



Changes to Registration Renewal

Registrations under the Agricultural Compounds and Veterinary Medicines Act 1997

A registration renewal application is made to renew the registration period and set a new registration expiry date for a trade name product.

What is changing?

MPI is changing the registration expiry period for trade name products from 3 years to 5 years.

MPI is changing the processing of variation applications, so that all variation applications (when granted) will be issued with a new registration expiry date. If a variation application is submitted within the 5 year expiration period, the new expiry date will be set for a further 5 years from the date the application is granted. A new Certificate of Registration will be issued with the new expiration date, along with the approval of the submitted product datasheet (PDS) and label.

These changes will come into effect for all applications formally received (accepted at pre-screen) from 1 January 2018.

From 1 January 2018:

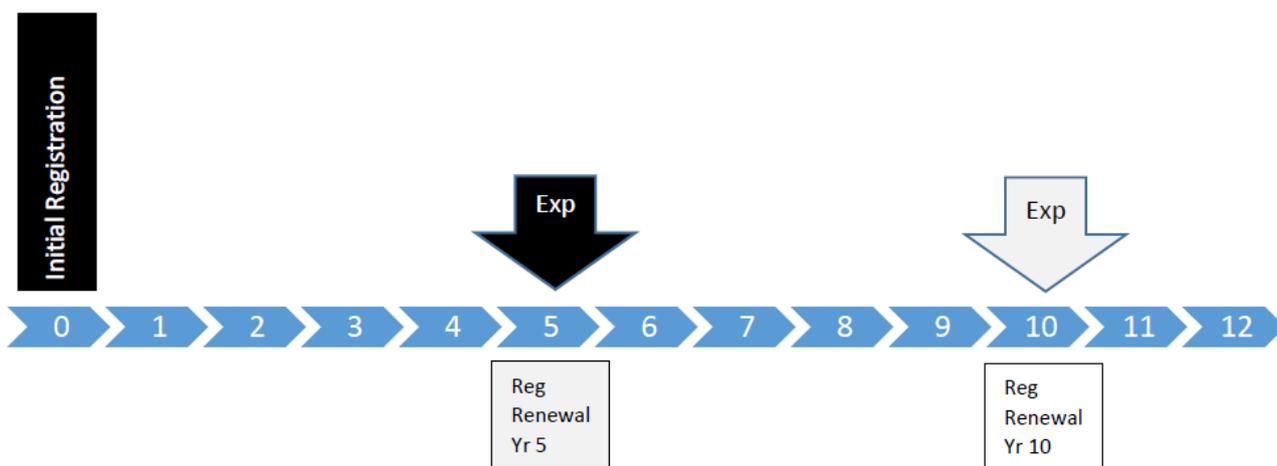
- The registration expiry period will be 5 years (except for those trade name products requiring a shorter registration period to manage risks).
- Registrations will be issued with a new expiry date of 5 years from granting of every variation or renewal application (except for those trade name products requiring a shorter registration period to manage risks).
- Simultaneous renewal and variation applications **will not** be accepted.

IMPORTANT NOTE: the registration date and expiry date can be found on the product's Certificate of Registration.

Examples of how the new process will work:

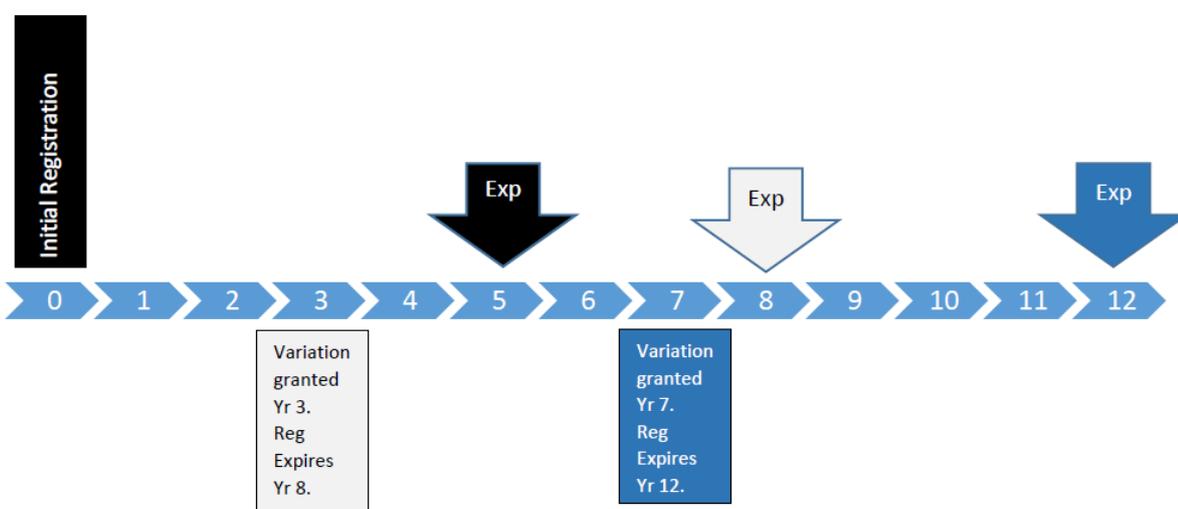
Example 1: A trade name product is registered year 0, expiring in year 5.

Assuming no variation applications are made, registration renewal applications are required at years 5 and 10.



Example 2: A trade name product is registered year 0 expiring in year 5, with a variation application granted in year 3.

A trade name product is registered year 0, expiring in year 5. A variation application is granted in year 3 with a new registration expiry date – the registration expiring in year 8. Another variation application is granted in year 7 with a new registration expiry date – the registration now expiring in year 12.



What do I need to do after 1 January 2018?

1. What do I need to do when submitting a variation application?

You must submit a complete PDS **and** label with the appropriate variation application forms.

Please provide the PDS as a new document with any requested changes, dated with the date of submission - do not provide a copy of the last MPI stamped version.

Please provide label content as both a clean version and version with any requested changes highlighted, dated with the date of submission - do not provide a copy of the last MPI stamped version. Ensure the label complies with the current MPI labelling guidance.

Upon granting the application, MPI will issue a new Certificate of Registration with the new expiry date, approved PDS and approved label.

2. When should I submit a registration renewal application?

We advise registration renewal applications should be submitted **no later** than three months prior to the registration expiry date. This allows sufficient time for MPI to process and grant these applications, before your product registration expires.

3. What do I need to do when submitting a registration renewal application?

A complete registration renewal application comprises:

- A complete signed and dated application form. The application form – '[Renewal of registration of an ACVM trade name product ACVM 1R](#)' can be found on our website.
- A complete label. Please provide label content as a new document dated with the date of submission - do not provide the last MPI stamped version. Ensure the label complies with the current MPI labelling guidance. MPI will approve label content as part of the renewal process.
- A complete signed and dated PDS. Please provide the PDS as a new document dated with the date of submission - do not provide the last MPI stamped version. MPI will approve the PDS as part of the renewal process. Also, please ensure you use the latest version of the appropriate PDS template (version August 2014), which can be found at our website:
 - [agricultural chemicals](#)
 - [veterinary medicines](#)
 - [vertebrate toxic agents](#)

Please note: for registration renewal applications, the label content plus the PDS submitted must have the same content as that currently approved. The exceptions are:

- If mandatory label statements have changed since the last approval. In these cases we advise updating mandatory label statements in compliance with the current MPI labelling guidance. (e.g. updating the management of residues mandatory statement from "It is an offence for users of this product to cause residues exceeding the relevant MRL in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards" to "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")
- If there are changes to the registrant contact details in the PDS or label, such as addresses, email addresses and phone numbers
- If there are changes to the New Zealand distributor or agent details.

4. What do I do if I have a product registered with Condition 86 and /or Condition 101?

For risk management purposes some products are registered with conditions requiring provision of additional information. The most common of these conditions of registration are:

Condition 86: "The registrant must provide a batch analysis, which confirms that the product meets the approved release specifications, from the first production batch at the new manufacturing site to Ministry for Primary Industries for approval prior to sale of product from this new site."

Condition 101: "The registrant must provide additional information specified by the Ministry for Primary Industries at or before the expiry of the current product registration period."

We advise that you must still comply with these conditions by providing the information as specified.

To streamline the receipt of registration renewal applications, please direct all renewal queries and registration renewal applications to the email inbox: regRenewalACVM@mpi.govt.nz

Annual Fees and Registration Renewal

MPI wishes to remind registrants that annual fees are separate from renewal of product registrations. Payment of annual fees **does not** renew a product registration.

Annual fees are a fixed fee payable by registrants, based on the number of products registered to them. They are paid in advance e.g. the current annual fees run from 1 October 2017 through to 30 September 2018. Reminder letters are sent to registrants each year, with payment due in September. The reminder letter asks you to view your list of registered products on the public register and advise us if you wish to de-register any of your products. Please note it is the responsibility of the registrant to ensure that their contact details are current, and advise MPI of any change.