

Estimated fees for ACVM regulatory assessment of veterinary medicines (July 2019)

Applications for Registration or Variation to Registration

To register a trade name product or vary one or more conditions on a trade name product under section 9 of the ACVM Act:

Application fee is \$135.00 (exc GST) / \$155.25 (inc GST) plus an assessment charge of \$135.00/hour (exc GST) / \$155.25/hour (inc GST) after the first hour (see estimate of time below).

Pre-screen of applications

Pre-screen is done to determine if all the information required (section 10 of ACVM Act) has been provided.

The fee is \$67.50 (exc GST) / \$77.63 (inc GST) plus an assessment charge of \$135.00/hour (exc GST) / \$155.25/hour (inc GST) after the first 30 minutes.

Processing time for assessment

The regulatory timeline as set In the ACVM Act is **40 working days**.

Note: If there is a significant new risk profile or change in the risk profile, public consultation will take an additional 30 working days and incur an additional charge of approximately \$150.

Multiple applications

If more than one application is submitted at the same time, the first application is charged as above and additional applications are charged on a cost versus time basis of \$135.00/hour (exc GST) / \$155.25/hour (inc GST).

Estimate of time

Estimated time DOES NOT cover assessment of data prior to regulatory appraisal. For the Data Assessment Service fees refer to "ACVM fees and charges for regulated and discretionary services".

Estimates below are given as a range, as time for individual applications will vary depending on technical input required.

New Applications

Type	Description of Type	Estimate of Time
A1	New Active Ingredient	20 - 30 hours
A2	Existing Active Ingredient with different profile, such as new use	12 - 18 hours
B1	Identical to Registered Product (all the same except trade name)	2 - 5 hours
B2	Similar to Registered Product (same active ingredient, same formulation type, same dose regime, same use patterns)	8 - 18 hours

Variation Applications

C1	Change Formulation	3 - 7 hours
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C2	Change Manufacturing Change or Add Manufacturer	3 - 7 hours
C3	Change Shelf Life, Change Packaging	3 - 7 hours
C4	Change or Add Target Species	6 - 13 hours
C5	Change or Add Claims/Diseases/Conditions	6 - 13 hours
C6	Change Dose Regime	6 - 13 hours
C7	Change Method of Administration	6 - 13 hours
C8	Change Withholding Period	6 - 16 hours
C9 No pre- screen fee	Change Name/Address of Manufacturer Change Label Text or Layout Change Trade Name Change Address of Registrant Transfer of Registrant	1 - 5 hours ACVM expected processing time = 15 working days

Registration

The fee for registering a product or for changing a registration is \$405.00 (exc GST) / \$465.75 (inc GST). Registrations are valid for 5 years, or a shorter time period if required for risk management purposes.

Registration Renewals

Registration renewals are charged out at cost v time based on the rate of \$135.00/hour (exc GST) / \$155.25/hour (inc GST)

Annual Fees

Annual fees (defined as the levy in the ACVM (Fees, Charges, and Levies) Regulations, which are separate from registration fees are \$540.00 (exc GST) / \$621.00 (inc GST) per registered trade name product.

Disbursements

The following disbursements relating to applications to register a trade name product are payable by the applicant. These are charged at the actual cost:

- external review
- expert review
- notification
- postage
- product testing
- travel and accommodation.

Applications for Provisional Registration

Processing time and fees for assessment

The regulatory timeline as set in the ACVM Act is **40 working days**.

The rate is the same as applications for registration.

Type	Description of Type	Estimate of Time
Provisional Registration	To carry out trial work with a trade name product (end use formulation) in order to obtain further data to support registration	5 - 7 hours
Variation to Provisional Registration	To vary the terms and conditions of a Provisional Registration	4 - 6 hours

Applications for Research Approval

Processing time and fees for assessment

The non-regulatory timeline is **40 working days**.

The rate is the same as applications for registration.

Research Approval	To enable the use of a substance that is not characterised as a trade name product for research	5 - 7 hours
Variation to Research Approval	To vary the terms and conditions of a Research Approval	4 - 6 hours