Ministry for Primary Industries
Manatū Ahu Matua

ACVM Workshop
25 February 2016

www.mpi.govt.nz

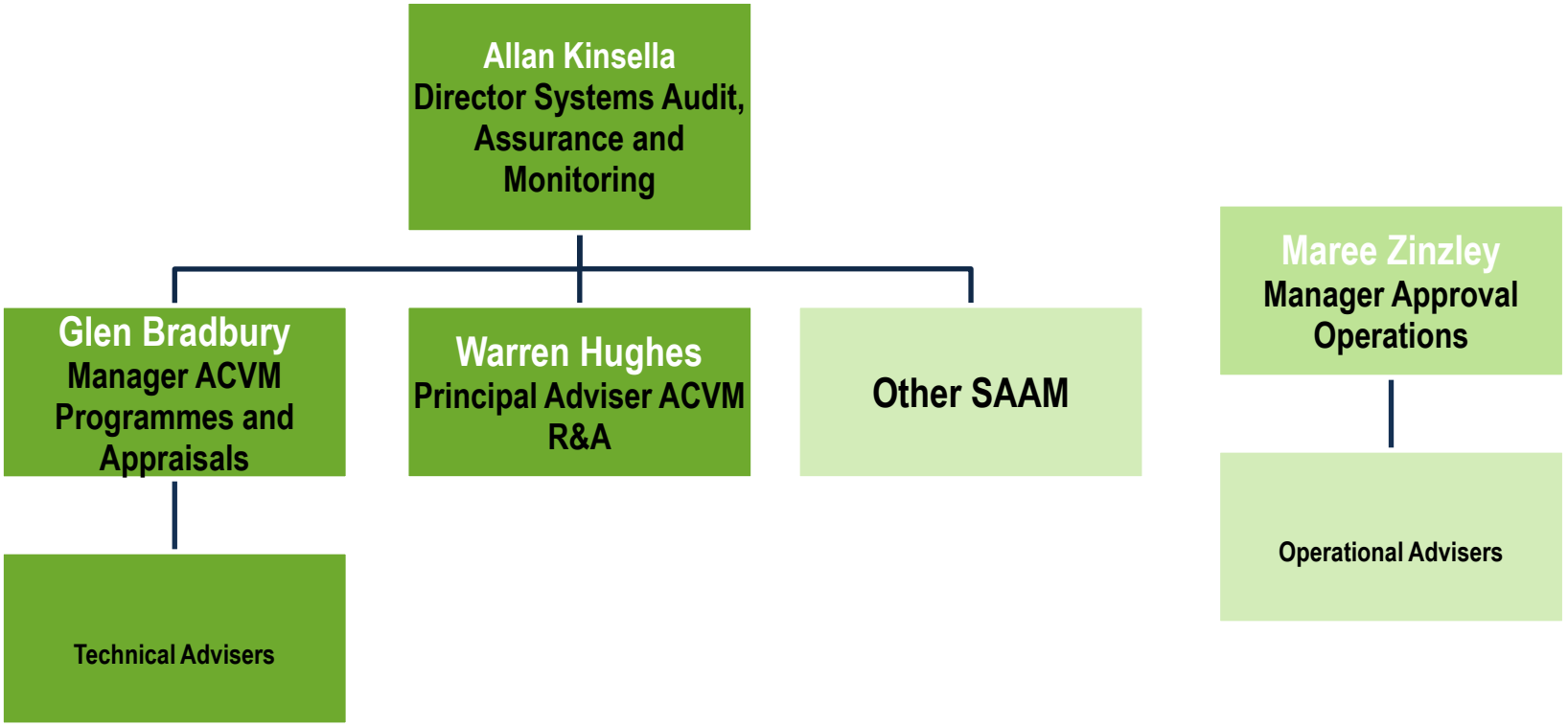
Presentations

Ministry for Primary Industries
Manatū Ahu Matua

ACVM Group Overview

www.mpi.govt.nz

SAAM Directorate



Agricultural Compounds Group

Glen Bradbury
Manager ACVM A&P

Warren Hughes
Principal Adviser ACVM R&A

Maree Zinzley
Manager Operations

Agricultural Chemicals and VTAs Assessors
Bruce Nalder
Rafael Barbieri
Sarah Lester
Wayne Severn
Joy O'Connor

Veterinary Medicines Assessors
Awilda Baoumgren
Alfredo Caicedo
Jennifer Doyle
Justin Mercier

Regulatory Programmes
Holly Jeboult-Jones
Francie Olliver

Teresa Robinson
Mark Henderson
Vu Mpofu
Shaleen Narayan
Gabi Hidvege
Andrew Barrowclough
Josh Leen

Contractors

Paul Spencer (Chem)
Jennifer Moran (Vet)
Meg Moffat (Vet)
Richard McKinley (Vet)
Chris Boland (Projects)
Jeanne Boland (Systems)
Karen Booth (Review)
Pip Cameron (Analysis)
Sarah De Barr (Procedures)

Our Role

To protect New Zealand's primary production sector through

- Assessment and Risk Mitigation
- Audit and Compliance Monitoring
- Responding to the needs of the MPI and the primary sector by providing leadership and specialist technical advice
- Leading the development and implementation of regulation to facilitate the administration of the Act

How we do it

- Registration of Agricultural Compounds (e.g. agricultural chemicals, veterinary medicines)
- Policy and standards (including input into international (VICH, OECD, Codex)
- Audit/assessment and certification
- Border monitoring and clearance
- Monitoring, review and response activities
- Ministerial communications and support
- Setting of limits and specifications (e.g.MRLs)

Our Connections

ACVM Group connects with

- Internal
  - Market Assurance, Biosecurity, Animal Products, Animal Welfare, Food, Chemical and Microbiological Assurances, Compliance, Policy, Legal, Systems Audit, Incursion etc.
- External
  - Manufacturers, Industry Associations e.g. Agcarm, Feeds, VCNZ & NZVA
  - Government Departments – MfE, DoC, MFAT, MBIE, Customs, MoH, EPA and other international agencies

Priorities for 2015-16

- Registration Review
- GMP Review
- Regulation of Fertilisers
- Animal Feeds Review
- Antimicrobial Resistance Direction Statement
- Data Protection Implementation
- International Harmonisation (Registration by Reference, Global Joint Review)
- Reassessments (Bismuth, Nonylphenol Ethoxylates, Carbadox, Dimetridazole, Anticoagulants, Clenbuterol, Calcium injectable products, Amitraz, Alphachorolose, and Key Strepto (Review of Controls)

Registration Review

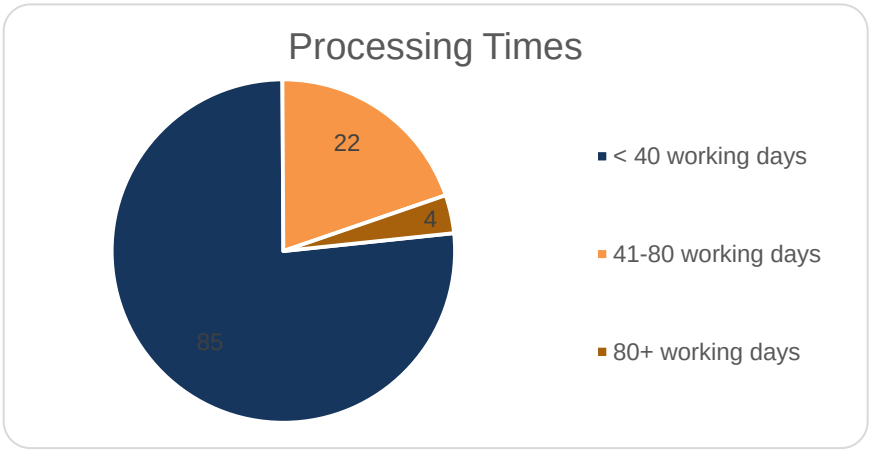
- Remove unnecessary complexity
- Improved transparency, robustness and accountability
- Better communication during process
- Streamline (reduce multiple handling)
- Minor variation assessment quicker
- Harmonisation (Labels, Assessment, systems)

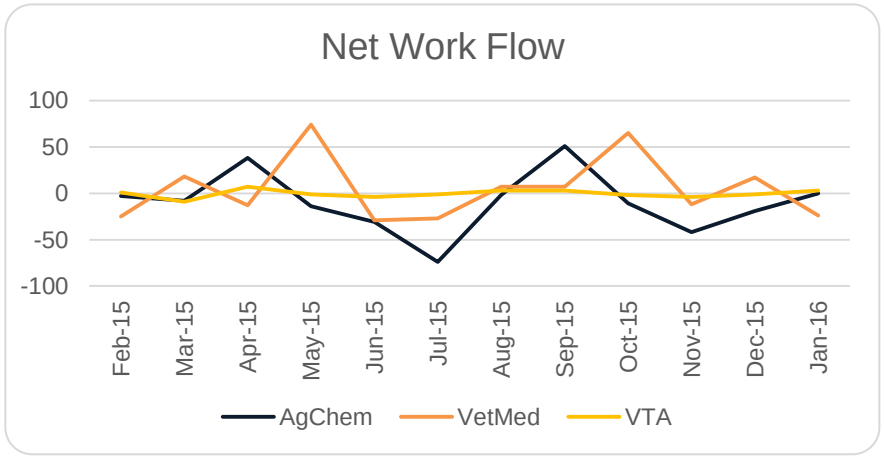
Resourcing

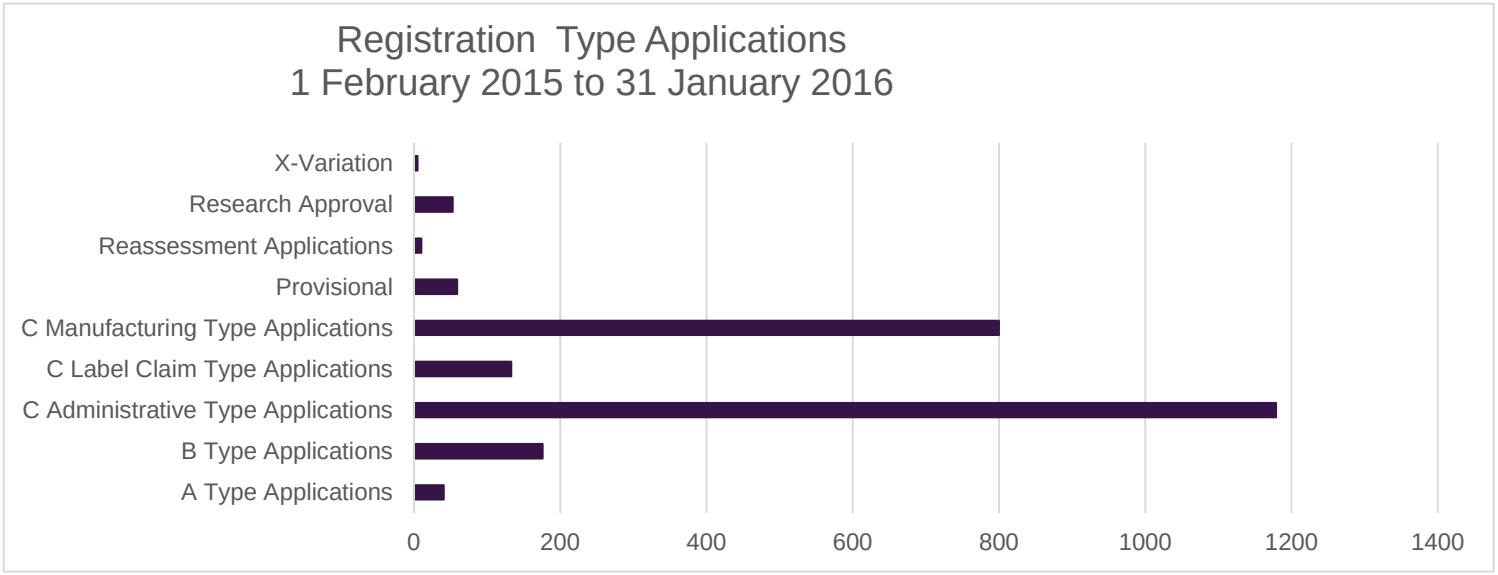
- Senior Veterinary Medicine Assessor
- Contractors for application backlog
- One vacancy
- Alignment to review outcomes – Possible changes

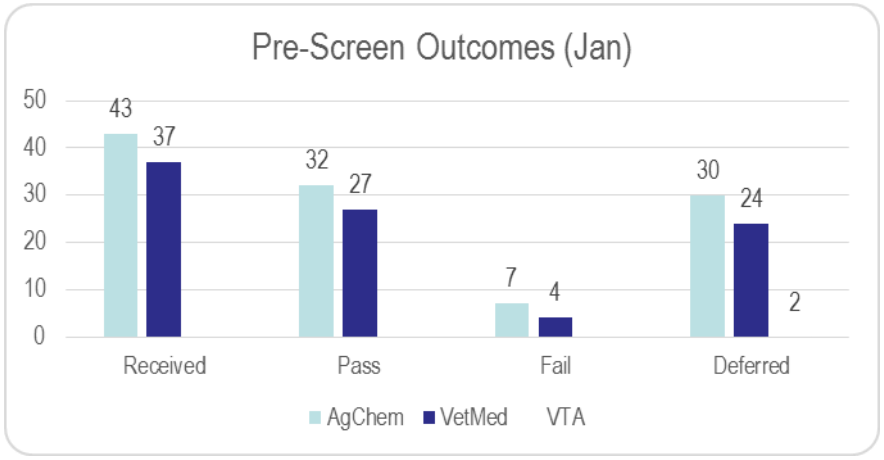
Applications

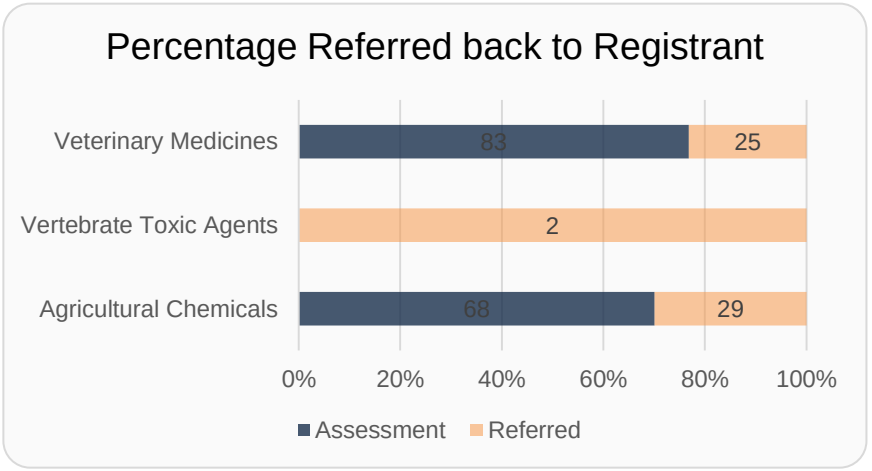
- 1778 applications processed (992/786)
- 77% completed within timeframe (66%)
- 20% within 80 days (VM's <40)
- 41 new products, 133 uses, 800 manufacturing

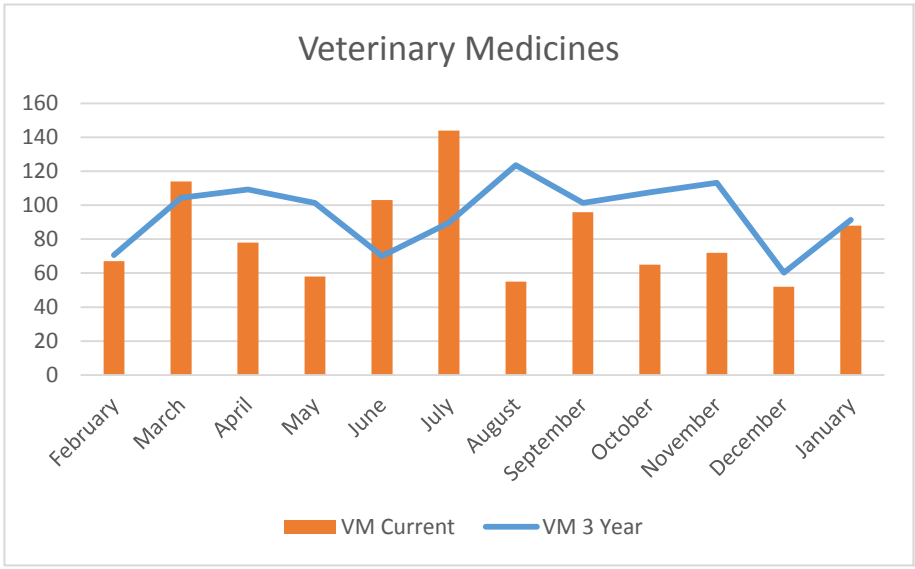

Processing Times
22
4
85
< 40 working days
41-80 working days
80+ working days

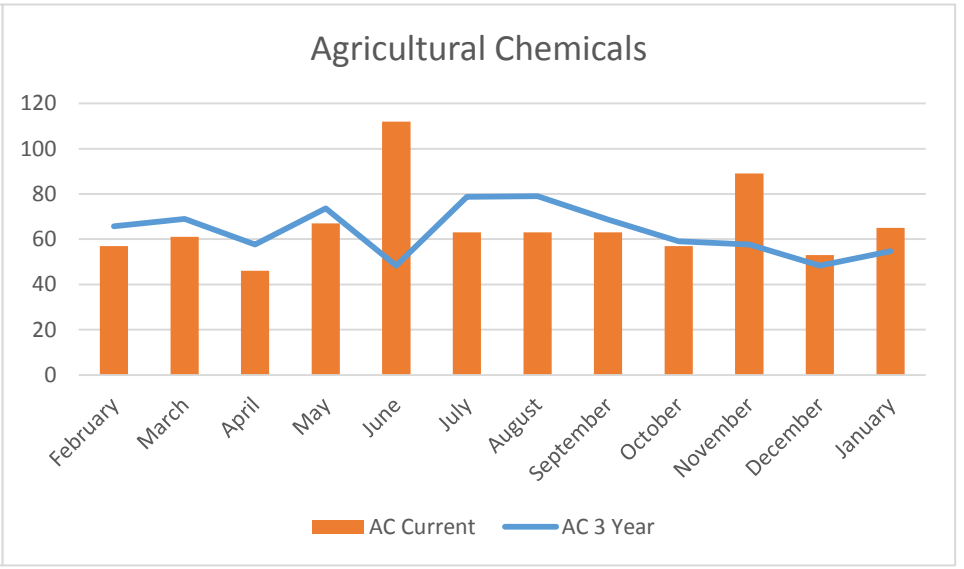

Net Work Flow
100
50
0
-50
-100
Feb-15
Mar-15
Apr-15
May-15
Jun-15
Jul-15
Aug-15
Sep-15
Oct-15
Nov-15
Dec-15
Jan-16
AgChem
VetMed
VTA


Registration Type Applications
1 February 2015 to 31 January 2016
X-Variation
Research Approval
Reassessment Applications
Provisional
C Manufacturing Type Applications
C Label Claim Type Applications
C Administrative Type Applications
B Type Applications
A Type Applications
0
200
400
600
800
1000
1200
1400


Pre-Screen Outcomes (Jan)
50
40
30
20
10
0
43
37
32
27
7
4
30
24
2
Received
Pass
Fail
Deferred
AgChem
VetMed
VTA


Percentage Referred back to Registrant
Veterinary Medicines
Vertebrate Toxic Agents
Agricultural Chemicals
83
25
2
68
29
0%
20%
40%
60%
80%
100%
Assessment
Referred


Veterinary Medicines
160
140
120
100
80
60
40
20
0
February
March
April
May
June
July
August
September
October
November
December
January
VM Current
VM 3 Year


Agricultural Chemicals
120
100
80
60
40
20
0
February
March
April
May
June
July
August
September
October
November
December
January
AC Current
AC 3 Year

Authorisations

- 150 Special Circumstances
- 700 Maintenance Compounds
- 56 GMP Audits
- 9 Operating Plans

Requirements/Guidance Documents

- Recognition of veterinarians – Complete
- Veterinary Operating Instructions – Complete
- MRL Standard amendment – Complete
- Information Requirements for Registration of Microbial Agricultural Chemicals Under Consultation
- Fertiliser regulatory options paper – Reviewing Submissions
- Compliance Policy – Discussion Paper Drafted
- Efficacy of Anthelmintics – Reviewing Submissions

Requirements/Guidance Documents

- Efficacy of Teat Sanitisers – Reviewing Submissions
- Vet Med Chemistry and Manufacturing – First Draft
- Vet Med WHPs – Prioritised for this period
- RVM Seller Requirements – Reviewing Submissions
- Ag Chem Registration Requirements –Final Draft
- Vet med labelling – Held
- Risk Management Framework Revision – Complete

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ACVM Expectations of Registrants

www.mpi.govt.nz

Today's Presentation Will Cover:

1. Technical risk assessment under the ACVM Act
2. What makes a good application?
3. What makes a bad application?
4. Meeting requests and communications
5. Post registration compliance

Technical Risk Assessment Under the ACVM Act

The purpose of the ACVM Act is to:

a) Prevent or manage risks associated with the use of agricultural compounds, being –

   (ia) risks to public health; and

   (i) risks to trade in primary produce; and

   (ii) risks to animal welfare; and

   (iii) risks to agricultural security

b) Ensure that the use of an agricultural compound does not result in breaches of domestic food residue standards

c) Ensure the provision of sufficient consumer information about agricultural compounds.

Technical Risk Assessment Under the ACVM Act

Agricultural compound means

> "any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed."

- The term includes veterinary medicines, agricultural chemicals, and vertebrate toxic agents (VTAs)

Technical Risk Assessment Under the ACVM Act

The purpose of the ACVM Act is to:

a) *Prevent or manage risks associated with the use of agricultural compounds, being –*

- *(ia) risks to public health; and*
- *(i) risks to trade in primary produce; and*
- *(ii) risks to animal welfare; and*
- *(iii) risks to agricultural security:*

→ **Determine whether the associated risks are acceptable**

OR

→ **Determine whether can be acceptable with registration conditions applied**

Technical Risk Assessment Under the ACVM Act

The purpose of the ACVM Act is to:

b) Ensure that the use of an agricultural compound does not result in breaches of domestic food residue standards

→ Set residue limits (MRL and MPL) to meet domestic and international requirements

→ Apply appropriate withholding periods

→ Apply additional controls when needed

Technical Risk Assessment Under the ACVM Act

The purpose of the ACVM Act is to:

c) Ensure the provision of sufficient consumer information about agricultural compounds.

Risk management through label and advertising information to:

→ Ensure all label information accurately reflects findings in the data package

→Require label statements and warnings when applicable

→Ensure user instructions and advice is complete and understandable

Technical Risk Assessment Under the ACVM Act

The key outcome of the risk assessment and product appraisal is:

To determine whether sufficient information has been provided to ensure the benefits of registration always outweigh the risks

What Makes a Good Application?

New Registrations

Application Type		Data Volume				
		Chemistry & Manufacturing	Residue	Efficacy	Safety	Toxicology
A1:	New active ingredient	◆	◆	◆	◆	
A2:	Known active ingredient with a new risk profile	◆	◆	◆	◆	
B1:	Identical to a registered trade name product	Dev	Dev	Dev	Dev	
B2:	Similar to a registered trade name product	◆	◆	⌘	◆	

- All applicable data must be provided for “A”
- Deviations can be considered for “B” but must be justified

What Makes a Good Application?

New Registrations – A1 Applications (Novel active)

- Complete data package including toxicology
  - Deviations are rarely accepted for A1, but can be considered in certain circumstances
- All data assessment non-conformances adequately addressed by the registrant
  - **It is not acceptable to rely solely on the data assessor's discussion of non-conformance**
- Any information available on the product internationally, especially Adverse Event Reports
- Proposed MRLs, if applicable

What Makes a Good Application?

New Registrations – A2 Applications (Known active, new risk profile)

- Complete data package
  - Deviations may be accepted in certain circumstances, but new risk profile must be addressed
- Comparison to other products containing that active is useful, but cannot be sole argument
- All data assessment non-conformances adequately addressed by the registrant
- Any information available on the product internationally, especially Adverse Event Reports
- Proposed MRLs, if applicable

What Makes a Good Application?

New Registrations – B1 Applications (Identical to a currently registered product)

- Must be identical in every way to a currently registered product except for the trade name
  - Registrant
  - All active ingredient and formulated product manufacturers
  - Formulation
  - All packaging, pack sizes, and closures
  - All claims and other label content
- If there are any differences, either the referenced product must be amended first, or the new product must be assessed as a B2

What Makes a Good Application?

New Registrations – B2 Applications (Similar to a currently registered product)

- “Generic” products
- Can argue to cross reference currently registered products provided they are not under data protection
- If under data protection, need consent from registrant
- Equivalence to the registered product must be established to allow complete cross reference

What Makes a Good Application?

New Registrations – B2 Applications (Similar to a currently registered product) Veterinary Medicines

- **Pharmaceutical equivalence –** the new product is capable of having the same pharmacokinetics (dispersion, distribution, bioavailability, biological activity, depletion, elimination)
  - **NOTE: this does not mean just the active ingredient(s)**
- **Therapeutic equivalence –** the new product is capable of achieving the same therapeutic or clinical outcomes
- Both must be addressed → one does not necessarily assure the other!

What Makes a Good Application?

Variation Applications

Application Type		Data Volume				
		Chemistry & Manufacturing	Residue	Efficacy	Safety	Toxicology
C1:	Change in formulation	◆	◆	◆	◆	
C2:	Change in manufacturing process	◆				
C3:	Change in shelf life or packaging	◆				
C4:	Additional target species		◆	◆	◆	
C5:	Additional disease/condition			◆		
C6:	Change of dose regime		◆	◆	◆	
C7:	Change to method of administration		◆	◆	◆	
C8:	Change in withholding period		◆			
C9:	Administrative changes	Explain the changes in a letter				

What Makes a Good Application?

Variation Applications

<u>ALL proposed changes</u> must be justified for both chemistry/stability of the product AND impact on the risk profile

- This may include C9 Administrative changes to the label
  - Example: New safety warnings after NZ or overseas adverse events; amended claims due to overseas product changes

It is not sufficient to state that efficacy, safety and residues are not impacted

- Must at least provide a technical discussion of why they are not impacted

What Makes a Good Application?

Variation Applications (C1, C2)

- For changes to the **formulation or manufacturing process**, this includes:
  - Validation of the new process
  - Data to demonstrate ability to meet approved product specifications
  - Technical discussion of the impact on product stability
  - Technical discussion of the impact on efficacy, safety and residue profiles

What Makes a Good Application?

Variation Applications (C2)

- For changes to the **active ingredient or formulated product specifications**, this includes:
  - Validation of the new process
  - Data to demonstrate ability to meet approved product specifications
  - Technical discussion of the impact on product stability
  - Technical discussion of the impact on efficacy, safety and residue profiles

What Makes a Good Application?

Variation Applications (C2) Veterinary Medicines

- For changes to the **approved active ingredient manufacturer**, this includes:
  - Batch Data (certificate of analysis) from the new AI manufacturing site
    - If specifications are different from other AI manufacturers, compare specifications and demonstrate equivalence
  - Technical discussion of the impact on product stability
  - Technical discussion of the impact on efficacy, safety and residue profiles

What Makes a Good Application?

Variation Applications (C2) Agricultural Chemicals

- For changes to the **approved active ingredient manufacturer**, this includes:
  - Batch Data (certificate of analysis) from the new AI manufacturing site
    - If manufacturer is APVMA approved, no data is required
  - Technical discussion of the impact on product stability
  - Technical discussion of the impact on efficacy, safety and residue profiles

What Makes a Good Application?

Variation Applications (C2)

- For changes to the **approved formulated product manufacturer**, this includes:
  - Validation from the new FP site
  - Production scale batch data or equivalent to demonstrate conformance to the approved specifications
  - Technical discussion of the impact on stability, efficacy, safety and residue profiles
  - Evidence of current GMP approval (Vet Meds and VTAs)

What Makes a Good Application?

Variation Applications (C3)

- For changes to the **shelf life or packaging of a product**, this includes:
  - Data to demonstrate ability to meet approved product specifications (at new shelf life or in new packaging)
    - This may need to include discussion regarding what happens if the product is released at the low end of the release specification
  - Technical discussion of the impact on product stability
  - Technical discussion of the impact on efficacy, safety and residue profiles

What Makes a Good Application?

Variation Applications (C4, C5, C6, C7)

- For changes to the **target species/crop, approved uses, and approved claims**, this includes:
  - Technical discussion of the impact on efficacy, safety and residue profiles
  - All supporting data and documentation including literature references

What Makes a Good Application?

Variation Applications (C9)

- For changes to the **product documentation including registration renewal**, this includes:
  - All information necessary to support the change
  - This includes an updated PDS and/or product label where changes are proposed that affect them
  - This may also include authorisation letters, new GMP certificates, or other verification documentation
- **Important to ensure the proposed change is administrative**
  - Example: Label changes to reword claims may need assessment

What Makes a BAD Application?

- Data absent, incomplete, or does not adequately address the risks
- Changes made that have not been identified
- No justification for lack of data or deviation request
- References not provided when argument relies on them
- Risk areas stated to be “not applicable”
- Data assessment non-conformances not addressed
- Administrative errors that impact the assessment
  - Incorrect or missing information in the PDS or label
  - Incorrect or missing application forms and documents
- For vet meds: Lack of evidence of current GMP approval

Meeting Requests and Communications

- Meeting requests must be submitted in writing to the Operations team outlining
  - Items to be discussed
  - Time frame for the meeting
  - Who is requested to attend (operations, technical, manager)
- Any relevant documents or material for review should be supplied in advance (at least one day before meeting)
- Please provide enough advance notice to allow us to prepare for the meeting and organise attendance

Meeting Requests and Communications

- Discussion of applications before and after technical appraisal should be directed to the operations team
- Discussion of applications during technical appraisal can be done through the operations team, the technical assessor inbox, or directly with the assessor
- Please do not contact the manager (Delegate) directly with queries about applications
- **This is to keep interruptions to application appraisal work to a minimum, and keep the Delegate separate from the appraisal process prior to application decisions**

Post-Registration Compliance

Adverse Event Reporting

- An **adverse event** is any observation in animals or plants that is **unfavourable** and **unintended**, including:
    - Side effects after treatment
    - An animal or crop safety issue
    - A residue issue
    - Lack of efficacy
    - Alleged interactions with other products

Post-Registration Compliance

Adverse Event Reporting

- All registrants must, as a condition of registration:
  - Notify MPI immediately for any significant adverse events
  - Investigate all AERs and report the outcome to MPI within 20 working days

Post-Registration Compliance

Variation from Registration Conditions

- A variation from registration conditions is when a product fails to meet the approved specifications
    - Stability failure
    - Packaging failure
    - Labelling issue
    - Results out of specification

- ACVMG must be notified of all variations from the registration conditions

Post-Registration Compliance

Variation from Registration Conditions

- The submission to ACVMG must include:
  - Details of the failure
  - Summary of investigations conducted thus far
  - Root cause (if known) and proposed corrective actions
  - Number of batches affected
  - Plan for affected batches
  - If the issue is product-wide, a time frame for amending the product approval (variation application)

❖ A submission form is currently under development

Post-Registration Compliance

Variation from Registration Conditions

Plan for affected batches

- **Batches still held on site**
  - Can apply for a batch release with justification and supporting data
- **Batches already in the market**
  - Risk assessment evaluating whether a recall is necessary
  - Appropriate data to support decision

Post-Registration Compliance

Recalls

- ACVMG must be informed if a registrant or manufacturer are considering action following possible faulty manufacturing, product deterioration or any other serious quality problems that may impact the risk profile of the product
- Need to provide
  - Risk assessment
  - Amount of product in the market
  - Proposed reassessment procedure
  - Updates as the recall progresses

❖ A submission form is currently under development

Post-Registration Compliance

New Information

- Registrants are conditionally required to report new information as soon as practicable that may impact:
  - The relevance of previously submitted data and information
  - The reliability or correctness of information on file
  - The risk profile of the product as previously assessed
- This may trigger changes to the product information, the need for a variation application, or a reassessment of the product or group of products affected

The ACVM Team Expects…

- All information needed for the assessment is complete and included in the application package
  - Clearly identify and justify all changes with respect to the product risk profile
  - Provide all data and supplemental information, including references
  - For variations, provide a comparison of “old” and “new” when discussing changes

The ACVM Team Expects…

- Correspondence and meeting requests are managed as requested
  - To allow assessors to stay focused on application work
  - To allow the Delegate to remain objective when reviewing applications for approval

The ACVM Team Expects…

- Post registration compliance matters are managed appropriately and in a timely manner
  - Product quality and pharmacovigilance monitored at all times
  - All adverse events, variations to registration conditions, manufacturing faults, and new information is technically evaluated and reported to MPI

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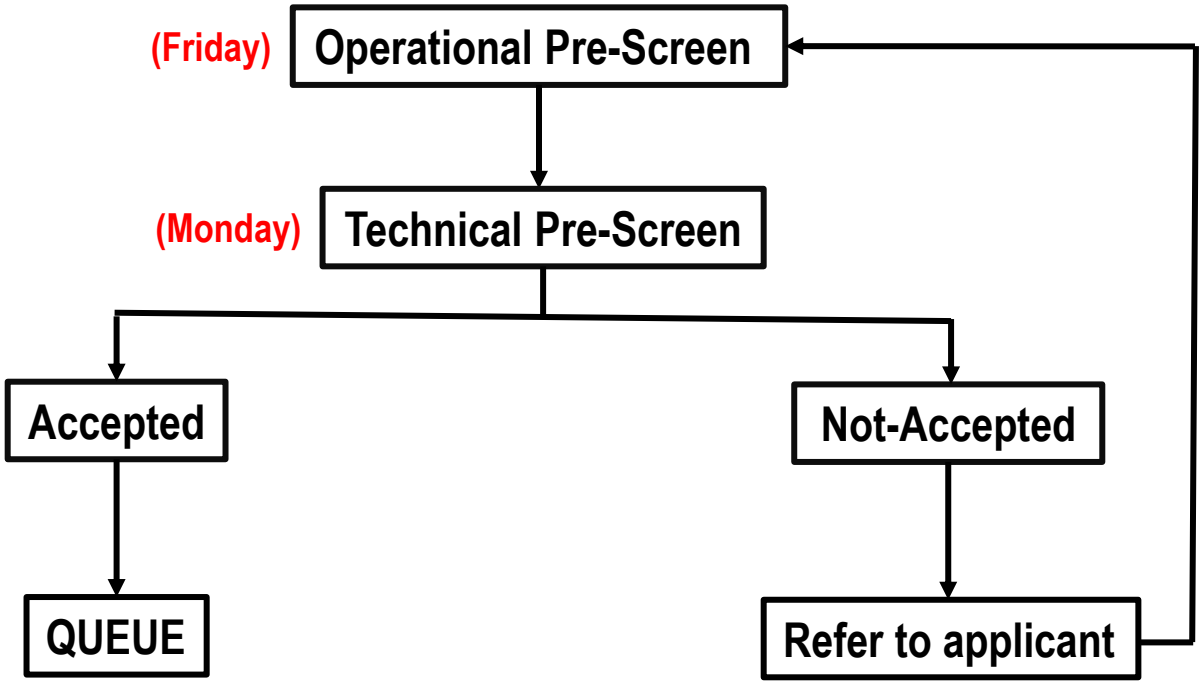
Pre-Screen

Agricultural Compounds and Veterinary Medicines

www.mpi.govt.nz

Pre-screen: flow chart



Approvals Operations Team

Regulation & Assurance

- The Approvals Operations Group process approvals under the:
  - Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997
  - Animal Products Act 1999
  - Food Act 2014
  - Wine Act 2003

Approvals Operations Team

- Receive the application (email, hardcopy)
  - Approvals Email
    - Will receive an automatic reply. This is your acknowledgement that your application has arrived.
  - Directly to Key Account Manager
    - We are looking into acknowledgement options under the ACVM review project.
- Complete Admin Pre-screen

Admin Pre-screen

- Correct application type or variation has been submitted.
- Correct application forms have been received and are complete .
- Check PDS and label against previously approved.
- Applications must be received at the very latest by Friday morning for Pre-screen on Monday.
  - The application will be put into Monday pre-screen provided the application is complete

Submission Errors – Admin Pre-screen

- Not signing the application form or PDS
- Not using the correct or current (2014) PDS or application forms
- Not attaching all the required info:
  - Application form
  - Variation form
  - PDS or PDS page
  - Labels (with tracked changes)
  - Current GMP (for VM & VTA)
  - Data e.g. COA

Submission Errors (Cont..)

- **The label or PDS has changes other than those requested in the application**
- **Manufacturers must be the same as previously approved, including QC labs**
- **Expiry and release specs have changed**
- **Changes to impurities**
- **If you discover a minor typo or ADMIN error, state this on the application form with an explanation**

Registration Renewal Application

Submit this form if it is <u>just</u> a renewal application

Renewal of registration of an ACVM trade name product
ACVM 1R (August 2014)

- This form is to be completed by the Registrant or their nominated New Zealand Agent/Consultant.
- Registration (section 21) of a non-exempt ACVM trade name product is required to avoid committing an offence (section 8) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- Under section 10 of the ACVM Act, you must fill out this form as part of your product registration renewal.
- Send this completed form and all required supporting documentation electronically to approvals@mpi.govt.nz
- Refer to the Privacy Act 1993 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

1. Trade Name of Product	Reg Number

2. Registrant Name

3. Documentation
Currently marketed label (required) **Complete PDS (required)**
Are there any changes? (delete one) NO YES NOTE: changes may require a variation application. **If YES, list here**
NOTE: If your product registration lapsed 3 or more years ago, you may be required to provide further technical data and/or re-register your product. In this case, we will advise you.

Variation Application Form

Submit this form for a Variation with a Renewal/C9 Application

Variation to registration of an ACVM trade name product ACVM 1V (October 2014)

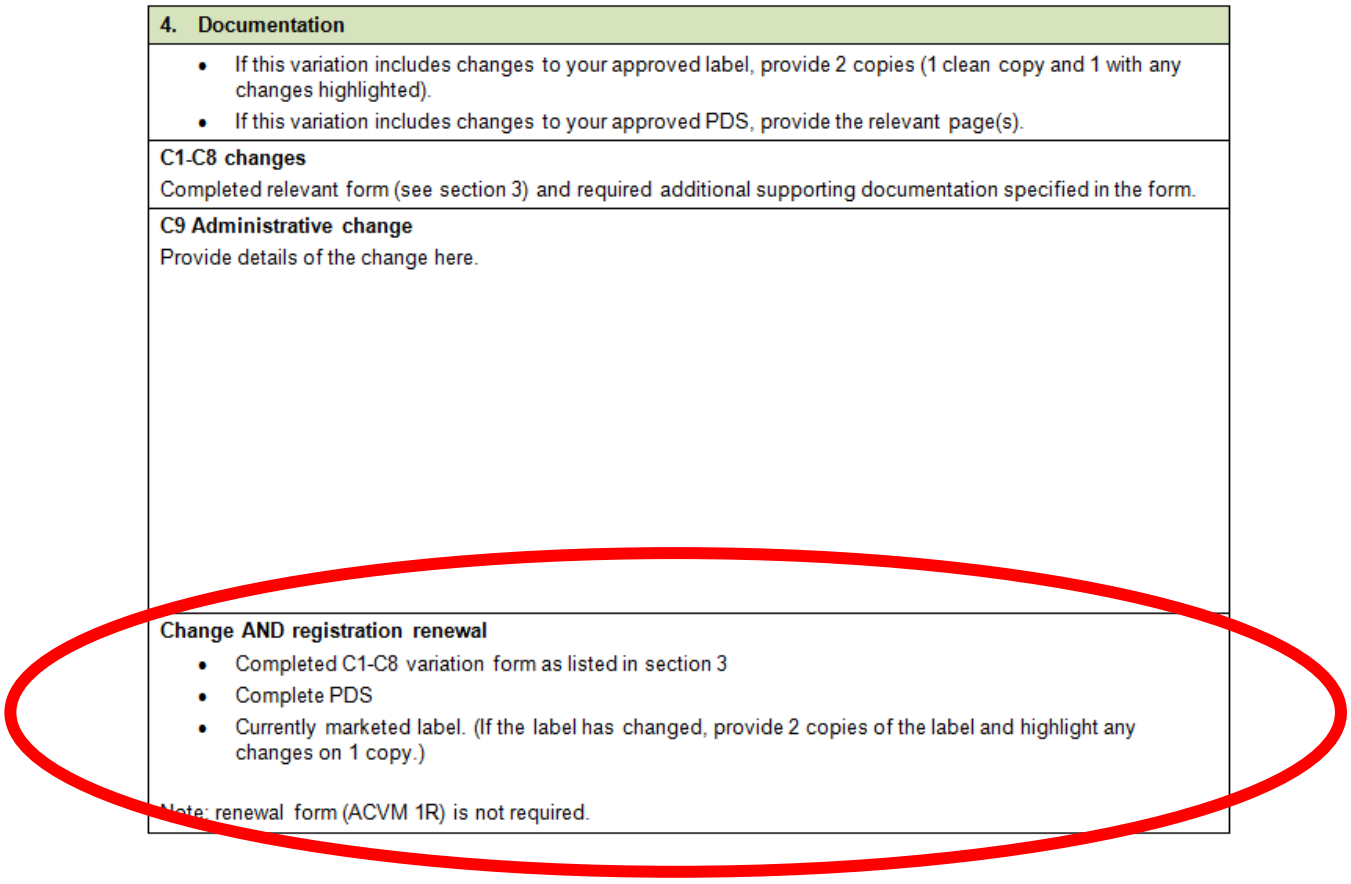
- This form is to be completed by the Registrant or their nominated New Zealand Agent/Consultant.
- Registration (section 21) of a non-exempt ACVM trade name product is required to avoid committing an offence (section 8) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- Under section 10 of the ACVM Act, you must fill out this form as part of your application to vary the registration of a trade name product.
- Send this completed form and all required supporting documentation electronically to approvals@mpi.govt.nz
- Refer to the Privacy Act 1993 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

1. Trade Name of Product	Reg Number

2. Registrant Name

3. Variation Application Type (Indicate type by highlighting in BOLD.)	Form to use
C1 Change in formulation	ACVM 6
C2 Change in active ingredient manufacturer	ACVM 7
C2 Change in formulation manufacturer	ACVM 8
C2 Change in manufacturing process, including changes in AI or formulated product specifications	ACVM 9
C3 Change in packaging	ACVM 10
C3 Change in shelf life	ACVM 11
C4 Extension of use to include additional target host or species C5 Extension of use to include control of additional pests, weeds, species, diseases or conditions	ACVM 12
C6 Change in dose regime or application rate or timing C7 Change in method of administration/application	ACVM 13
C8 Change in withholding period	ACVM 14
C9 Administrative change, such as phone number, postal/email address.	Provide details in section 4 below. No additional form required.
Registration renewal in addition to the variation	Provide relevant C1-C8 variation form as listed above and documents specified in section 4 below. Renewal form (ACVM 1R) is not required.

Variation Application Form (Cont..)



4. Documentation

- If this variation includes changes to your approved label, provide 2 copies (1 clean copy and 1 with any changes highlighted).
- If this variation includes changes to your approved PDS, provide the relevant page(s).

C1-C8 changes

Completed relevant form (see section 3) and required additional supporting documentation specified in the form.

C9 Administrative change

Provide details of the change here.

Change AND registration renewal

- Completed C1-C8 variation form as listed in section 3
- Complete PDS
- Currently marketed label. (If the label has changed, provide 2 copies of the label and highlight any changes on 1 copy.)

Note: renewal form (ACVM 1R) is not required.

- **http://www.foodsafety.govt.nz/industry/acvm/documents/forms-templates.htm**

Implications for the Registrant

- Every time an adviser requests information, the application goes into hold and to the bottom of the queue
  - Once all issues with the adviser are resolved, it then goes into the queue for technical assessment or pre-screen
- Delayed approval
  - 40 working day regulatory timeframe starts once we receive a complete application (RR or C9s) or acceptance at pre-screen
- Increased cost – we charge for extra time taken

How to Submit Documents

- Use the current PDS and application forms
  - http://www.foodsafety.govt.nz/industry/acvm/documents/forms-templates.htm
- Individually attach and name files
- List the attachments
  - Easier to track if something is missing (may save you a pre-screen fee)
- If there have been any label changes, please submit a tracked and a clean label

Technical Pre-screen: What is it?

- Scan through application submitted to ensure enough information has been supplied to do the assessment

Pre-screen: information required

	C & M	Residue	Efficacy	Safety	Toxicology
A1 New Active	●	●	●	●	●
A2 Known active new risk profile	●	●	●	●	
B1 Identical to a registered TNP	◊	◊	◊	◊	
B2 Similar to a registered TNP	●	●	×	●	
C1 Change in formulation	●	●	●	●	
C2 Change in manufacturing process	●				
C3 Change in shelf-life or packaging	●				
C4 Additional target species		●	●	●	
C5 Additional disease/condition			●		
C6 Change in dose regime		●	●	●	
C7 Change in method of administration		●	●	●	
C8 Change in WHP		●			
C9 Administrative changes	Explain changes in a letter				

● Information must be provided or a request for deviation submitted

× therapeutic equivalence

◊ deviation from information

Pre-screen: checking additional information

- DVs and appropriate certificate
- DAS non-conformances addressed
- EPA / Biosecurity / MoH approval
- public gazetting required
- eligibility for data protection

Pre-screen: set up an orderly request (1)

- For ‘Minor Variations’ (i.e. change in AI manufacturer):
  1) Variation application form (ACVM 1B)
  2) Additional form (i.e C1: Change Formulation ACVM 6)
  3) supporting evidence (i.e. CoA)

Pre-screen: set up an orderly request (2)

- For ‘Major Variations’ (i.e. new use patterns) and ‘New Products’:
    1) Data
    2) Scientific arguments in lieu of data
    3) References to relevant documents
    4) Non-conformances addressed
    5) An index is very helpful when dossiers are presented

Pre-screen: what can you do to go through?

- Review the information requirements
- Ensure everything we might need to assess the risks under the ACVM Act are there
- Tables comparing current and proposed changes (and supporting argument)

Pre-screen: what can you do to go through?

- Appropriately support the change with **sound scientific** arguments

- Ensure the correct form(s) are provided and **every section** is filled in

Pre-Screen Outcome

- The applicant will be emailed the outcome of Pre-screen by mid-week

- Pre-screen Accept

  - General ‘this application has been accepted at pre-screen’ email is sent

- Pre-Screen Not-Accept

  - An email stating why the application was not accepted is sent to the Registrant

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Reassessments

Agricultural Compounds and Veterinary Medicines

www.mpi.govt.nz

Reassessment under section 29

A reassessment is considered when:

1. Significant new information on a matter related to the use of a registered trade name product or group of trade name products has become available; or

2. There has been a significant change in the use of any or all of the registered trade name products.

Sources of Information

- New scientific evidence
- Adverse events
- Serious or consistent non compliance
- Legislative changes
- International standards and agreements

Process

- Assess new information and determine if reassessment should be considered
- Advise affected parties of proposal to reassess
- Review comment from affected parties and preliminary findings
- If required, initiate reassessment
- Identify interim actions/controls
- Reassessment processed as a variation to registration

Reassessments 2016/17

Bismuth - Proposed

Amitraz – Proposed

Key Strepto – Proposed

Carbadox – Proposed

Dimetridazole – Proposed

Anticoagulants – Proposed

Clenbuterol & Calcium inj - Proposed

Alphachorolose – Proposed

Dichlorvos – Underway

Completed 2015

- Organophosphates
- Ionophores

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Review of Decision

Agricultural Compounds and Veterinary Medicines

www.mpi.govt.nz

Review of Decision under section 77A, ACVM Act

- Formal process to be followed
- Initiated after decision is made
- In writing specifying grounds
- Received within 20 days of decision
- 40 – 60 working days
- May require additional information
- Outcome is final

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Maximum Residue Levels under the Food Act 2014

www.mpi.govt.nz

What's Changed?

- **Legislation**
  - Previously Maximum Residue Limits (MRLs) were set under the Food Act 1981 as a standard
  - From 1 March 2016 Maximum Residue Levels will be set under the Food Act as a notice

What's Changed?

- **Legislation**
  - Food Regulations 2015 set the rules
    - Regulation 138 to 144
    - Clarifies concentration of foods
    - Can set time limits and other conditions on MRLs
  - The numbers are set in a notice not the regulations

What's Changed? (cont)

- **Terminology**
  - Maximum Residue Levels not Limits
  - It is a notice not a standard
- **Signing**
  - Director-General signs the notice
    - ➢ Minister no longer involved

What's Changed? (cont)

- **Timelines**
  - No Minister ➔ faster turnaround
  - Should be able to increase the number of MRL rounds per year

What's NOT Changed?

- **Criteria**
  - Basically the same except for concentration
    - Follow Codex Classification of Food and Feeds
    - Default MRL of 0.1mg/kg
    - Imported Food can meet Codex MRLs or NZ MRLs or default MRL

What's NOT Changed?

- **Process**
  - –No significant change
  - ➢MRL requests via applications made under ACVM Act
  - –WTO notification (60 days)
  - –Public consultation

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ACVM Amendment Bill

www.mpi.govt.nz

Background

- MPI reviewed Part 6 of the ACVM Act on protection of confidential supporting information (commonly referred as data protection)
  - Covec Report produced
  - Public Consultation

ACVM Amendment Bill

- Introduced into Parliament by the Minister for Food Safety in August 2015
- Now at Select Committee
  - Submissions closed on 29 January 2016
  - Report back date is 15 April 2016

Data Protection

- **Innovative Active Ingredients**
  - Current protection period will be extended
  - If within the first 3 years of the 5 year period, a new use claim is made, 1 extra year is added up to a maximum of 3 years
    - Maximum of 8 years protection for proprietary data (original plus 3 use claims), and proprietary data submitted for applications made between the 4 - 8 year period will NOT have data protection

Data Protection (cont)

- **Non innovative products**
  - Currently no data protection is given
  - There will be 3 years of data protection (does include provisional registration)
- **Variations to non innovative products**
  - There will be 3 years of data protection (does include provisional registration)

Data Protection (cont)

- **General**
  - Data protection period starts on Director-General granting or refusing registration or the variation
  - If no decision made, then data protection period ends 3 or 5 years after the application has been made
  - Removes link to Provisional Registrations on the definition of innovative active ingredient

Data Protection (cont)

- **General**
  - Consequential amendments required to other legislation such as Hazardous Substances and New Organisms Act
  - Does not change the rules on how MPI handles proprietary data

Other Changes

- The Bill makes minor changes to terminology in the ACVM Act for consistency purposes and/or to clarify the existing law

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Registration Review Project

www.mpi.govt.nz

Introduction

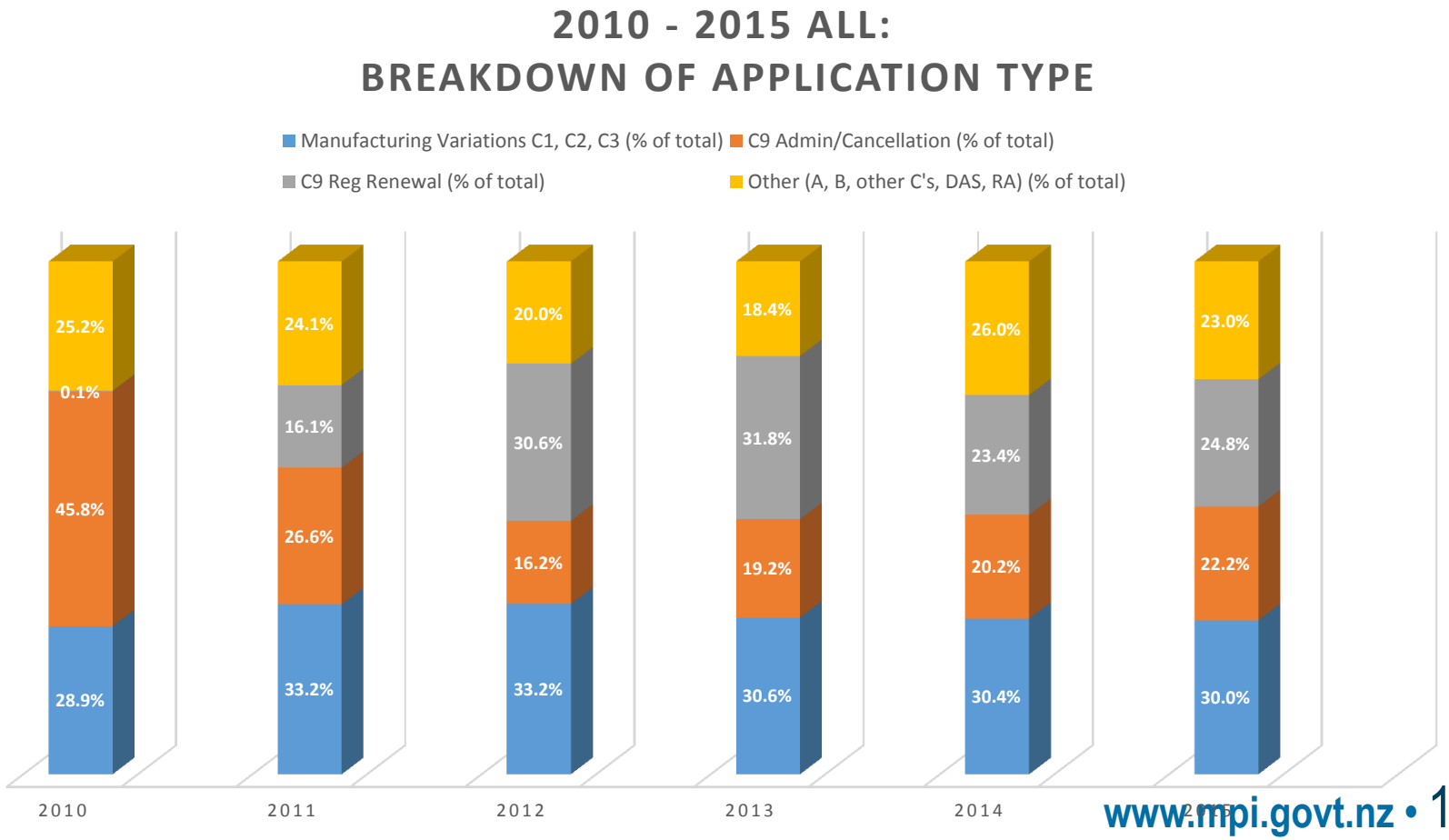
- Initiated late 2015 in response to:
  - performance against statutory timeframes
  - industry feedback and lobbying
  - changing landscape of ACVM activities
- Scope - end to end review of the registration process

Project Objectives

- Maximise benefits to registrants by:
  - Consistently meeting statutory timeframes
  - Providing consistent timely communications
  - Ensuring registration process is robust
  - Providing appropriate level of regulatory oversight to manage risks
- Maximise benefits to ACVM by:
  - Improving efficiency of registration process

Current State

- ACVM receives ~2,600 applications/year



Areas of Exploration

- Application pathways – working smarter
  - Defining pathways that streamline applications
  - Establishing criteria
- Use of technology - enabling
  - Optimise internal systems for improved performance
  - Secure submission
  - User interface

Next Steps

- Streamlining current processes
- IT Business needs analysis initiated
- Development of potential application pathways
- Trialling specific improvement initiatives

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Information Requirements Update

www.mpi.govt.nz

Currently Under Review

- Efficacy of Teat Sanitisers
- RVM Seller Guidelines
- Anthelmintics Efficacy (Cattle, Sheep, Goats and Deer)
- Bioequivalence of Veterinary Medicines
- Veterinary Medicine Chemistry and Manufacturing
- Ectoparasiticide Efficacy

Efficacy of Teat Sanitisers

Main changes from the current standard

- More detailed guidance
- More specific guidance and requirements around field trial work
- Removal of outdated test methodology
- Aligning more with best international practice

Efficacy of Teat Sanitisers

Current Status

- Submissions currently being reviewed
- Final document being drafted

Next Steps

- Summary of submissions will be prepared
- Final document revisions
- Should be complete by the end of March

RVM Seller Guidelines

Main changes from the current standard

- More detailed guidance clarifying current expectations
- Labelling expectations for supply to end users
- Specifying requirements for non-vet entities
- Clarifying expectations for 3rd party functions

RVM Seller Guidelines

Current Status

- Submissions have been reviewed
- Final draft of guideline in progress
- OP template revisions to incorporate amendments

Next Steps

- Internal review of the new Operating Plan template
- Release of revised guidance and template
- Decision of time frames for updating approved OPs
- Should be complete by June 2016

Anthelmintics Efficacy

Main changes from the current standard

- More detailed guidance
  - Rainfast claims
  - Combination (multi-active) anthelmintic products
  - Field trial design
- "Effective" and "Highly Effective" thresholds
- Aligning more with WAAVP and VICH requirements

Anthelmintics Efficacy

Current Status

- Submissions are currently being reviewed
- Final document being drafted

Next Steps

- Summary of submissions being prepared
- Should be complete before spring 2016

Bioequivalence of Veterinary Medicines

Main changes from the current standard

- Aligning New Zealand requirements with the latest VICH requirements
- More specific detail on
  - When bioequivalence is appropriate
  - Data generation
  - Deviation arguments
  - Dissolution testing

Bioequivalence of Veterinary Medicines

Current Status

- First draft completed

Next Steps

- Finish internal consultation
- Draft will be circulated via AVMAC
- Likely to be completed by Spring 2016

Veterinary Medicine Chemistry and Manufacturing

Main changes from the current standard

- Alignment with international requirements where appropriate
- Complete revision to provide more detailed guidance
  - Manufacturing processes
  - Validation
  - Stability requirements
  - Chemistry and manufacturing pharmacovigilance
  - Post-registration expectations
- Appendices to provide more detailed guidance

Veterinary Medicine Chemistry and Manufacturing

Current Status

- First draft is close to completion

Next Steps

- Complete draft → Internal consultation → External consultation
- Will likely need revision of other documents like the PDS and application forms once complete

Ectoparasiticide Efficacy

New Standard

- Currently being drafted based on VICH and WAAVP guidance
- Will be New Zealand focused
- Welfare threshold-based information requirements

Ectoparasiticide Efficacy

Current Status

- The first draft is currently being written

Next Steps

- Complete draft → Internal consultation → External consultation
- Timeframe to completion to be determined

Upcoming Information Requirements Reviews

- Information requirements for determination of a residue WHP for veterinary medicines – Next Priority
- Efficacy of Antibiotics
- Efficacy of Veterinary Medicines: Consolidated Information Requirements
- Labelling and Advertising Requirements
- Research and Target Animal Safety requirements to be reviewed and updated as needed

Other Document Revisions

Additional guidance and document revisions will likely be needed after completion of ongoing reviews:

- GMP Review
- AER Management Review
- Post-Registration Management Review
- Feeds Review
- Registration Review


Any Questions?
approvals@mpi.govt.nz