Statement on Veterinarians and Manufacturing of Veterinary Medicines

This statement should be read in conjunction with:

- the Veterinary Medicines section of the VCNZ Code of Professional Conduct and related explanatory notes
- MAF Guidance on Manufacturing and Developing a Documented System to meet conditions of exemption from registration for Compounded Veterinary Preparations under the ACVM (Exemption) Regulations 2011

Introduction

There are three kinds of exemptions from registration in the ACVM Regulations 2001 based on:

- recognition of the profession. This exemption relates only to veterinarians (using human medicines, compounding preparations, or using under MAF permit).
- the kind of product ie the way the product is made or the ingredients used (ie homeopathic and herbal preparations).
- the scope of claims made about the product (eg to treat a kind of condition, coughing, diarrhoea, minor injuries and skin abnormalities, etc

The three exemptions are not mutually exclusive. A veterinarian could be compounding a herbal preparation for the topical treatment of a minor injury in an animal.

Three separate entries in the Regulations provide exemption from registration.

However there must be at least one relevant entry in the Regulations relevant to what a veterinarian is doing (or making) or else the resulting preparation must be registered.

Compounding vs manufacturing

A number of the activities involved in compounding and manufacturing are the same (eg developing the master formulation, formulation, packaging and labelling, quality testing).

The distinction between the two is that the outcome of manufacturing is a trade name product destined for general sale, while the outcome of compounding is a preparation designed to treat a particular animal (or group of animals) in a particular case.

By virtue of a prescribed exemption from registration, veterinarians can **compound** a preparation (referred to as a compounded veterinary preparation CVP) that would otherwise require registration. The preparation must be for a particular animal (group of animals) in a particular case. For example, a veterinarian can prepare a solution for treating corneal ulcers for an animal under his or her care.

To take advantage of the exemption from registration veterinarians must have a documented system in place governing the compounding activity. The relevant clauses of the ACVM (Exemption) Regulations are 7, 10, 12 and 14. These are explained in more detail in the MAF Guidance on Developing a Documented System to meet conditions of exemption from registration for Compounded Veterinary Preparations under the ACVM (Exemption) Regulations 2011.

Veterinarians cannot **manufacture** a preparation for general sale as a trade name product under the same prescribed exemption from registration for compounded preparations. The same solution for treating corneal ulcers would require registration before it could be manufactured and offered for sale as a trade name product. A veterinarian would have to meet the same requirements for registration as any other registrant/manufacturer.

Other exemptions from registration

A veterinarian, like anyone else, can manufacture a trade name product that fits any of the product groups (based on scope of claims) specified in schedule 2 of the ACVM (Exemption) Regulations 2011. For example, a veterinarian can manufacture, without registration, a saddle sore trade name product to be applied topically, as long as the ingredients are not absorbed systemically, and do not include prescription medicines (ref Medicines Act), antibiotics, hormones or any substance prohibited by countries importing NZ primary produce. The directions for use must make it clear that it is for the treatment of minor injuries or to prevent dermatological abnormalities. Claims to treat more serious problems would nullify the exemption from registration.