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ACVM News & Views

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Applications revisited (again!)

From July-December 2014, only 29.9% of 1150 applications passed prescreen on the first attempt.

Applications overview

For the six-month period from July-December 2014, we received a total of 1150 regulatory applications (see table on page 2). This total excludes all the non-regulatory applications such as class determinations, data assessments, deviation and operating plan approval requests.

To process applications across four different pieces of legislation (ACVM Act, Animal Products Act, Food Act and Wine Act) we have six advisers on the Approvals Operation Team. On the technical assessment side, we have two assessors for veterinary medicines and three for agricultural chemicals/VTAs. These assessors also provide support to other parts of MPI: 25 hours/week of their time is allocated to applications.

Administrative prescreen

When applications arrive, they are screened for completeness by the Approvals Operation Team.

During the July-December period, only 29.9% of the

Basic submission errors noted in admin prescreen

*Not using the correct, current forms
Not signing the application form
Not signing the PDS
Not supplying all the required information
Not supplying ANY data at all
Not putting required regulatory statements or updated MPI website address on label
Not supplying changed labels*

1150 applications passed this administrative prescreen on the first attempt. The other 70.1% had multiple attempts. Failure to pass the administrative prescreen SIGNIFICANTLY increases processing time. Every time an adviser requests information, the application goes to the back of the queue.

Technical assessment

Once all administrative issues are resolved, an application goes into the queue for technical assessment or technical prescreen. (The 40 working day regulatory timeframe starts once we receive a complete application or acceptance at prescreen.)

Tips for preparing applications

When you submit your application, please remember to:

- Use the current PDS (the issue with printing the AC PDS has been fixed) and application [forms](#)
- Individually attach and name files.
- List the attachments--makes it easier to track if something is missing and may save you a prescreen fee.
- If there have been any label changes, submit two labels (one tracked and one clean).

If you make a good application, it passes admin checks and gets to technical assessment quickly, the assessor has fewer questions during appraisal, and post-assessment administration is quicker. This means faster registration and less cost.

Avoiding delays in approval

If we require PDS and/or label amendments:

- Address everything we have requested.
- Do not change anything we have not requested.



resistance statement on agricultural chemical labels

Labels on agricultural chemicals must contain the mode of action group (MOA) and resistance management statements (if applicable) to manage the development of insect, pathogen and weed resistance. This has been a requirement since the ACVM's [Labelling Agricultural Chemicals](#) was revised in May 2014.

A large number of applicants are not adding MOA and resistance statements on their product label. This significantly adds to processing time and creates a backlog of pending applications as assessors wait for applicants to provide the required label amendments. Assessors must also check if the label amendments provided by the applicant are fit for purpose.

What wording is required?

There is no template for resistance statements. Applicants can find appropriate resistance management strategies (example at right) and MOA group on the [New Zealand Plant Protection Society \(NZPPS\) website](#).

What if there is no management strategy?

If the NZPPS website does not contain a resistance management strategy covering the group to which your particular product belongs, the MOA group and general advice on managing resistance should be placed on the label. However, we advise applicants to contact the [New Zealand Committee on Pesticide Resistance \(NZCPR\)](#) for guidance on the development of a suitable strategy.

Expectation

We expect applicants to comply with current label requirements. Please make sure your product label contains all mandatory information on it before lodging an application for a new product, for a variation, or for a registration renewal. This will speed up the application process.

Other useful links

[Herbicide Resistance Action Committee](#)
[Fungicide Resistance Action Committee](#)
[Insecticide Resistance Action Committee](#)

resistance statement (example only)

Resistance prevention or management
Product_name contains the GROUP C1 insecticide, atrazine. Do not use another product containing a herbicide in the same group in conjunction with Product_name when applying the resistance prevention or management guidelines below.

(Details of the resistance guidelines for this product then follow.)

Applications, continued from page 1

Type	Ag Chem	Vet Med	VTA
A1 New active ingredient	3	3	-
A2 Registered active ingredient with new risk profile	5	7	-
B1 Identical to existing product	1	3	1
B2 Similar to existing product	41	21	-
C1 Change formulation	21	13	-
C2 Change or add manufacturer	61	173	3
C3 Change packaging/shelf life	17	42	5
C4 Change target crops/species	10	1	-
C5 Change claims, diseases, conditions	11	6	-
C6 Change dose regime, application rate, timing	2	9	1
C7 Change method of application/administration	1	4	1
C8 Change withholding period	3	-	-
C9 Admin change	66	166	4
C9 Registration renewal	138	141	6
C10 Reassessment	11	-	-
Notifications	38	24	-
Research approval	14	1	12
Provisional registration	35	12	2
X-variation	-	11	-
Total	478	637	35

updates

Data protection

The amendment to the data protection rules under the ACVM Act is progressing. MPI is hopeful to have it introduced into Parliament prior to the 3rd quarter of 2015. When introduced into Parliament, the Bill will go to Select Committee for its consideration. In the Select Committee process, stakeholders will have an opportunity to make submissions on the Bill.

Until the amendment is passed into law, the current data protection rules apply. These rules only relate to applications for registration of a product containing a new active ingredient. Once the product is registered, the new active ingredient gains five years' data protection.

Proprietary data submitted to the EPA for a part 5 approval under the HSNO Act for the same product will also be eligible for five years' data protection. However, to be eligible for this data protection under the HNSO Act, applicants MUST apply for registration under the ACVM Act either prior to or at the same time as they make their applications under the HSNO Act.

Data assessors

Data assessors now have a ['one stop shop' page](#) on our website. This page, which can also be accessed from the [ACVM landing page](#), has links to:

- information and application form to become a listed data assessor
- listed data assessors
- data assessment report templates.

The list of DAs provides contact details, scope and status of their listing. At this point, the status of all of the listed DAs is 'provisional'. Once MPI is confident that a provisionally listed DA is competent in a scope, he/she will be given 'full' listing in that area.

If you have questions about the listed data assessor process, email us (data.assessors@mpi.govt.nz).

Staff

As part of MPI's plan to provide staff with the opportunity to expand skills, Adviser **Andrew Freeth** from the Approvals Operations Team has been seconded to MPI's Policy Team until February 2016. His replacement is **Shaleen Narayan** who comes to us from the Branch Administration and Regulatory Services Team.

Cost recovery

MPI has recently been consulting on changes to the fees, charges and levies across multiple pieces of legislation, including fees and charges under the ACVM Act. Interaction with the various industries involved resulted in a good number of submissions on the topic. These submissions have been analysed and a summarised version has been incorporated into a paper that is currently being reviewed by our Ministers. This paper details the recommended changes to the fees, charges and levies under the multiple pieces of legislation, and it will ultimately go to a Cabinet committee seeking approval. We anticipate a reply from the Cabinet committee by the end of March. Look for further communication on this in the coming months.

Thank you to everyone who attended one of the roadshows on offer.

international meeting:

VICH

23-26 February 2015, Washington DC

Warren Hughes, as part of the Australia/New Zealand observer delegation, attended the latest VICH Steering Committee (VICH SC) and OutReach meetings. The VICH SC discussed progress on guidance material in the various Expert Groups. Of particular interest to Australia and New Zealand, two task force groups are working on the efficacy of combination products and on whether the guidelines on anthelmintic products require updating.

The electronic formatting guideline was finalised and will come into force for members in February 2016. A copy of the guideline

should be available shortly on the VICH website.

OutReach

The OutReach forum had representation from six continents although numbers were down from previous meetings. This forum provides an opportunity for non-VICH members and observers to be updated on VICH activities and to encourage as much as possible the adoption of VICH guidelines.

Global Animal Health Conference

A reminder was circulated about an upcoming 4th edition of the Global Animal Health Conference. It is being organised by the

International Federation for Animal Health (IFAH) with the support of the Organising Committee partners and funded by the Bill and Melinda Gates Foundation.

The conference is scheduled to take place from 24-25 June 2015 in Dar Es Salaam, Tanzania.

Further details of the conference can be found on the IFAH website (<http://www.ifahsec.org/4th-global-animal-health-conference-regulatory-convergence/>).

The next meeting will be in late October 2015 in Tokyo and will be in conjunction with the VICH conference (held every 2-3 years).

annual fees notice for registrants

The annual fees process will start in May when you will receive letters:

- 1. advising you to check your registered products on the website register*
- 2. explaining the de-registration process if you no longer wish to market products*
- 3. asking for any address changes for posting invoices.*

product patents and gazetting

*If your company is applying for a type A2 application (registered active ingredient with new risk profile) and you are going through the process of obtaining a patent for that trade name product, we **strongly advise you to let us know** about this when you submit your application. This is to give us a heads-up so that if the product requires gazetting, we can give you the opportunity to withdraw your application until the patent has been approved.*

