser Notice and cover the scope of products, MPI needs to amend the definition of fertiliser stated in the ACVM (Exemptions and Prohibited Substances) Regulations 2011, as it is not appropriate to develop definitions under the Fertiliser Notice. This amendment will be combined with other changes required to the Regulations. Until we are in position to consult on changes to the Regulations, work on the Fertiliser Notice will be limited.