Submission to the Productivity Commission:

Review of Regulatory Burdens on Business-Primary Sector

The Veterinary Manufacturers and Distributors Association Ltd (VMDA) has notified the Commission that it will provide a Submission in relation to the above-mentioned review. Its Submission is provided below.

By way of background VMDA, among other things, makes representations and interfaces with Australia's Agricultural and Veterinary Chemicals (AgChem) Regulator - the Australian Pesticides and Veterinary Medicines Authority (APVMA) - and the Department of Agriculture Forestry and Fisheries (DAFF).

VMDA is a member-driven organisation, and members are encouraged to contribute to the successful future of the animal health industry by sharing their concerns and expertise with colleagues. The majority of member companies are manufacturers operating in NSW, Victoria, Queensland and South Australia. Current membership consists of 28 manufacturers, 4 consultant member companies (that service manufacturers) and 2 wholesalers that operate in a number of states.

Of the 28 manufacturers 4 are international companies and their turnover varies from slightly approximately $10 million to $65 million per annum. The bulk of the manufacturing membership consists of small to medium Australian owned enterprises whose individual turnover of registrable veterinary products varies from $1 million to $10 million. In addition, 9 of the manufacturer members are also members of PIAA, another industry organisation that VMDA represents at industry forums such as the Industry Liaison Committee of the APVMA. In terms of total turnover this grouping represents almost half of the Australian animal health market.

VMDA has been provided with the Commission's Issues Paper and in accordance with the guidance provided in that Issues Paper our comments are not limited to legislation and formal regulations, but also include quasi-regulation, such as codes of conduct, advisory instruments and notes. The focus of our Submission is on four matters.

1. Complex Federal /States Institutional Structure leads to long delays

VMDA recognises that in a federation such as ours consultation/decision making mechanisms under the Constitution between Commonwealth agencies/government and state agencies/government are essential in order for the National Registration Scheme (NRS) for Agricultural and Veterinary (Agvet) Chemicals to work. The institutional arrangements are as follows:

Primary Industries Ministerial Council (PIMC), consisting of the agriculture ministers from the Commonwealth Government, the States and Territories and New Zealand. PIMC seeks advice on agricultural and veterinary chemical issues from a committee of experts, the **Product Safety and Integrity Committee (PSIC)**.This committee includes high level representatives from Australian and State/Territory government primary industry or agriculture departments, CSIRO and the APVMA. In turn the PSIC gets advice from sources such as the **Registration Liaison Committee** (RLC) consisting of representatives of APVMA and state agencies.

However, out of the complex system, as described above, it appears to VMDA that the States almost have **veto** powers on matters under consideration for inclusion in regulations, APVMA guidelines and notices. We cite two issues as examples.

a) Industry, that is, our Association, and others have been advocating for years to have a fast-track arrangement for veterinary products requiring a lower level of registration called Listed Products. In 2004 the Code was amended to enable a system of listed products to be implemented. We understand that because of insistence by some States the legislation was framed in such a way that regulations needed to be put in place relating to standards required for such products etc. The legislation now requires the Minister to approve **each** listed product. The legislation has been interpreted in such a way that the system that has been established is so slow that to date no regulation has yet been put in place, in spite of the best efforts of officials. Following our representations the APVMA agreed that the arrangement needed changing to one where the CEO, APVMA has the power to authorise the standards etc for Listed Products. This was eventually agreed, even though there was resistance by one State on the matter. We have recently been assured that we will get a system that is truly fast-track and less expensive than the normal registration of product along the lines we agreed with APVMA.

b) For some time VMDA has made representations not to provide Annual Returns to the APVMA. We have been advised by DAFF that the Annual Returns required by the APVMA are required under the Government's international obligations.

However, the accuracy of the data so collected leaves much to be desired as it is patchy and involves a high degree of double-counting. Our arguments in favour of dropping the requirement were so compelling that the Commonwealth Department of Agriculture Forestry and Fisheries (DAFF) put a paper to the PSIC in May 2007 seeking its agreement to a review of the annual return provisions of the *Agricultural and Veterinary Chemicals (Administration) Act 1992 (*the Administration Act).

We have been informed that:

> "*the Committee's (PSIC) deliberations on this paper, a number of jurisdictions were reluctant to support the proposal to remove the annual return requirement from the Administration Act because of its potential usefulness for targeting where, and for which chemicals, usage data should be collected. In this regard, the Committee acknowledged that the current information collected from chemical manufacturers and importers has limited value in a chemical usage sense. The Committee also noted that the Tasmanian Government was conducting a data usage collection exercise in its jurisdiction which, if successful, could be used by other governments to collect usage data in their respective jurisdictions. Accordingly, removal of the current provisions in the Administration Act, at this stage, was considered to be premature until such time as a better alternative is available.*
>
> *The Committee therefore decided* ***not*** *to support the proposal to remove from the Administration Act the requirement for registrants to provide annual returns to the APVMA. However, it agreed that the proposal should be re-considered once the Tasmanian Government's data collection work is completed, which is anticipated to be before the next Committee meeting in November this year."*

These are only but two examples that serve to illustrate how the process of regulation making etc under the current arrangements can inordinately delay matters and thus impose a cost on industry.

VMDA Recommendation

In considering the solution to the slow processes, mentioned above, we make the following **recommendation** which is anchored in a precedent. We recommend that delays in a regulatory sense can be overcome by adopting similar arrangements as are

current in respect of Poisons Scheduling. By law, State health departments are responsible for scheduling matters, and rather than go through the difficult process of changing those laws, each State cedes the scheduling decisions to the Commonwealth via the National Drugs and Poisons Scheduling Committee (NDPSC). The States have agreed that they will universally and uniformly adopt the scheduling decisions of the NDPSC. The APVMA and the States have often cited the legislative involvement of the States in the NRS as the (non-changeable) reason for having to defer to some States on issues such as control of use, which products they object to, etc. It would be a simple matter for the States to adopt the same type of instrument to cede to the APVMA the decision-making process on all agvet chemicals and to agree to adopt the subsequent decisions.

2. Harmonisation of Control of Use

Under the NRS the control of use of Agvet Chemicals registered by the APVMA is exercised by the States. However, 'control of use' issues differ from State to State. Differences are generally related to specific diseases and are often confined to **crop chemicals** because of the diversity of what is grown in different geographical/climatic areas. Such differences rarely occur with vetchems except where there are specific pests which may affect say, cattle in Queensland and which are not a problem in non-tropical areas. VMDA would however comment that differing instructions for application rates, uses etc. based upon pests which may behave differently in some climatic regions may well be a justified position.

Other current impediments are:

1. For each State a separate permit is required for salespersons selling S4's to vets concerning the type and amount of samples they can take with them in their cars.

2. Each State has its own animal ethics requirements, which are based on the NRS but they each vary slightly such that they require their own set up. Approval by an animal ethics in one State does not permit trials to be undertaken in another State.

VMDA considers these arrangements to be unnecessary duplications of work and effort, fairly typical of state empire building.

VMDA Recommendation

We recommend that such matters could however be handled by the APVMA without the input of the States except on an advisory basis.

3. Greater Risk Management by APVMA to reduce regulatory burden

Risk management is considered a key part of APVMA activities, particularly during product registration assessment, yet there is very little detail on how this assessment is performed.

Any risk assessment should include risk management strategies such as known properties of the product, experience/advice of suitable overseas regulators, GMP, label instructions etc.

The APVMA should develop clear guidance on the preparation and evaluation of risk/benefit analysis; this should improve the transparency of assessment reports and regulatory decisions. This would also then feed into MORAG (Manual of Requirements & Guidelines).

- Currently the APVMA requires certain products be trialled across several States, this is often not justified.

- Animal ethics considerations encourage researchers to use a few animals as possible, yet MORAG insists all products for use on food producing animals be efficacy tested in Australia, even when they may have been tested overseas unless strong justification is put forward.

- The APVMA has signed a number of agreements with overseas regulators allowing for more co-operations between agencies. This co-operation should be used to reduce data requirements.

Apart from the above, VMDA has been at the forefront in recommending to APVMA the use of listed products considerations (see our item under heading 1) for exempting certain products, called reservations, from the purview of registration altogether. This would involve greater risk management. To Parma's credit, it has recently moved to consider products for reservation and it has recommended their acceptance to the PSIC. Prior to that, it has produced a paper entitled "Scope of APVMA regulations" which our Association has endorsed.

The recent ANAO report on the APVMA entitled "Regulation of Pesticides and Veterinary Medicines" strongly recommends the use of greater risk management by this regulator.

VMDA Recommendation

VMDA recommends greater use of risk management by the APVMA by taking cognizance of the above-mentioned details and the ANAO's suggestions in regard to risk management.

4. Inconsistent application by APVMA staff and outsourced advisors of guidelines and regulations.

The following issues were raised previously by VMDA with the CEO of APVMA.

- Inconsistency between evaluators of similar products or issues
- Failure of the APVMA internal evaluators to interpret and/or amend 'requirements letters' generated by external reviewers
- Failure of APVMA staff to respond within statutory timeframes
- Failure of AMVMA to respond at all
- Inability of reviewers to respond in other than the maximum allowable time
- Failure to provide copies of reviews prior to requesting further data or refusing registration
- Additional requirements requested long after external review
- Requesting technical explanation of data at screening
- Lack of acknowledgement of errors/inconsistencies when decisions were reversed following argument from applicants/registrants

The APVMA has since asked for specific examples. At a subsequent meeting with Joe Smith and Martin Holmes the issue was raised of the fear that many members have developed, of being victimised should they make specific one-on-one complaints. Joe Smith gave a guarantee that this would not occur, and of course said quite clearly they (the APVMA) could never respond directly to industry complaints if they were unaware as to the specifics of the concerns.

It is appreciated that APVMA has guaranteed to respond without recrimination to individual industry complaints, although it is not clear what form those responses might take.

Unfortunately Members are often (usually) reluctant to share the details of their problems with other Members, who are often their commercial competitors and it has proven difficult to obtain details of individual cases to put to APVMA for review.

However, individual cases can (should) be seen as representing examples of matters that are of concern to industry and the most satisfactory solution is to deal with the general principles and practices rather than just put out bush fires as they occur. If APVMA can accept that approach and accept that the list above identifies areas of concern to Industry generally an explanation of the nature of the concerns under each dot point should enable a review of principles and practices to determine what can be done to improve APVMA's service to Industry.

4.1 Inconsistency between evaluators of similar products or issues

These inconsistencies take a number of forms. Some examples are:

a). Labels & leaflets
As part of a corporate rebadging a number of labels/leaflets were submitted for approval of name changes and minor reformatting/rewording to make the labels more compliant with the labelling code. The labels were not treated as a suite of documents as was requested. Rather they were dealt with by three individuals who each required a different set of alterations to be made. A considerable amount of time and effort, (including a visit to APVMA in Canberra) was required to resolve a problem that should not have existed. The individuals handling the changes appeared to be essentially clerks with little to no technical understanding of the contents of the labels and their recommendations were not vetted by a technically competent person.

Other problems encountered relate to the interpretation of what constitutes an acceptable product name and method of application.

b). Trial protocols
Companies that seek approval of trial protocols before undertaking field trials have had no guarantee in the past that the reviewer who approved the original trial protocol will be the reviewer who reviews the trial report once the trial is completed. This has led to the ludicrous situation where a company has had their trial protocol approved, only to be advised following review of the final report that the trial was of unsatisfactory or unacceptable design.

4.2 Failure of the APVMA internal evaluators to interpret and/or amend 'requirements letters' generated by external reviewers

A not infrequent cause of complaint by Members is that APVMA does not appear to read (and amend) reviewer's reports (particularly safety and efficacy) to ensure the Reviewer's comments and requirements are consistent with any deficiencies noted and with the requirements of MORAG. Because this is not done, Companies may be obliged to spend unnecessary time and effort in refuting a reviewer's comments and requirements even when they are not relevant to MORAG requirements.

4.3 Failure of APVMA staff to respond within statutory timeframes

It has been a not infrequent complaint that APVMA have not responded with pre-screen or other advice within the statutory time-frame for that advice. This view is enhanced by the lack of transparency in how the time to complete a review is computed.

4.4 Failure of APVMA to respond at all

We understand that individual cases have been referred to APVMA. It is our request that APVMA should take the steps that are necessary to ensure that APVMA officers always respond in an appropriate and timely manner.

4.5 Inability of reviewers to respond in other than the maximum allowable time

Although appreciating the difficulties faced by APVMA in finding reviewers and using external agencies, Industry believes the time frames, in general, are unnecessarily long and frustration increases when those timeframes are apparently exceeded. This view is enhanced by the lack of transparency in how the time to complete a review is computed.

Presumably part of the solution is to increase the number of available reviewers and require them to complete their reviews in the time allotted. The time allotted should also be related to the size and complexity of the package to be reviewed and not simply be related to the statutory time frame.

4.6 Failure to provide copies of reviews prior to requesting further data or refusing registration

We understand that individual cases have been referred to APVMA. It is our request that APVMA should take the steps that are necessary to ensure that APVMA officers always respond in an appropriate and timely manner and that copies of reviews are routinely provided when they are the basis for requesting further data or for refusal of registration.

4.7 Additional requirements requested long after external review

We understand that individual cases have been referred to APVMA. The particular issue here is that external review of a product may raise a number of specific questions that require the submission of further information. After the company concerned supplies the information to answer those questions a further set of questions or requests for data may be made that do not relate to the questions raised in the initial external review.

It should be made clear that only the questions raised by the first external review are required to be addressed and that the only further data that will be required are data to further elucidate the answers to those specific questions.

4.8 Requesting technical explanation of data at screening

Screening is intended to ensure that the applicant has provided information against

all of the required headings in MORAG. It is not intended to be a technical review. VMDA has been advised that, during screening, companies sometimes receive requests for technical detail which has already been provided in the dossier and would be recognisable to the external reviewer. This quasi-technical review at screening may be undertaken by individuals not technically qualified to understand the data or their significance. This leads to delays in processing of the application as the clock is stopped whilst the company responds to an unnecessary request.

- Lack of acknowledgement of errors/inconsistencies when decisions were reversed following argument from applicants/registrants

  This issue has been acknowledged by APVMA and hopefully is being addressed.

VMDA Recommendation

VMDA recommends that the Commission give consideration to the above-mentioned matters when framing its report to Government.

VMDA
June 2007