



To: Ministry for Primary Industries
ACVM.consultation@mpi.govt.nz

Submission on:

MPI Guidance Document – Approval of Operating Plans for Sellers of Restricted Veterinary Medicines

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Submitter:

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1. Introduction

- 1.1 Agcarm welcomes the opportunity to comment on the guidance document - Approval of Operating Plans for Sellers of Restricted Veterinary Medicines.
- 1.2 Agcarm has provided the following comments to clarify and elaborate on the guidance document.

2. Summary of the submission

Agcarm supports the guidance document, with some minor amendments.

3. General Comments

3.1 Definitions

3 Definitions

Breaking down means to repack or disassemble product by removing proprietary secondary and/or tertiary packaging keeping primary packaging intact.

A definition of primary, secondary and tertiary packaging should be included.

3.2 Trained personnel

4.2.1 Personnel

(1) Only trained personnel identified and outlined in the operating plan may engage in activities relating to the sale of RVMs.

The level of training that is required should be identified. It should include, but not be limited to, understanding legal obligations, storage conditions, stability, safety and restrictions or conditions of the sale for veterinary medicines.

3.3 Storage

The transport of products between facilities should also be included in the operating plan.

*(8) If you are using a third party warehouse or storage facility, the control and storage of product at the third party facility **and while in transit** must be included in your operating plan at the relevant steps.*

3.4 Verifying the purchaser/distribution

Section 4.3 sets out the conditions for providing veterinary medicines within New Zealand. What are the conditions for selling veterinary medicines for export or to veterinarians outside New Zealand?

Further clarification should be included in section 4.8 Entities handling export-only RVMs.

3.5 Quality control and compliance monitoring

Section 4.9 states that there should be regular monitoring with internal audits performed of the operating plan. The frequency of the internal audits should be defined.

3.6 Review of the Operating Plan.

The operating plans should be reviewed every three to five years.

4 About Agcarm

Agcarm is the industry association for manufacturers and suppliers of crop protection and animal health products. For further information and a full list of members, see www.agcarm.co.nz.

These products protect public health, improve animal welfare and help environmental management. They:

- Play a pivotal role in growing high yield, sustainable food and fibre products;
- Help supply healthy, nutritional and affordable food;
- Keep New Zealand's agriculture, horticulture and forestry sectors internationally competitive.

Our members are committed to safety, innovation and product stewardship.