Australian Veterinary Association

A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals

Discussion Paper Response

10 February 2010
1. **Introduction**

Members of the veterinary profession are highly trained in clinical pharmacology and the appropriate use of veterinary medicines and have obligations to maintain continuous professional development. Use of veterinary medicines is a fundamental part of veterinary practice and supporting the diversity of clinical conditions that are faced veterinarians are assigned various prescribing rights by State Veterinary Practitioner Boards and Departments of Health. It is essential that a national control of use scheme recognise the pivotal position veterinarians fulfil in maintaining the health and welfare of animals in their care and the critical role of prescribing rights and accompanying professional responsibilities.

The following are responses to the questions relevant to the AVA that have been posed and this submission will also provide some general comment on some related issues that our association considers important. This response follows our first submission (Appendix 1) which was presented in July, 2009. The AVA has minimal experience of the actual registration process so we will leave comment on the most effective national structure to others.

We believe that a national scheme must ensure that veterinarians and agriculture and veterinary chemical users have timely access to the most effective and safe veterinary medications/chemicals to ensure Australia’s agricultural productivity, high animal welfare standards and international competitiveness are not compromised.

1. **Recommendations**

**Key areas of focus for the Review:**

1. Residues, food safety and the export market are identified as principal risk areas and these are also seen as ‘public good’ issues and need appropriate government funding.

2. The regulatory framework and registration process currently imposes major costs and delays which translate to potential adverse impacts on animal welfare. An increase in the efficiency of the chemical review process is paramount.

3. Develop national consistency regarding the Control of use of agvet chemicals in Australia (with local needs and conditions recognised in legislation where appropriate).

4. Compile and publicise a list of exceptions to national regulations to accommodate local conditions/requirements (refer Q1 below).

5. Timely access to chemicals, once they have completed the registration process, needs to be provided to ensure Australia’s agricultural industries have the opportunity to utilise the most effective products to maintain efficiency and productivity and enable the highest standards of animal welfare to be maintained. Access to all current veterinary chemicals with improved spectrum of activity, safety and efficacy is vital for Australian farmers to lift productivity and compete internationally.

6. Education and explanation of changes to legislation will need to be disseminated by the relevant authority to all stakeholders as any changes are implemented. This will ensure user compliance and the further development of QA schemes to minimise risks.

7. Manpower shortages can be addressed by contracting overseas experts for data review, in order to avoid delays in the registration process. Another very viable option is for companies to contract experts (approved beforehand by the regulator) that provide an overview of the sectional data and opinions on adequacy or otherwise. This is used in Europe and NZ very successfully. The
argument against (reviewers in the pocket of companies) is not real as those reviewers have to maintain accreditation in order to continue to be on the list of approved reviewers. This also addresses one of the issues of who pays for the review – clearly the company pays for this independent assessment. This has been resisted strongly by APVMA.

8. Research permits for studies. The current system allows for small scale trial permits in limited areas. This is an improvement. If this category does not fit a particular study then research permits have to be applied for with ridiculously long approval times and data needs that are close to what is required for full registration. The data that is available for these studies is often limited (especially in early projects and true R&D companies). This acts as a major disincentive to invest in early stage research in Australia for global product development – it can be done quicker and with less fuss in other regions such as Europe and the US. This is despite the risk of residues being eliminated for example where treated animals are incinerated. There is currently no flexibility.

2. Questions

Questions posed requiring comment on this discussion paper:

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<td>Q1</td>
<td>In either the current state and territory control of use or APVMA responsibilities for agvet chemicals, are there any gaps, overlaps or unnecessary inclusions and, if so, what are they?</td>
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<td>i) Relevant legislation is spread among departments and Acts in most jurisdictions. It is difficult for veterinary practitioners to get a picture of all pieces of legislation affecting prescription and use of agvet chemicals in animals. No summaries of medical, drug, environmental and veterinary legislation are made by central state agencies.</td>
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<td>Gaps and overlaps do occur:</td>
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<td>ii) Responsibilities between State regulatory authorities within a state (e.g. DPI and Dept of Health) can be unclear in some areas – e.g. Control of use – monitoring of compliance feed mills, veterinary clinics with respect to drug use and dispensing - leading to confusion &amp; increased risk.</td>
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<td>iii) Inclusion of animal welfare as a criterion for consideration in registration of both agricultural (pesticide) and veterinary chemicals is required. This would have to be dealt with correctly as it could have serious negative outcomes for control of feral/vertebrate pests if not worded correctly.</td>
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<th>Section 6</th>
<th>The National Registration Scheme</th>
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<td>Q2</td>
<td>How effective are the current registration arrangements for facilitating adequate chemical access for minor uses?</td>
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<td>i) The APVMA provides a robust scientific risk based assessment process but this process can be very slow and leads to unpredictable time frames for registrants. This impacts on registrants’ ability to plan and budget for market access and can seriously impact on the cost benefit of registering a new product including products that are in use overseas. This has a flow on effect of reducing therapeutic...</td>
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options in the field, which can lead to suboptimal industry productivity and have potentially negative impacts on animal welfare.

ii) It is important to have data requirements that will encourage manufacturers to seek registration of new products or uses (minor uses). More support for minor usages must be encouraged, especially for food producing animals. It may be possible to vary standards in the case of minor use, e.g. waive the requirement for a radio-isotope study as the first step in defining tissue residues and animal withholding periods for food animal species closely related to a major food animal species (e.g. to increase the likelihood of developing analgesic agents in sheep). It could also be possible to guarantee the applicant exclusivity of such data generated, in the case of molecules whose patent protection has lapsed, for a realistic period.

iii) Any assessment and review process must be transparent in regards to registration and risk.

### Section 7 Issues for Consideration in Developing a National Framework

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<th>Q3</th>
<th>What particular costs or benefits would arise from greater integration of assessment, authorisation and control of use of agvet chemicals?</th>
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<td>i)</td>
<td>Simpler regulatory environment and greater surety to the practitioner and the client that all requirements are being met, with no additional costs which would reduce costs to the practitioner in seeking to obtain all relevant information.</td>
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<td>Benefits:</td>
<td>Having a better integrated approach to assessment, authorisation and control of use would be of benefit to all stakeholders in providing consistency of approach and well defined boundaries.</td>
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<td>Costs:</td>
<td>The costs associated with greater integration may not be that much greater than those incurred in the existing system – but would be more efficiently applied.</td>
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<th>Q4</th>
<th>What do you take the precautionary principle to mean? What are the potential costs or benefits that could arise from adoption of a more precautionary approach in circumstances where lack of full scientific certainty exists in agvet chemical assessment, registration or control of use?</th>
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<td>i)</td>
<td>Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation or threats to human, animal or plant health. A risk based / outcome based approach is necessary, at the moment, the balance is in favour of no use. Greater use of risk management initiatives with monitoring of effectiveness in reducing risks could be more widely adopted.</td>
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<td>ii)</td>
<td>Prioritise registration requirements. In the case of food animal products, human consumer safety should be paramount and non-negotiable. Locally generated target animal safety and efficacy data requirements, the environment and trade must also be considered. The Australian system is much more strident in practice than European and US requirements despite supposedly all using VICH or OECD guidelines. There is a real lack of expertise in OCS and APVMA for new molecule...</td>
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review. This makes for a no risk policy. OCS also are removed from the interface and are very bureaucratic and non responsive. Toxicology expertise should be in APVMA.

iii) The risk - based approach which has been successfully used by APVMA in these circumstances provides a practical means of assessment which has greater flexibility than employing the precautionary principle.

Q5 How responsively and effectively does the APVMA appear to take up information provided by industry or signatories to the National Registration Scheme?

i) Although the APVMA appears to be sensitive and responsive, this can be seen to be slow and inefficient at times.

Q6 How could information be more effectively provided by industry or signatories to the National Registration Scheme and how could it be better integrated into the APVMA’s regulatory activities?

Section 8 Assessment Registration and Access to Chemicals

Q7 What would be the advantages/disadvantages of adopting an assessment process for new chemicals or products based on an agreed time for an agreed data set?

i) This would allow industry to confidently plan market access and marketing strategies and provide certainty to the process. This will encourage manufacturers to register newer products that will be available to the agricultural industry and veterinarians in a predictable manner.

Q8 What are the most important ways in which the efficiency of the APVMA’s assessment process could be enhanced?

i) Inclusion of animal welfare as a criterion for consideration in registration of both agricultural (pesticide) and veterinary chemicals in developing the animal welfare requirements it will be important to give appropriate consideration to registration of products used in the control of feral animals and vertebrate pests.

ii) Preparedness to consider target animal safety and efficacy data generated abroad (e.g. for the same pathogen species).

Q9 How close is the alignment between chemical/product risk and effort in the assessment process and how best could it be enhanced?

i) One example is the inflexibility of the registration system means that ‘immunobiologicals’ (including their utilization by vets to mass medicate newborn piglets) get caught up in a regulatory framework which takes little account of:

- Overall risk
- Appropriate controls including already existing storage & testing arrangement
- Risk/benefit
- Industry need
- Animal welfare

ii) Could be enhanced by following processes used by other authorities for low risk chemicals or products (e.g. APVMA approach to registering dairy plant cleaning...
Q10  What is the benchmark against which the performance of the APVMA should be assessed?

i) Most applicants have experience with overseas regulatory authorities. When the APVMA announced its registration timetable a few years ago, industry accepted this in the main because it provided a planning framework. The disappointment has been that the APVMA has failed to comply with its self-imposed timelines.

Some of the key measures of the success of APVMA are:

1. Timely and cost efficient availability of all important international Agvet chemical products to Australian industry
2. No unregistered Agvet chemicals illegally available in Australia
3. No adverse events affecting target animal species, human health, environment or trade emanating from label use of any APVMA registered product
4. No adverse events associated with confusing or illegible labels

Other performance measures

- Alignment and benchmarking with overseas agvet regulatory authorities (FDA, NZ, etc) is not obvious and such alignment could lead to significant time and cost savings in registration.
- From an operational perspective, benchmarking with overseas counterparts is likely to provide valuable comparisons regarding all aspects of APVMA’s remit.

Q11  What is the evidence that assessment would be more efficiently performed without the APVMA being required to carry out either efficacy or trade assessment? How would the risks that are currently managed through APVMA assessment of efficacy or trade risk be adequately managed in the absence of that responsibility?

Q12  What would be the advantages and disadvantages of introducing a requirement for re-registration of agvet chemicals after a set time?

i) Advantages: Some products that have been registered for long periods may not meet current requirements for safety; efficacy and OH&S. re-registration would address this.

ii) Disadvantages: added cost to the registrant may lead to deregistration of valuable low volume, low profit products. Some older low risk products would readily meet requirements but usage may not justify costs to registrants of development of registration data research. Good safe chemicals could be lost.

iii) The need for reregistration should be based on risk rather than an obligatory and
| Q13 | Is there a case to be made for revision of the APVMA’s compliance powers and, if so, what improvements are needed?  
   | i) Need to know how effective APVMA has been in the compliance area to answer this. |
| Q14 | Is there evidence to suggest that there would be net benefits from government budgetary support of applications for minor use permits?  
   | i) Minor use permits cover crucial chemicals that could be lost due to the costs of registration not being commercially justified due to the low volume of sales.  
   | ii) Minor use permits for veterinary chemicals may be required for very small numbers of animals to ensure effective treatments are available. The requirement may only be for one owner and both animal welfare and productivity would both be affected if the cost of permits is too high. In this case government budgetary support would enable meaningful increases in productivity.  
   | iii) Registration of some chemicals is justified on the grounds of food safety, animal welfare or environmental benefit but not economic to the registrant e.g. aquatic animal treatments. In this case government budgetary support would enable meaningful increases in productivity. |
| Q15 | What role, if any, could off label access to chemicals for minor use play in an integrated national system?  
   | i) Off label use is and always will be an important tool for minor species/crop health management.  
   | ii) It should be limited to those with training and expertise such as veterinarians.  
   | iii) Off label use of veterinary chemicals is currently well managed in some States through registered veterinarian and plays a vital role in managing animal health and welfare and productivity in minor species.  
   | iv) Off label use of ag chemicals is also important in the management of minor crop health, and auditing systems need to be in place to ensure accountability. |
| Q16 | What are alternative systems for minor use and specialty crops/animals?  
   | i) Minor use permits, as already exist, but with less onerous application requirements. In the USA, FDA has developed a Minor Use Minor Species MUMS) program to facilitate safe and rational use of agvet chemicals in minor species. |
| Section 9 | Control of Use |
| Q17 | What is the evidence that a particular approach to control of use is/is not effective and efficient:  
   | • in agricultural use, or;  
   | i) Registration requirements for low risk chemicals can be onerous.  
   | ii) No coverage of ‘compounding pharmacy’ products used by veterinarians.  
   | iii) Surveillance and policing of unregistered agvet chemicals does not seem to be
well resourced but is viewed as an important priority by the AVA.

iv) Consideration of approaches used by /alignment and benchmarking with overseas agvet regulatory authorities (FDA, NZ, etc) is not obvious and such alignment could lead to significant time and cost savings in registration.

v) Control of use (after the point of sale) encompasses the areas of:

- Training and licensing
- Monitoring and auditing
- Surveillance and enforcement

Control of use is currently managed by the States and Territories and inconsistencies occur with all of the above dot points. Current legislation in some states e.g. WA, is inadequate, unclear and poorly communicated and leads to consequent risks by the end user. Some of these risks include:

- Residues and withholding periods
- Identified risks of serious resistance in human disease bacteria to antibiotics
- Products often not registered but used routinely for particular trade species. Improved awareness is needed of the unacceptability of this practice with farmers and veterinarians.
- Use of drugs to manage OH&S risks
- Impact of drug use on OH&S
- There is generally less risk from farmers who routinely use and are familiar with specific chemicals.

Risk management is more effective when based on education and responsible use and supply.

vi) Off label use (OLU) in ‘on farm’, food animals is also a major area of inconsistency with legislation differing between the States that makes a usage that is legal in one State being illegal in another. OLU is seen as being a significant benefit in the management and treatment of minor species and this usage must be maintained. In the US and Canada there are FDA managed systems such as ‘Minor Use, Minor Species’ (MUMS) to cover this issue which is further supported by the Food Animal Residue Avoidance Databank (FARAD) which assists veterinarians prescribing off label.

- Off label use is also important in companion animal practice eg where some human drugs have to be used in the absence of registered products. Potential impact on human health is carefully examined and addressed through CE and guidelines.
- In urban amenity horticulture or sectors such as management of golf courses and other sporting venues, or;
- In pest and weed control?

Q18 Is there a need for flexibility of control of use to respond to local or regional issues, and how could such flexible arrangements be delivered by a single national regulator, if at all?

i) There must be an ability to have local flexibility (state level) in dealing with local or
regional issues, such as where there are particular industry or environmental (e.g. arid zone/remote zone) influences.

ii) Finalise the ongoing review of the APVMA labeling codes as soon as possible to give force to the proposed new use controls. Controls to be generally consistent with the national control of use principles endorsed by the Standing Committee on Agriculture and Resource Management (now Primary Industries Standing Committee) in August 1999.

iii) State and Territory Health department controls should be subservient to the national control of use regulator who will be responsible for supply and use controls for veterinarians. It is essential in the process of developing national use control legislation that State and Territory poisons/therapeutic goods legislation is not permitted to unintentionally subvert the national use controls.

iv) Controls over feed mills using prescription animal remedies to medicate feeds to be applied by the national control of use regulator rather than State and Territory Health Departments to ensure consistency.

v) Removal of discrepancies in relation to state and territory controls including appropriate regulation of label controls under “Restraint” headings. Many older instructions under “Restraint” headings are inappropriate and not a consequence of an APVMA risk assessment. They unreasonably restrict a veterinarian’s ability to use the product off-label. The APVMA must have the ability to easily require the removal or amendment of such statements. Wording which applicants can use to protect their products from inappropriate use by non-veterinarians also needs to be developed.

vi) As above, clarifying those instructions on the label of a veterinary chemical product which must be followed by the users has long been a problem. Anomalies occur in labelling which can create difficulties for users e.g.

- Products with the same drug active ingredients but differing withholding periods
- Labels with convoluted instructions.

Certain label instructions need to be identified as essential to ensure the desired compliance by users with those instructions. In general all users of veterinary chemical products, who are not veterinarians, should use products only on the animals included on the label and at the dose rates and by the methods of administration indicated on the label. This may require a review of existing label statements. Lay persons should not be given direct access to restricted chemicals. The Standing Committee on Agriculture and Resource Management (SCARM, now Primary Industries Standing Committee) principles provided for veterinarians to treat single animals of a major food producing species with any product. Such low level use on small numbers of valuable animals, or to reduce suffering in individual animals, should present no risk to health or trade. But because there are some important (plant) poisons of stock (for example nitrite and cyanide) for which there are no registered or permitted treatments, it may be more useful to extend this exemption to specific numbers of animals of each species to deal with urgent treatments for poisonings for which there are no approved products (either registered or permitted).

vii) Current State and Territory poisons and therapeutic goods legislation requires a label which identifies the supplying/prescribing veterinarian to be affixed to all supplied/prescribed prescription-only or compounded products. There are considerable differences between jurisdictions in relation to what information is
required on these labels. This labelling is considered to be important in confirming legal supply and identifying the supplier, but could be removed from Health controls and, for the relevant veterinary chemical products, be included in national use controls.

viii) Clear requirements in relation to veterinary use and supply of unregistered products (perhaps some form of a cascade system).

ix) Suitable controls over supply by compounding pharmacies (perhaps again based on some form of a cascade system). Controls could rest entirely with the proposed national legislation. These facilities usefully prepare alternative versions of registered products, and unregistered products, on prescription, but they have also been known to prepare and “market” certain products rather than relying on individual prescriptions. This is clearly a supply issue which should come under the same control as other supply of veterinary chemical products and be nationally consistent.

x) Where permits are issued, provide for an offence provision of failing to comply with the permit.

xi) Supply of date-expired products, both agricultural and veterinary, by retailers and veterinarians, is currently prohibited. But anyone, including veterinarians, may continue to use such products. Where such use is considered to pose any significant risk a mechanism to impose controls over the use is required, either within the legislation or by way of other instruments such as declarations or control orders.

**Q19**

What is the evidence that government penalties are more effective than industry incentives in achieving compliance with chemical use rules?

i) **Consistent national controls are essential combined with nationally consistent monitoring and enforcement of use controls. Rules without enforcement are meaningless.** Even with extensive use controls non-compliance is identified – there is no effective industry mechanism to achieve chemical use controls.

**Q20**

To what extent is there a need for a balance to be determined between government compliance action and industry mechanisms?

i) **Compliance and enforcement using industry co-regulation is particularly relevant to the AVA and veterinarians.**

ii) **Performance monitoring should be based on measurement and reporting to allow for continuous improvement.**

**Section 10**

**Competencies, training, accreditation and licensing**

**Q21**

What evidence is there that training is effective in improving agvet chemical use?

**Q22**

Should there be a required level of training for access to agvet chemicals and, if so, what should be the basis for establishing that requirement (e.g. level of training and scope of operation, such as commercial operator or private landholder)?

i) **Users of agvet chemicals should be trained. The level of training should be determined by risk assessment of the type of chemical (e.g. poison scheduling), its intended use (food/companion animal?), the scope of the intended use and the educational background of the prospective user.**
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<th>Possible Structures for a National Regulatory Scheme</th>
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<td>Q23</td>
<td>Under what conditions could a single national regulator be expected to deliver assessment, authorisation and control of use services effectively and efficiently and, if so, would there be a need for flexibility at a regional level?</td>
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| Q24        | Is there a harmonised model of governance that would provide control of use by state agencies that was effective, efficient, integrated with assessment and authorisation and consistent across jurisdictions:  
- from the models considered in section 11, or;  
- alternatives not mentioned here? |
| Q25        | With respect to permit applications, regional knowledge and access to local advice what would be some of the disadvantages and advantages of control of use by either:  
- a single national authority, or;  
- harmonised provision by state agencies?  
- A single national authority would have the advantage of consistency across the country but disadvantage of being difficult to be consistent with related state legislation such as medical/drug, use of controlled substance legislation and environmental and public health/residues issues. |

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| Q26        | What other key principles need to be considered in assessing the case for or against cost recovery?  
- i) The APVMA needs to be adequately resourced to ensure it can provide regulatory services in a timely and cost effective manner. The AVA believes that adequate IT infrastructure must be funded by the government and human resources management, with appropriate succession planning, be in place to ensure an efficient risk analysis and registration process.  
- ii) Industry and the agriculture sector cannot be forced to fund an inefficient system that is currently impacting on Australia’s agricultural production and productivity. Provision should be made for government funding of e.g. litigation insurance. Registration levy funding should not be used for fighting court cases. |

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<th>Is Cost Recovery of Control of Use Appropriate?</th>
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| Q27        | What other arguments are there in support of government funding of control of use regulation, particularly monitoring compliance, investigation and enforcement?  
- i) Not all benefits accrue to the manufacturers/registrants or users of the chemical. There are flow-on benefits in the manufacturing, marketing and foreign income spheres, and there can be improved environmental outcomes. |
| Q28        | What is the view of stakeholders regarding the arguments made for cost recovery of monitoring compliance, investigation and enforcement, particularly:  
- cost recovery would not be inconsistent with the Government’s policy |
objectives;

- the regulated industry is a beneficiary of the regulatory activities; and
- the users of agvet chemicals create the need for the regulatory activity.

| Q29 | What is the potential impact of cost recovery of control of use regulation on:
|     | • manufacturers, if it results in higher regulatory fees; and
|     | • the users of agvet chemicals, if it results in higher prices for agvet chemicals?
|     | i) many food products are price sensitive and or have to compete with subsidised overseas products. Some will be lost.

| Q30 | What are the potential risks that an increase in the cost of agvet chemicals will result in higher levels of improper usage?

3. General comment

Some of the issues raised in the following section have already been presented in the first submission but warrant further emphasis.

Governance/policy development:
The AVA believes that a registered veterinarian should not need to receive additional chemical use training before giving advice on veterinary chemicals as their use is usually with minimal risk to either the user or the environment, compared to the use of agricultural chemicals.

Registration (regulation to the point of sale):

1. Data requirements that will encourage manufacturers to register new products or uses (minor uses) and more use of overseas data are supported, where Australian use conditions are sufficiently similar.
2. Open, transparent, evidenced based (registration and risk) veterinary medicine assessment and approval with an ongoing reassessment and review processes to ensure continued support rather than obstruction of the practice of veterinary medicine.
3. More support for minor uses, especially for food producing animals.
4. Clearing the backlog of chemical reviews is seen as a priority to enable valuable new medicines to become available. The current system results in unacceptable delays for products available to veterinarians. If the APVMA needs to conduct its own safety testing, delays would be even more unacceptable.
   Consideration should be given to external (from APVMA) consultants assessing new registrations to expedite the registration process (especially for pharmaceuticals and parasiticides).
   Clearing the backlog of chemical reviews should be considered a high priority.
5. Strongly support mutual recognition of overseas assessment as long as the data are generated by a similar overseas body such as the APVMA as this will reduce duplication and cost to the manufacturer and expedite the registration process and also reduce animal testing.
6. Time frames are currently mandated and the clock should be stopped only by certain listed events but at least negotiation with the registrant would allow alternative sources of evaluations at the registrants to speed up the process.
Assessment timeframes for new products need to be consistent with published guidelines.

7. The precautionary principle should only be clearly defined and only used as a very last resort in the absence of serious and essential data.

8. The AVA is conscious of FSANZ causing delays on matters like residues and that the Ministers can override the science. This system should be amended.

9. Removal of the Administrative Appeals Tribunal would in the AVA’s view remove an important check system that would close a window of review and challenge to unilateral APVMA decisions.

Control of Use (regulation after sale):
1. Consistent national controls. We need certainty and consistency in the regulatory process.
2. Nationally consistent monitoring and enforcement of use controls.
3. Compliance and enforcement using industry co-regulation (particularly relevant to veterinarians).
4. Ability for local flexibility (state level) in dealing with local situations.
5. Limiting “off label” use by veterinarians would remove an essential treatment option for veterinarians but we accept there are “restraint” limitations and in many states, any “do not” is mandatory for veterinarians as well as other users. Placing all the true veterinary limitations under a “restraint/s” heading would be advantageous.
6. Legislation covering control of use should include a ‘cascade system’ similar to that in the UK. Veterinarians use registered products wherever possible, as these products have been tested to ensure efficacy, safety and residues. Products should only be used ‘off label’ and compounded products should only be used if there is no appropriate registered product available.

Performance monitoring:
1. Continuous improvement based on measurement, auditing and reporting is supported. The development of feedback loops that encourage continuous refinement of prescribing information is seen as very useful.

Funding and cost recovery:
1. We believe that the APVMA should be adequately resourced by funding by Government, (since this should be considered for the good of the community) and a user pay system for registrants.
2. Commonwealth must fund public good activities.

Other issues in which we think the AVA would have a direct interest, and which could therefore be identified to PSIC by AVA would include:

Registration:
1. Inclusion of animal welfare as a criterion for consideration in registration of both agricultural (pesticide) and veterinary chemicals (noting that this could have serious negative outcomes for control of feral/vertebrate pests if not worded correctly).
2. Finalise the ongoing review of the APVMA labelling codes as soon as possible to give force to proposed new use controls.
Control of Use:
1. Controls to be generally consistent with the old Standing Committee on Agriculture and Resource Management (SCARM) national principles.
2. State and Territory Health department controls to be subservient to APVMA supply and use controls for veterinarians.
4. Controls over feed mills using prescription animal remedies to medicate feeds to be applied by the national control of use regulator rather than State and Territory Health departments.
5. Removal of discrepancies in relation to state and territory controls including appropriate regulation of label controls under “Restraint” headings.
6. Rationalisation of label restraint statements on veterinary chemicals such that only those under a “Restraint” heading apply to veterinarians. This may require a review of existing label statements.
7. Clear requirements in relation to veterinary use and supply of unregistered products (perhaps some form of a cascade system).
8. Suitable controls over supply by compounding pharmacies (perhaps again based on some form of a cascade system).
9. Where permits are issued, provide for an offence provision of failing to comply with the permit.
10. Improve assessment and response to reports of adverse experiences.

The Australian Veterinary Association
10 February 2010

For future contact with the association on this initiative, please direct all enquiries to;
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APPENDIX 1.

Australian Veterinary Association

Re: National Regulatory Framework Review

The Australian Veterinary Association (AVA) is pleased to have the opportunity to provide comment prior to the independent consultation process into the single National framework into the regulation of agricultural and veterinary chemicals.

For future contact with the association on this initiative, please direct all enquiries to;

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The AVA considers that the following items are important and worthy of support in any future National Framework for the regulation of agricultural and veterinary (agvet) chemicals.

Governance/policy development:
We do not believe that a qualified veterinarian needs to obtain a certificate of compulsory training before giving advice on agvet chemicals as we believe the veterinary degree alone qualifies to veterinarian to do so.

Registration (regulation to the point of sale):
1. Data requirements that will encourage manufacturers to register new products or uses (minor uses) and more use of overseas data are supported.
2. Open, transparent, evidenced based (registration and risk) veterinary medicine assessment and approval with an ongoing reassessment and review processes to ensure continued support rather than obstruction of the practice of veterinary medicine.
3. More support for minor uses, especially for food producing animals.
4. Clearing the backlog of chemical reviews is seen as a priority to enable valuable new medicines to become available. The current system results in unacceptable delays for products available to veterinarians. If the APVMA needs to conduct its own safety testing, delays would be even more unacceptable. Consideration should be given to external (from APVMA) consultants assessing new registrations to expedite the registration process (especially for pharmaceuticals and parasiticides). Clearing the backlog of chemical reviews should be considered a high priority.
5. Strongly support mutual recognition of overseas assessment as long as the data is generated by a similar overseas body such as the APVMA as this will reduce
duplication and cost to the manufacturer and expedite the registration process and also reduce animal testing.

6. Time frames, these are currently mandated and the clock should be stopped only be certain listed events but at least negotiation with the registrant would allow alternative sources of evaluations at the registrants to speed up the process. Assessment timeframes for new products need to be consistent with published guidelines.

7. The precautionary principle should be clearly defined and only used as a very last resort in the absence of serious and essential data.

8. The AVA is conscious of FSANZ causing delays on matters like residues and that the Ministers can override the science.

9. Removal of the Administrative Appeals Tribunal would in the AVA’s view remove an important check system that would close a window of review and challenge to unilateral APVMA decisions.

Control of Use (regulation after sale):
1. Consistent national controls. We need certainty and consistency in the regulatory process.
2. Nationally consistent monitoring and enforcement of use controls.
3. Compliance and enforcement using industry co-regulation (particularly relevant to veterinarians).
4. Ability for local flexibility (state level) in dealing with local situations.
5. Limiting “off label” use by veterinarians would remove an essential treatment option for veterinarians but we accept there are “restraint” limitations and in many states, any “do not” is mandatory for veterinarians as well as other users. Placing all the true veterinary limitations under a “restraint/s” heading would be advantageous.

Performance monitoring:
1. Continuous improvement based on measurement, auditing and reporting is supported. The development of feedback loops that encourage continuous refinement of prescribing information is seen as very useful.

Funding and cost recovery:
1. We believe that the APVMA should be adequately resourced by funding by Government, (since this should be considered for the good of the community) and a user pay system for registrants.
2. Commonwealth must fund public good activities.

Other issues in which we think the AVA would have a direct interest, and which could therefore be identified to PSIC by AVA would include:

Registration:
1. Inclusion of animal welfare as a criterion for consideration in registration of both agricultural (pesticide) and veterinary chemicals (noting that this could have serious negative outcomes for control of feral/vertebrate pests if not worded correctly).
2. Finalise the ongoing review of the APVMA labelling codes as soon as possible to give force to proposed new use controls.

Control of Use:
1. Controls to be generally consistent with the old Standing Committee on Agriculture and Resource Management (SCARM) national principles.
2. State and Territory Health department controls to be subservient to APVMA supply and use controls for veterinarians.
3. Standard advertising controls to be implemented for prescription animal remedies consistent with the Galbally Review.
4. Controls over feed mills using prescription animal remedies to medicate feeds to be applied by the APVMA rather than State and Territory Health departments.
5. Removal of discrepancies in relation to state and territory controls including appropriate regulation of label controls under “Restraint” headings.
6. Rationalisation of label restraint statements on veterinary chemicals such that only those under a “Restraint” heading apply to veterinarians. This may require a review of existing label statements.
7. Clear requirements in relation to veterinary use and supply of unregistered products (perhaps some form of a cascade system).
8. Suitable controls over supply by compounding pharmacies (perhaps again based on some form of a cascade system).
9. Where permits are issued, provide for an offence provision of failing to comply with the permit.
10. Improve assessment and response to reports of adverse experiences.

The Australian Veterinary Association

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