

VETERINARY MANUFACTURERS & DISTRIBUTORS ASSOCIATION

AMENDMENT TO SUBMISSION TO

The Senate Rural and Regional Affairs and Transport Legislation Committee

Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill

Amendment provided as advised at the Committee Hearing February 4th, 2013

I have attached the amended information relating to compounding which was discussed at the hearing. The amendment includes an expanded explanation of the problems with the practices of some compounding companies, and our suggested wording for an amendment to the Agvet Code which would alleviate the problem. The changes from our original submission are highlighted.

Compounding and the Definition of a Veterinary Chemical Product

The illicit availability of compounded products from some suppliers threatens the welfare of animals (no controls on quality of ingredients or the manufacturing process). This is effectively illegal manufacture of unregistered products in unlicensed facilities and undermines the regulatory processes administered by the APVMA.

At present the Agvet Code specifies that compounding must be carried out “in the course of the practice, by the person preparing the substance or mixture of substances, of his or her profession as permitted by or under a law of this jurisdiction”. Where a breach of these rules such as manufacturing of batches, supply of more than is necessary for the treatment of one animal, advertising of specifically formulated finished products etc. occurs, the regulatory agencies for compounding pharmacists claim that they cannot act on matters relating to veterinary products, and the APVMA claims that it cannot act where it is necessary to first identify and deal with a breach of the legislation of another jurisdiction. This has created a “black hole” where this illegal and potentially dangerous manufacture of veterinary medicines in unlicensed premises is not able to be prosecuted.

In addition to the current remedial actions underway involving various levels of government, the professions, and industry, the VMDA recommends that the definition of a veterinary chemical product in the Agvet Code is amended to ensure that:

- a) the rules of compounding for veterinary products are specified so that it is not necessary to rely upon legislation in another jurisdiction to assess if the product meets the definition of a compounded product and,
- b) where a registered product exists which would be suitable for the treatment required, compounding of a copy of that product or an alternative presentation of that product without a valid pharmacological or dosage reason, would NOT BE EXEMPT from the provisions of the Agvet Code.

In other words, any copy of a registered product must also be registered and meet the required standards for ingredients, manufacturing principles (GMP) and premises, as is the case for licensed manufacturers, and SHOULD BE the case for compounding pharmacies.

Proposed amended definition of a veterinary chemical product:

Agvet Code

Schedule

Part 1

S. 5 (4) (a)

A veterinary chemical product does not include:

(a) a substance or mixture of substances that is:

- (i) prepared by a pharmacist in accordance with the instructions of a veterinary surgeon; or
- (ii) prepared by a veterinary surgeon;

as a single course of treatment for one identified animal for a specific identified condition and provided that:

- (iii) there is no registered veterinary product available for the treatment; or
- (iv) there is no registered veterinary product available for another species or for a different condition which would be suitable for the treatment, or
- (v) there is no registered human medicine available which would be suitable for the treatment or
- (vi) there is a specific requirement by the veterinary surgeon for a dosage form or concentration of active ingredient/s, not available from the above options

(b) a substance or mixture of substances declared by the regulations not to be a veterinary chemical product.

Jim Adams
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