Submission to the Productivity Commission:

Chemicals and Plastics Regulation

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 (Ag & Vet Chem) 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 29 manufacturers, 4 consultant member companies (that service manufacturers) and 3 wholesalers that operate in a number of states.

Of the 29 manufacturers 4 are international companies and their turnover varies from 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, some 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. In relation to products excluded by the study, the Issues Paper acknowledges that "Some of these exclusions may create boundary issues in assessing key regulators. For example, the APVMA regulates pesticides (which are included) and veterinary medicines (some of which are not included)" (p8) and "Participants should not feel that they have to limit their comments based on a very narrow interpretation of the industry definition used in the terms of reference. What matters is that the regulatory issues are particular to chemicals and plastics, and may not recognise boundaries created for statistical purposes" (p9). We take it therefore that Veterinary Medicines are included in the study.

The focus of our Submission is on four matters.

1. **Regulations exercised by the States (last Question on p12 of Issues Paper refers)-Control of Use over Agvet Chemicals require harmonisation**

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.

Under the NRS the control of use of Agvet Chemicals registered by the APVMA is exercised by the States and VMDA supports the continued exercise of this regulatory power by the States. However, it is important to note that 'control of use' issues differ from State to State. Differences are generally related to specific diseases and are often confined to **crop chemicals** (agchems) because of the diversity of what is grown in different geographical/climatic areas. Such differences rarely occur with **veterinary chemicals** (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 such arrangements to be unnecessary duplications of work and effort.

VMDA Recommendation

We recommend that control of use regulations between States be harmonised through the Commonwealth States Consultation mechanisms.

2. Greater Risk Management by APVMA (first Question on p13 of Issues Paper refers) 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.

VMDA has been advised that the APVMA is developing a document on APVMA's Risk assessment which it hopes to put on its website. In the meantime VMDA makes the following points to encourage APVMA to include the matters raised in them to be included in the document being prepared. This would also then feed into MORAG (Manual of Requirements & Guidelines). Our points are as follows:

- Currently the APVMA requires certain products be trialled across several States. It is not clear to industry under what circumstances trials across several States are necessary.
- Animal ethics considerations encourage researchers to use as few animals as possible, yet MORAG requires all products for use on food producing animals be efficacy tested in Australia, even when they may have been tested overseas. In this regard VMDA notes that MORAG also states that the APVMA will consider scientific argument that Australian efficacy data not be provided, on a case-by-case and notes that APVMA has registered a number of products on the basis of overseas efficacy data only. It is however not clear under what circumstances, in general, it will accept overseas data for registration.
- 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 (the Globally Harmonised System (GHS) referred to on page13 of the Issues Paper focuses on the pesticides side of APVMA operations.
- 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 3) for exempting certain products, called reservations, from the purview of registration altogether. This involves greater risk management.
- VMDA has welcomed the APVMA initiative entitled "Scope of APVMA regulations" which covers products earmarked for listing and reservation. Our Association has endorsed that paper and it is pleased that that it has been endorsed by the Product Safety and Integrity Committee (PSIC) and subsequently by the Primary Industry Standing Committee.

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

VMDA understands that APVMA has undertaken to pursue this matter not only in terms of its financial management but also in terms of its regulatory arrangements.

VMDA Recommendation

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

3. Complex Federal /States Institutional Structure leads to long delays (first Question on p21 of Issues Paper refers) including implementation of low risk arrangements (listed products)

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) and its Primary Industry Standing Committee, 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 have essentially **veto** powers on matters under consideration for inclusion in regulations, APVMA guidelines and notices. We cite three 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 that can be categorized as *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 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 cumbersome and largely unworkable. Only after some three years have the regulations for certain, very limited, classes of product and

their standards come into force (October 2007). In spite of the best efforts of officials, the legal procedures have proved to be ridiculously slow and convoluted.

- Following our representations the APVMA agreed that the arrangement needed changing to one where the CEO, APVMA has the power to authorize 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.
    - However, it is now necessary for another set of regulations to be put in place permitting the CEO of APVMA to sign off on other products to be classified as listed products. This will again take some time.

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:

> *"in 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."*

c) VMDA has an issue regarding Data Protection Arrangements which were enacted in 2004 (this is strictly a Commonwealth matter, though the States have had an input in the formulation of the arrangements). The issue is the requirement of the regulator making *early disclosures* of applications. This does **not** apply to veterinary products in other countries' data protection arrangements ie Europe or the US. VMDA has pointed out that it is not commercial for any company through *early disclosure* to pre-announce its intention to bring a new veterinary product into the market place. Even the basic name of a product is sufficient for competitor companies to work on developing counter measures in the market place before the new product is released.

- Changing legislation is difficult as it relies on the Parliamentary processes which are time-consuming, even though there is a positive case for change. VMDA considers that the Productivity Commission should recommend to Government to reverse the *early disclosure* provisions for veterinary products in the Data Protection Legislation.

These are but three examples that serve to illustrate how the process of regulation making etc under the current arrangements can inordinately delay matters and thus impose unnecessary costs and delays 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 to those that 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. A similar arrangement should be proposed for agvet chemicals without the States giving away their function of control use (which VMDA recommends should be harmonised through the consultation mechanism -see recommendation under item 1 above). As far as the *early disclosure* issue is concerned we consider that the Productivity Commission should recommend to Government to reverse these provisions for veterinary products in the Data Protection Legislation.

4. Inconsistent application by APVMA staff and outsourced advisors of guidelines and regulations (Questions on p24 of Issues Paper refer).

VMDA has, in the past, raised a number of administration issues with the then CEO of APVMA on matters of greatest concern to members and these were identified in the

ANAO review. APVMA provided written responses to most of these issues. These responses can be found in the APVMA Comments on Factual Errors and Statements Requiring Further Clarification in Submissions in relation to the (Productivity) Commission Study "Annual Review of Regulatory Burdens on Business: Primary Sector". VMDA is of the opinion that, whereas in some instances the APVMA response was appropriate in acknowledging an issue and its significance and identifying appropriate remedial action, in other cases the APVMA response missed the point of the VMDA position.

For instance, VMDA identified as an issue the failure of APVMA internal evaluators to interpret and/or amend 'requirement letters' generated by external reviewers. The APVMA response was to state that 'External Reviewers do not generate requirements letters; the APVMA generates requirement letters.' The point at issue is that external reviewers do not always provide reviews that are fully consistent with the requirements of MORAG and make suggestions in their reports as to what further requirements should be met. When APVMA generates the requirements letter there appears to be little or no evaluation of the reviewer's suggestions to confirm that they are requirements necessary to satisfy MORAG. This then involves the applicant in considerable time and effort to either supply unnecessary data or negotiate the real requirements.

Again, VMDA identified a problem with APVMA staff not always responding within statutory time frames, particularly at application screening or at other times. APVMA responded that 'the statutory time-frame for making an initial determination at screening of an assessment is one month. APVMA statistics show that in approximately 95% of applications, the initial screening determination is made within the one month statutory time-frame.' What this response does not acknowledge is that many of the applications APVMA receives are simple ones that require very little intellectual input. VMDA suggests that the 5% of applications that are not dealt with within statutory time frames are the more complex submissions, such as for immunobiologicals or new actives/products and that such submissions are not appropriately resourced/handled.

Other matters raised by VMDA relate to communication issues and VMDA acknowledges that APVMA is aware of these issues and progress is being made in addressing at least some of them. VMDA looks forward to further progress being made by the newly restructured APVMA.

VMDA Recommendation

VMDA is of the opinion that the solution to these issues is to be found in the implementation of the recommendations of the ANAO Report on the Regulation of

Pesticides and Veterinary Medicines. Recommendations 2, 3, 4 and 6 are particularly relevant to this item (4).

VMDA
October 2007