VMDA
The Veterinary Manufacturers and Distributors Association Ltd
ABN 29 819 231 380
PO Box 789 Bowral NSW 2576
Telephone: 0447 715 515
Email: vmda@vmda.com.au Website: www.vmda.com.au

Committee Secretary
Senate Rural and Regional Affairs and Transport Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

By Email: rrat.sen@aph.gov.au

Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Veterinary Manufacturers and Distributors Association

Submission

With Australia's unique position in agriculture, we should have one of the world's best animal health industries. Our producers should have access to low cost veterinary medicine inputs and be the recipients of innovation and technology which can help them in a competitive global environment, and our pets should have cost-effective treatments available to them.

Instead, the APVMA has become a barrier to the provision of low-cost products by demanding unnecessary data for a range of common commodities. In addition, the barriers to development of new products rank among the highest in the world. The result is that foreign earnings are enhanced while local development, manufacture and production are disadvantaged. We are being strangled by the current regulatory environment. This needs to be addressed as a matter of urgency.

The Veterinary Manufacturers and Distributors Association (VMDA) is one of the peak bodies representing the animal health products industry in Australia.

Our membership comprises companies both small and large, mostly manufacturing and supporting jobs within Australia. VMDA members are responsible for the manufacture and marketing of the largest number of registered veterinary chemicals of any representative group in our industry.

We have attached the VMDA submission to DAFF on the legislative changes for your information.

However, in the interests of expediency, we also note here the elements of the legislative changes that we believe still require addressing, and those issues from our submission which we believe are of particular importance to our industry, to trade, and to the health and welfare of the animal population of Australia.

MQL:

The VMDA seeks assurance that the successful Manufacturing Licensing Group will continue to be administered by the current MQL group financed by industry with standards maintained by the current auditing system, and that it is run independently of the Compliance Group.

The role of MQL and its contracted auditors is to ensure that everything in the manufacturing area is in accord with the Australian Code of GMP for veterinary chemical products, and under the new Cost Recovery arrangements it will be fully cost-recovered.

The role of "Compliance" is to police the registration system financed by the central APVMA funding, and manufacturers are entitled to be assured that the system for which they are paying operates as agreed, albeit independently.

Cost of Reform Implementation:

The VMDA is concerned that the cost of implementation of some key elements of these reforms (e.g. the re-registration system) is dependent upon the introduction of changed fees as proposed in the Cost Recovery Discussion paper (December 2011), despite the fact that these Cost Recovery arrangements cannot be finalized until the "First Principles" cost recovery process has been assessed and agreed and therefore the introduction of these elements of the reform package would appear to be not sustained by certainty in funding.

Re-Registration:

The VMDA continues to oppose the concept of re-registration for Vetchem products on the basis that this appears to be aimed specifically at Agchems which do not have a GMP manufacturing scheme, established standards, and approved actives. Vetchems have also had in place for many years an Adverse Experience Reporting Program which readily reflects problems in the field with any registered product.

All of these elements are present, active and enforced for Vetchems, ensuring a level of quality that is not available for Agchems.

We recommend restricting the re-registration scheme to Agchems which are clearly the target for outside pressure groups.

Data Protection for Companion Animals:

The Australian industry is opposed to this extension. From available information, Australian companies have been unable to acquire data utilizing resources protected by "Data Protection". To extend this protection to companion animals will deprive Australian Industry of products specifically developed for Australian conditions and which, for the equine industry, form a substantial export market to more than twenty countries.

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 situation is effectively illegal manufacture of unregistered products in unlicensed facilities and undermines the regulatory processes administered by the APVMA.

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 where a registered product exists, compounding of a copy of that product would NOT BE EXEMPT from the provisions of the Agvet Code. In other words, any copy of a registered product must also be registered, as is the case for licensed manufacturers, and SHOULD BE the case for compounding pharmacies.

Proposed amended definition of a veterinary chemical product:

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; and must not be

(iii) identical or closely similar to a currently registered product;

or

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

The VMDA is supportive of Better Regulation and the associated legislative reform required to accomplish the necessary and practicable changes.

The VMDA supports science-based risk assessment. We support the proposed development, publishing and implementation of a risk framework for APVMA decisions.

Where changes are demonstrably beneficial for animal welfare and other key considerations, even at a cost to industry, we remain supportive and have indicated that support in previous submissions on regulatory reform, cost recovery, etc.

Yours sincerely

(signed)
Jim Adams
President/Executive Director
VMDA