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Agvet Chemicals
(Better Regulation Reforms) Section
Department of Agriculture, Fisheries and Forestry
Canberra ACT

By Email to: agvetreform@daff.gov.au

VMDA Submission
Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012

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.

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

We do however, recognize that some of the proposed changes are not necessary and believe that the intended outcomes can be achieved by existing or different options which do not have adverse consequences. Further, where costs are not justified in terms of the outcomes to be achieved, or the impost on industry would have greater adverse effects than the initially expressed concerns, the VMDA suggests that the suggested alternative options and/or maintenance of the status quo, be adopted.

The VMDA notes that many of the changes suggested by this organization and others have been made in the revised draft, but equally there are many more that have not been addressed. We commend the positive changes made and urge that further amendments suggested by the VMDA and other bodies be reconsidered.

Sincerely,

(signed)

Jim Adams
President

There are several positives in the amended Draft Bill which are deserving of support:

- The VMDA supports science-based risk assessment, and commends the publication of the Risk Compendium.
- The electronic lodgement of applications will enhance and streamline the application process.
- No impediment to the use of relevant overseas assessments and decisions including reliance on those overseas decisions.
- Overseas holders of registrations and approvals will be required to appoint a nominated agent in Australia.
- Continuing recognition of the BP(Vet), EC (Vet), BP and USP (Vet) standards for veterinary active ingredients.
- Improvements to predictability and transparency of APVMA science-based decision making.
- Recognition that data required for approval of low risk products can be proportionate to the risk.
- We understand that the data requirements for "re-registration" will now consist only of what a registrant "has or would be expected to have", and in this case the VMDA supports this latest clarification, while still maintaining overall that the re-registration system for Vetchems is a waste of financial and human resources.
- The "triggers" for reconsideration have also been clarified to mean that overseas bans must be from two authorities in DIFFERENT JURISDICTIONS and that their decision/s must be to BAN ALL USES of a chemical or product before their actions create a "trigger" for the APVMA to reconsider a product or active. We also understand that once activated and reconsidered, if the product is approved to remain on the market in Australia, it cannot be "re-triggered" before the next re-registration period (i.e. 7 – 15 years). Again with the proviso that we do not support the re-registration process, we commend the changes to the reconsideration arrangements.

<u>Areas of concern:</u>

<u>MQL:</u>

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.

The MQL system must be run independently of the APVMA Compliance Group. The role of the APVMA auditor is to ensure everything in the manufacturing area is in accord with the Australian Code of GMP for veterinary chemical products. Australian auditors are required to have many years of practical manufacturing experience.

The role of "Compliance" is to police the registration system financed by the central APVMA funding, whereas under the new (proposed) Cost Recovery arrangements Manufacturers Licensing is "cost-recovered" 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 finalized.

This process will still be ongoing at the time of the scheduled introduction of the amended Agvet Code and therefore the introduction of these elements of the reform package would appear to be not sustained by certainty in funding.

Pre-Application Assistance:

While the VMDA appreciates the intention to provide pre-application assistance to applicants, and to rebate the cost of this from the application fee, we believe that a better, optional arrangement would be for this assistance to be provided during the application's assessment when further information may come to light which requires additional consultation. Should an applicant request assistance both before and during the application process, then full cost recovery should apply.

Preliminary Assessment:

11 (1) …"APVMA must complete a preliminary assessment within one month…" and (3) "otherwise the APVMA must refuse the application" would appear to suggest that if the APVMA fails to complete its assessment within the prescribed time due to internal failures, the application will be refused. This needs to be clarified or amended.

11 (4) We commend the change which allows the application to be altered after it has passed preliminary assessment, on the basis that this will allow the correction of minor errors (from either side) without compulsory rejection of the application due to "apparent defects" which may or not be valid.

HOWEVER, we reject 11(3) which still maintains that an application that "appears" not to meet the application requirements must be rejected without the applicant (at this early stage) having the opportunity to correct any administrative deficiencies or omissions. This imposes an unnecessary burden on industry and in fact creates more work for the APVMA to subsequently re-assess the entire application if it is re-submitted. We recommend that "may" replaces "must" in this sub-section.

Reconsideration:

This has the potential to deprive veterinarians, farmers and animal owners of proven products. The focus should be on veterinary products with reported adverse experiences, including the "triggers" discussed earlier. Further, Section 30 (1) is an invitation to anybody including special interest groups to "swamp" the APVMA with potentially frivolous demands for reconsideration, which will have to be considered utilizing valuable and scarce resources.

We recommend deleting or modifying this section.

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.

In addition, more than half of registered Vetchems have more than one active constituent which further complicates the concept of re-registration when one of the actives is due for re-registration at an earlier time than another active in the product, or earlier than the product itself.

The program is also indicated to impose a significant and unnecessary net cost on the APVMA at a time when its running costs are under scrutiny and pressure.

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 by the world renowned innovators in Australia.

Australian developed and manufactured products for the equine industry form a substantial export market to more than twenty countries. This will be retarded if we do not have free access to available data.

Sections 112 and 123 – Issuing of Permits and Licences:

The VMDA regards the restrictions in both of these sections which prohibit the issuing of Permits or Licences to persons or corporations considered responsible for breaches of relevant legislation at any time in the preceding 10 years to be draconian.

It is entirely feasible that a person or corporation responsible for even an administrative breach which has been zealously pursued by the regulator could have their ability to operate in their chosen field removed. Even a breach of a permit condition could lead to a manufacturing licence subsequently being not granted. The punishment in instances such as this threatens to significantly outweigh the crime.

Although the legislation provides for the APVMA to still allow a licence or permit to be issued in "Special Circumstances", that criterion is too vague and subjective to be relied upon when considering the livelihood of an individual or the continued operation of a company upon which families depend.

We recommend that the "must" is amended to "may", allowing for negotiation and/or argument.

Licence cancellation to prevent risk of…:

Similarly, the VMDA cannot conceive of a situation where the entire manufacturing licence of an entity would need to be cancelled to prevent "imminent risk…", as opposed to simply suspending or cancelling the registration of the product concerned.

As mentioned in our earlier submission, we well remember the unfair impost on businesses and the families of employees caused by the peremptory and unnecessary actions of the TGA in the Pan Laboratories fiasco, not to mention the cost to the taxpayer.

We recommend that this option is removed from the legislation.

Concerns with extemporaneous dispensing (veterinary compounding):

2.1 Compounding pharmacies are currently preparing products which are closely similar to registered products and supplied to veterinarians as replacements for registered products.

2.2 This practice is becoming widespread, particularly in the equine and small animal veterinary fields. Veterinary products prepared by compounding pharmacies are not subject to the rigorous controls of registered products. Compounded products are not manufactured under GMP and there are no trials conducted of their efficacy or safety. The use of compounded products is becoming widespread increasing the risk to animal safety.

2.3 The definition of a veterinary chemical product allows for veterinarians to purchase from a compounding pharmacy any product. If this definition was tightened to exclude products closely similar to registered products this practice would be reduced.

We recommend that the definition of a veterinary chemical product be amended as follows:

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.

Summary:

The VMDA has supported many elements of this legislation, and generally supports the concept of Better Regulation Reform.

We do however believe that there are significant unintended consequences which have not been clearly identified by government, but which have been identified by various submissions made over the course of 2012, and that these should be incorporated in the Bill where they do not (and this is mostly the case) adversely affect the overall aims of the legislation.

Jim Adams
President
6 November 2012