



Pharmacy Board of Australia

Submission on Compounding Guidelines

July 6, 2014

The Veterinary Manufacturers and Distributors Association (VMDA) is a peak body representing registrants, manufacturers, distributors and consultants engaged in the veterinary pharmaceutical industry in Australia. Our members include more than 30 companies employing Australians in support of our local industry and export markets.

The VMDA supports the right of pharmacists and veterinarians to compound medicines where necessary for the welfare and wellbeing of patients, including animals. We recognise that there are situations where existing available medicines and/or dosage forms may not be suitable for a particular patient.

We commend your Guidelines as published, in particular the reference to Veterinary products:

Veterinary products

Pharmacists who intend to compound simple and complex veterinary products are expected to have undertaken education in the compounding of products for the treatment of animals and to have undertaken sufficient training.

and the definition of compounding in the Guidelines:

Compounding means the extemporaneous preparation and supply of a single 'unit of issue' of a therapeutic product intended for immediate use by a specific person in response to an identified need. For the purposes of these guidelines, the practice of compounding is classified as either simple or complex compounding. Unless otherwise stated, the guidance provided in these guidelines applies to both simple and complex compounding.

However we have for some time been concerned at the activities of some compounding organizations that are supplying veterinary medicines outside

of the rules and principles of compounding. This is an apparent breach of the Agvet Code, the Act of Parliament governing the registration and manufacture of veterinary medicines, administered by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The relevant section of the Agvet Code 1994 (as amended 2014) is as follows: (underlining and emphasis is ours)

5 Definition of *veterinary chemical product*

(4) 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;

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;

It is our contention therefore that for compounding to be legitimate and permitted under the Agvet Code the preparation of any such substance must be ‘in the course of the practice.....as permitted by or under a law of this jurisdiction’.

Any manufacturing and supply of veterinary medicines that falls outside of legitimate compounding is therefore a breach of the Agvet Code and can be considered to be illegal manufacture of unregistered veterinary medicines.

Specifically, we are concerned with compounding chemists ‘manufacturing’ batches of product, developing and advertising their own specific formulations and pricing, and manufacturing products without adequate attention to quality assurance and target species safety. While the compounding activities are theoretically at the request of the prescribing veterinarian and therefore responsibility for the suitability of the compound, dose rates etc. lies with the veterinarian, it is clear that in the cases of concern to us the compounding pharmacy has initiated the formulation and is in reality advertising and supplying a finished product to the veterinarian.

Supply to the market of copies of existing registered veterinary medicines, while not explicitly prohibited, is clearly disadvantageous to the local industry which must comply with registration and manufacturing quality standards, while the compounded medicine is “exempt” from these requirements.

The salient issues are therefore:

- Risk to animal health and safety due to inadequate safety and efficacy data to support the formulations provided.
- Risk to trade and public health from inadequately formulated and researched products used in food producing species.

- Risk to the viability of the local manufacturing industry and ongoing product development due to unfair competition from unregulated entities.
- Failure to act in what is a growing ‘market segment’ will encourage others to enter this market, resulting in even more widespread illicit activities and difficulties in policing and controlling the availability of improperly formulated, manufactured and marketed drugs.

While acknowledging our concerns and those of others including the veterinary profession, the APVMA has consistently maintained that:

- They are unable to prosecute a breach of the Agvet Code where such a breach is dependent upon a breach of another Act of Parliament under which the APVMA has no authority.
- Even where they have clear evidence of breaches of the advertising provisions of the Agvet Code, such breaches do not warrant prosecution because of a lack of sufficient ‘public interest’ for the Director of Public Prosecutions to act. (While it is clearly the responsibility of the DPP to decide matters of ‘public interest’, the APVMA has improperly made this determination for itself in advance and so not even submitted the evidence to the DPP for consideration).
- When conducting ‘pre-announced’ premises inspections of compounding pharmacies, they have been ‘unable to find’ evidence of any ‘bulk manufacturing’ or ‘stockpiling’ of product (despite the advertising by some of these organisations promising manufacturing and delivery terms that could not be met by extemporaneous compounding).

In addressing the issue of illicit compounding, the VMDA has been instrumental in forming a ‘Compounding Working Group’, chaired by VMDA Vice-President Ian Saunders, and including representatives from the APVMA, the Commonwealth Department of Agriculture, State Governments, the Australian Veterinary Association, Australian Veterinarians in Industry, and PCCA Pty Ltd, representing compounding pharmacists.

This Working Group is in agreement with the concerns raised by the VMDA and believes that the long term resolution of the problems lies in attitudinal change on the part of veterinarians and pharmacists to comply with both the spirit and the law of compounding, and legislative change which will make clear the requirements necessary for legitimate compounding to take place, and to specifically prohibit those activities that are ‘manufacturing masquerading as compounding’.

The VMDA believes therefore that the following key elements if addressed, will lead to a satisfactory environment where legitimate compounding will continue to be advantageous to the pharmacy and veterinary professions and their patients:

- **A clear and concise explanation for the professions of what is legitimate compounding and what is not. To this end the Australian Veterinary Association has developed and published “The Australian Veterinary Association (AVA) Guidelines for the Preparation and use of Compounded Pharmaceuticals”. A copy of this document is attached to the email with our submission.**
- **Inclusion in the Australian Pharmacy Board Guidelines of a specific reference to Veterinary Medicines (not just those for food producing species) and the Agvet Code, so that there is a direct link between the rules of compounding for pharmacists and the compounding of veterinary medicines that would render pharmacists in breach of their own guidelines if they fail to follow the rules in respect of veterinary medicines, and facilitate prosecution by either the pharmacy regulator or the APVMA.**
- **The introduction of a ‘Cascade System’ similar to that existing in the United Kingdom. This would ensure that veterinary medicines are only compounded where there is a genuine need with no viable alternative. A cascade system would work as follows:**

If there is no veterinary medicine authorised in Australia for a specific condition, the veterinary surgeon responsible for treating the animal(s) may, in order to mitigate unacceptable suffering, treat the animal(s) in accordance with the following sequence:

- (a) a veterinary medicine authorised in Australia for use in another animal species or for a different condition in the same species; or, if there is no such product**
- (b) either**
 - (i) a medicine authorised in Australia for human use, or**
 - (ii) in accordance with an import approval from the APVMA, a veterinary medicine from another country acceptable to the APVMA;**
- or, if there is no such product;**
- (c) a medicine prepared extemporaneously, by a vet, pharmacist or a person holding an appropriate manufacturer’s authorisation.**

If the animal(s) are food-producing animals, then the following additional conditions apply:

- the treatment in any particular case is restricted to animals on a single holding**
- any medicine imported from another country must be authorised for use in a food-producing species in the other country**
- the pharmacologically active substances contained in the medicine must**

have MRLs

- the prescribing vet must specify an appropriate withholding period, having regard to any statutory minimums in the Regulations
- the prescribing vet must keep specified records.

A medicine prescribed in accordance with the cascade may be administered by the prescribing vet or by a person acting under their direction.

Responsibility for the prescription and use of the medicine remains with the prescribing veterinary surgeon.

The VMDA commends your review of compounding guidelines and requests that you consider our input when finalising them.

A handwritten signature in black ink, appearing to read 'Jim Adams', with a long horizontal flourish extending to the right.

Jim Adams
President / Executive Director
VMDA
June 6, 2014