Deviation from Information Specified in the ACVM Registration Information Requirements

ACVM guideline

1. Background

ACVM Registration Information Requirements (available on our website) specify the information that must be in an application to register a trade name product under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. However, the requirements allow applicants to explain why, in particular cases, certain information should not be necessary or why some alternative information should allow the potential risks to be assessed.

For example, if your product is known to be very similar in formulation to an already registered product, you can request the ACVM Group to cross-reference data for the similar registered trade name product on which we hold the required information.

In other cases, you may request us to accept references to equivalent data that was produced for another purpose but is equally valid and relevant to the requirements, or otherwise justify a deviation.

2. Asking for advice on a deviation

If you want to know our view on a particular deviation from the specified information requirements, you can request advice on the deviation. You must provide a case why less or different information could be considered equally valid and relevant to the required information, and sufficient to assess the relevant risks. We will assess the request and issue a letter with the appropriate advice.

If an advice letter supports the deviation from the specified information, you must include this letter in your actual application. This will highlight and support the deviation without giving the impression that the information requirement has been formally waived under section 16(4)(a)(ii) of the ACVM Act. Follow this process if the deviations from the information requirements are significant to ensure applications for registration are complete and avoid time delays in the registration process.

In some instances, the deviations requested are straightforward and do not require significant justification. Examples of this are B1 type applications (where the formulations and manufacture are identical) or applications involving direct cross-reference to claims made on appropriate reference products to which equivalence is supported. For these types of deviations, it is sufficient to incorporate a justification into the cover letter accompanying the application for registration. These deviations will be considered as part of the review and evaluation of the application.

If there is any doubt as to whether the request is straightforward, contact us for advice (approvals@mpi.govt.nz).

3. Preparing a deviation request

As with all our applications, if you set up an orderly request (that is, include contents pages, tab sections etc) time required for assessment and costs can be greatly reduced. The main thing is to submit **all** the relevant information. For straightforward requests it may be sufficient to include all information in the cover letter. For more complex or detailed deviations, supporting information will need to be appended. We expect the following to be covered in your request.

Details of the deviation

Provide a concise description of the actual deviation requested. Include the application type to which the deviation will apply. Also include in this section an overview of what you are providing to support the application.

For a deviation from registration information requirements (for example, a variation in trial design), describe the actual deviation from the requirements.

If it is an application to cross-reference (see below) data held on another product registered by us, fully explain and include details of the reference products (trade names and ACVM registration numbers).

Supporting argument

Discuss how the information provided is sufficient to demonstrate equivalence with information requirements. Impacts on ACVM risk thresholds must be discussed (for example, a slightly different formulation can have a significant impact on pharmacokinetics in the animal, resulting in a different risk profile from an efficacy, safety or residue perspective).

All statements must be supported. Cite references and discuss relevance. (Include all referenced articles.) If data is supplied, discuss it along with any deviations from requirements. If a large amount of data is supplied, it must undergo data assessment first.

Discuss each deviation and its impact on relevant information requirements:

- Veterinary medicines should discuss the impact of each request with regards to animal safety, efficacy and residues in separate sections as relevant.
- Agricultural chemicals should discuss the impact of each request on residues, efficacy, crop safety and good agricultural practice (GAP).
- Vertebrate toxic agents (VTAs) should discuss the impact of each request on how the bait matrix is affected and why impacts on animal welfare remain unchanged.

4. Cross-referencing data

If your registration is to rely on cross-referencing data from that held by us on another registered product, note the following.

- The product must be registered by us and have the same active ingredient(s) and formulation type as your product.
- Registration overseas is not considered sufficient to support the application as we do not hold data that can be used to assess risks under the ACVM Act.
- New active ingredients are under data protection for a period of 5 years. If you wish to reference data on such products before this period ends, you must include a letter from the registered product's registrant to permit reference of their data.

Cross-referencing veterinary medicines

Read the therapeutic equivalence information requirements (link below) before preparing your application.

Discuss the relevance of the cross-referenced data to your application. You must demonstrate that your product is similar to the registered one (for example, by comparing similarities between formulations in active and excipient ingredients). Any differences in formulation and manufacturing processes must be discussed. It is possible to appear chemically similar to another product but have a different action within the animal due to different pharmacology.

Address any potential interactions of all ingredients, not just the active. Chemical and physical properties, and specifications of the ingredients should be addressed. For example, specify and supply appropriate compendial standards, discuss and provide evidence for the particle size of active and, where appropriate, comparative chemistry to prove the active ingredient molecules are equivalent.

If the use patterns are not identical to the referenced product, these must be discussed and justified.

ACVM Registration Standard and Guideline for Therapeutic Equivalence of Trade Name Products (52 KB PDF)

Cross-referencing agricultural chemicals

Discuss the relevance of the cross-referenced data to your application. You must demonstrate that your product is similar to the registered one (for example, by comparing formulations, formulation types, active ingredient rate etc).

Any differences in formulation must be discussed. It is possible to appear chemically similar to another product but have a different action when applied to the plant/soil/seed etc.

If the use patterns are not identical to the referenced product, these must be discussed and justified.

Cross-referencing vertebrate toxic agents

Discuss the relevance of the cross-referenced data to your application. You must demonstrate that your product is similar to the registered one (for example, by comparing formulations, the different bait matrixes that exist, and how this may impact on palatability and weathering etc).

5. Requesting a deviation

Your request must contain the following information:

- Trade name of the product
- Name and address of registrant
- Contact person's name and email details
- Type of application to which deviation will apply (such as A1, B2)
- Details of deviation requested
- Copy of proposed product label.

Append any relevant information (as explained above)

- A comprehensive discussion on the deviation requested. This should include summaries of how any data and literature provided is relevant to the application
- Product data sheet (PDS) if available (or at least full formulation)
- All relevant supporting data (for example, trial data, chemistry data etc)
- Supporting literature (and discussion of relevance to application).

Submit your request

If possible, please send your request by email with all relevant documentation as attachments (approvals@mpi.govt.nz).
If you are unable to use email, send your request by post with all relevant documentation (Approvals and ACVM Group, PO Box 2835, Wellington 6140).

6. Fee for deviation advice

The fee for deviation advice is based on a cost versus time for processing at the hourly rate of $152.92. An invoice will be sent to you.