Review of agvet chemicals regulatory framework

Via- https://haveyoursay.awe.gov.au/agvet-chemicals-regulatory-reform/survey_tools/online-form

GOAT VETERINARY CONSULTANCIES – goatvetoz
SUBMISSION

August 2020

Contents

Submission by Goat Veterinary Consultancies - goatvetoz

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She has also had a strong interest in veterinary chemical regulation. She was the Standards Officer for Queensland and General Manager, Product Integrity in Biosecurity Queensland. She also was a member of the last APVMA advisory Board before it was removed from the legislation. She has submitted many submissions to various reviews of the agvet chemical regulatory system and these are on her website- www.goatvetoz.com.au .

Executive summary

The goat industry has experienced rapid growth in the last decade. It has been reclassified from a minor to major species, mostly due to the rapid growth of export trade in meat goats, accompanied by large commercial dairy and fibre herds supplying domestic and export trade. Unfortunately many agvet chemicals registered for use in major species, especially anthelmintics and antibiotics, do not include goats as a labelled species. There is a reluctance by major pharmaceutical companies to carry out the required residue testing for meat and milk required in Australia, even though overseas data exists for both the efficacy and, in some cases, residues for the chemicals in goats. The lack of access to appropriate agvet chemicals impacts adversely on goat welfare. A review of the current system to allow veterinarians to prescribe off label for goats, including agvet chemicals with restraints (due to no local data for residue in goats, although such data exists for the agvet chemical Overseas).

Key points to improve access to veterinary medicines for goats are as follows:

1. Access to a full range of veterinary medicines is needed for all goats, even if used for milk for human consumption. They are essential tools for goat owners and veterinarians to ensure good goat welfare. Labels should not automatically include a “DO NOT USE in animals whose milk is used for human consumption” statement just because the registering company decides not to spend the money on milk with-holding periods. Veterinarians cannot override a DO NOT USE statement, even though they know this drug is used overseas. Instead registrants that do not wish to fund milk with-holding periods should just state on their label that no milk with-holding period is available. Veterinarians can then use their judgement to write one on a prescription. Alternatively veterinarians can use the meat with-holding period (which is always longer) or a default milk with-holding period. In the UK there is a default milk with-holding period for unregistered products (not just stating they must never be used) of 45 days and similarly it is 35 days in New Zealand (NZ Food Safety 2019).

2. Quality of products is critically important and the APVMA must continue Good Manufacturing Practice audits especially for overseas factories as there have been many problems reported of substitutions and ineffective vaccines in medicines made overseas.
3. Efficacy (and effectiveness) important for registered products
4. Registration of all veterinary medicines for production animal species is desirable, especially with respect to MRLs and WHPs but with global amalgamations of agvet chemical companies this is becoming more difficult. After amalgamations, vet medicines are often dropped from their range. Veterinarians must also be able to prescribe non-registered vet chemicals that have been used for decades and are mentioned in vet textbooks e.g. zinc sulphate (for foot baths), ammonium chloride (for urinary calculi prevention) and lime sulphur (for skin problems).
5. While the use of registered products for other animal species for minor species is desirable but if not possible, veterinarians must be allowed to prescribe as needed.
6. It is unlikely that registration will be possible for all products needed for veterinary practice so veterinarians must have the flexibility to prevent animal suffering by using vet medicines not registered for that particular species or even compounded or human medicines.
7. A regulatory system that facilitates and supports the availability of veterinary medicines and works closely with the veterinary profession is the most desirable outcome.
8. Support an APVMA board and meetings to share information by regulators
9. Market forces have failed in many cases e.g. in vaccines for sore mouth (also called orf or contagious ecthyma), which is a very crude live vaccine that can introduce the disease into a non-infectious herd. This vaccine has not improved in 40 years, despite all new research into vaccines. We need funding for CSIRO or the Commonwealth Serum Laboratory that will look at the needs of smaller industries where market size does not drive improvements.
10. While the government has an emergency permit ready to go for a Foot & Mouth Vaccine no such permits are ready for goat pox and PPR, two of the most deadly exotic disease of goats. Vaccination is critical for early control and hence they need to be prepared now so there is no delay in the case of any outbreak.

AGVET REVIEW INTRODUCTION

PROPOSED VISION STATEMENT

The proposed 'vision statement' for the system that the panel is inclined towards is:

An Australian regulatory system for agvet chemicals that provides all Australian primary producers and veterinarians with timely access to a similar range of approved agvet chemicals to their overseas competitors, while preserving human, animal, plant, and environmental health.

1) Do you support the proposed vision for the agvet chemicals regulatory system and is it sufficient to meet the needs of all stakeholders?

    a) What, if any other considerations should be included in the vision?

Do you have any suggestions for reforms that could assist in achieving this vision that are not canvassed in this paper?

DISCUSSION

I would add the words “and effective” after approved. I would hate to see the US system implemented in Australia where vet medicines do not have to prove they are effective and it is just “buyer beware”.

Chapter 1: IS THE NATIONAL REGISTRATION SCHEME WORKING AS NEEDED?

1.1 State of the system

Discussion questions

2) Do you agree or disagree with the future trends identified and their implications for the agvet chemicals regulatory system?

   a) Are there additional implications for the regulatory system posed by the trends identified that the panel has not adequately addressed? If yes, please provide details.

   b) Are there other trends that the panel needs to consider in designing the future system?

DISCUSSION

Companion animals will expand in number and type and small companion goats have recently become very popular. This will drive more demand for additional veterinary medicines for their care and welfare. Unlike commercial goats, their owners will demand treatment where commercial goat keepers would just humanely destroy goats.

Many more vet medicines are being made available for dogs and cats and pet goat owners will demand a similar increase in treatment options, including chemotherapy, immunotherapy and new biologicals.

1.2 What should be the core objectives of the future system?

The purpose of the agvet chemicals regulatory system is to protect the health and safety of people, animals, plants and the environment and provide safe and timely access to ***effective*** agvet chemicals.

It should allow veterinarians and goat owners to the full range of effective tools to treat or prevent disease for best animal welfare and also to reduce the risks to the health and safety of people, animals, plants and the environment.

Re the panel's proposed hierarchy of objectives:

Discussion questions

3) Do you support the proposed overarching primary purpose statement for the agvet chemicals regulatory system being safety and access?

   a) Do you agree that the proposed hierarchy of simplified objectives provides greater clarity of their relative importance and is this supported? If not, why?

   b) Are there objections to removing the domestic chemical manufacturing objective? If so, what are the objections?

   c) Do you agree that the current objectives for efficiency, transparency and risk-based science are more appropriately expressed as principles governing design of the system? If not, why?

   d) Are there other objectives that should be considered?

DISCUSSION

Ideally they should all be on the one levels but if not possible then animal welfare must come before trade.

1.3 What principles should underpin design of the system?

Discussion questions

4) Do you support the principles proposed to guide design and reforms to the future agvet chemicals regulatory system? If not, why?

   a) How could these principles be enshrined to ensure they are met?

   b) Do you have suggestions for additional principles that should be considered by the panel?

DISCUSSION

Efficacy and effectiveness assessments must be considered for best animal welfare.

1.4 Is a risk-based system better than a hazard-based system?

Panel's view

The panel is of the view that it is critically important that Australia's future regulatory system is based on risk, not hazard alone. Such an approach provides for a more scientifically robust and comprehensive regulatory system, and incorporates hazard assessments along with exposure and use, to determine chemicals suitable for use and the safest way of using them. This approach also ensures that users and the community have access to the broadest suite possible of safe chemicals to manage pests and diseases.

Discussion question

5) Do you agree that the regulatory system needs to have a risk-based focus to provide for a more scientifically robust and comprehensive system? If not, why?

DISCUSSION

Yes – the system must be risk based not hazard based.

Chapter 2. WHO SHOULD ULTIMATELY BE RESPONSIBLE FOR ASPECTS OF THE SYSTEM?

2.1 How should the supply of agvet chemicals be regulated?

Panel's view

The panel has a strong view that there is little justification for considering any changes to the current approach of a single national regulator for the supply of agvet chemicals.

2.2 Who should lead key responsibilities and reforms for the national system?

Discussion question

6) What governance structure might be best for delivering the Australian Government's responsibilities in the national regulatory system?

   Do you see merit in a time-limited High-Level Steering Committee to drive implementation action on the regulatory reform agenda?

DISCUSSION

2.3 Should control of use be nationally consistent?

Option 1 Expanded applied law model

Option 2 Commonwealth exercising its full constitutional reach

Option 3 Re-invigorating the existing Intergovernmental Agreement on control of use

Discussion questions

7) Which of the three reform options outlined do you support and why?

   a) Which option is likely to deliver the best chance of consistency in control of use and the greatest likelihood of success and why?

   b) What risks do you foresee in implementing any of the options proposed?

DISCUSSION

Prescriptions need to be harmonized as currently every state or Territory requires a different format.

2.4 Should there be shared responsibilities between industry and government?

Discussion questions

8) Do you support the addition of co-and-self regulatory approaches to agvet chemicals management (across all levels of a product lifecycle like the Australian Packaging Covenant) to deliver more effective and efficient outcomes than direct regulation alone?

   a) Do you support the panel's proposal for a holder accreditation scheme? Would the proposed levels of accreditation provide greater incentives for industry compliance?

   b) Is there additional value in limiting the scope for a holder based on the nature of the registration?

   c) Do you agree with the panel's proposal for formal training requirements for users to access (purchase) agricultural chemicals above a certain volume?

   d) Do you have suggestions for how existing assurance schemes such as GMP could be used to streamline assessment processes?

   e) Is there value in a statutory duty of care on industry and/or users to strengthen incentives for responsible use of chemical products to minimise risks to human health, animals and the environment?

   f) Can you think of any alternative or additional measures the government could implement to strengthen the responsibilities of regulated entities and users?

DISCUSSION

2.5 Is compliance and enforcement effective?

Panel's view

The panel notes that state and territory regulatory powers to control agricultural chemical and veterinary medicine use differ from jurisdiction to jurisdiction, as does the approach to compliance by the various regulators. The panel is inclined to recommend a national approach to compliance and enforcement of agvet chemicals use that employs a consistent set of compliance and enforcement tools. For example, there could be a more consistent approach to: licensing of chemical users; monitoring and investigative powers; record-keeping requirements; and the full suite of administrative actions, plus civil and criminal penalty provisions with a consistent range of available sanctions.

Discussion questions

9) Should detection and investigation measures be augmented to better treat the risks posed by agvet chemicals?

   a) Do agvet chemicals regulators need more effective and nationally consistent tools and sanctions than they already possess to manage the risks for which they are responsible?

   b) Do agvet chemicals regulators have appropriate resources, appetite and/or incentive to use the detection and enforcement tools they have? If not, how could this be addressed?

   c) Are you confident that regulators will detect non-compliance (in particular, that which poses the greatest threats to human and animal health and the environment) and respond appropriately? If not, what should/could be done differently?

   d) Should agvet chemicals registration-holders be screened in some way to ensure they are reputable? Why, why not?

Goat Veterinary Consultancies – goatvetoz proposals

The technology exists to make major users of agvet chemicals e.g. sheep lice dippers or aerial/commercial spray contractors to use a specific tracer chemical to be used to all their solutions so that any residues can be traced back to the commercial applicator. Regulators can then put their resources from investigations that are often impossible to find the cause, to checking that commercial applicators are using their tracer.

I am not confident with state regulators as I often see on Facebook posts about people providing imported or home-made natural vet medicines or stating they provide drenching services for goats using "off-label" sheep drenches for goats. I often report these but they still occur.

Manufacturers of agvet chemicals should be suitable persons, the same as veterinarians must be. The Qld Veterinary Surgeon's Board (www.vsb.qld.gov.au or https://forms.business.gov.au/aba/servlet/SmartForm.html?formCode=VSB-RR) requires:

"•letters of good standing

•certificates of good fame and character"

as well as a degree.

Chapter 3 WHAT CHEMICALS ARE CURRENTLY REGULATED?

3.1 Should the system only include chemicals for primary producers, veterinarians and non-urban land managers?

Panel's view

The panel is disposed to removing from the scope of the agvet chemicals regulatory system products with limited relevance to primary production or animal welfare. As examples this would include most consumer goods, pool and spa chemicals, antifouling paints and some veterinary products.

The panel considers that this would give a clearer 'identity' to the agvet chemicals regulatory system: it supports Australian primary production, veterinarians, and non-urban land management.

The panel is also disposed towards the introduction of restrictions of 'veterinary use only', where warranted for animal welfare, along similar lines to that adopted for agricultural chemicals currently under the auspices of Restricted Chemical Products. The panel considers that at the minimum, and to the extent not already addressed through scheduling, injectable veterinary products should require the direct involvement (either in administration or under their instruction) of a veterinarian.

Discussion questions

10) Do you support the proposal to remove consumer products and pool and spa chemicals, anti-fouling paints and certain over-the-counter companion animal products from the agvet chemicals regulatory system? If not, why?

    a) Do the benefits of the proposed removal of these products outweigh the risks? If not, why?

    b) Are the new definitions of a plant protection product and veterinary medicine supported? If not, why?

    c) Do you agree that certain product uses, such as those administered by injection, warrant the direct involvement of veterinarians, separate to the controls under the poisons scheduling?

DISCUSSION

In the USA veterinary medicines do not have to prove they are effective and this should never be allowed in Australia. A US herbal dewormer is widely advertised and even though scientific published research has shown it not to be effective, it is widely used and many goats suffer as a result.

Products administered by injection should be under the direction of a veterinarian or a veterinarian's prescription.

3.2 Should agricultural and veterinary chemicals be regulated together?

Discussion questions

11) Are there areas where the approach to agricultural chemicals and veterinary medicines should be different?

    a) Should there be separate requirements specified in the legislation for veterinary medicines and agricultural chemicals? If so, what should these requirements be?

DISCUSSION

Efficacy & effectiveness evaluations are critical for animal welfare so I support accreditation for all factories (Australian or overseas) that make vet medicines.

Chapter 4: ARE THERE GAPS IN AGVET CHEMICALS REGULATION OR MANAGEMENT?

4.1 Can we assess use by region, pest, disease or other instead of state boundaries?

Discussion questions

12) What are the merits of considering boundaries (other than state) that might be relevant to the use patterns of agvet chemicals use?

    a) What are the merits of considering regions of significant environmental interest, such as those adjacent to the Great Barrier Reef, or unique environmental values, for restrictions or bans on some agvet chemicals uses?

    b) What are the merits of mandating five yearly label reviews (by the holder) to remove where appropriate state references and aligning with the review of safety data sheets?

    c) Is it possible to establish pest groupings?

DISCUSSION

National consistency is to be encouraged.

4.2 Should benefits be considered in assessments?

Discussion questions

13) Would a benefits test as proposed be a useful addition to the agvet chemicals regulatory system?

    a) Are the benefits outlined appropriate?

    b) Are there additional benefits that should be considered?

    c) Should the benefits test have the two purposes proposed?

DISCUSSION

4.3 Should the impact of chemical combinations matter?

Discussion questions

14) Is the area of chemical combinations highlighted worth exploring?

   a) How might consideration of the impacts of chemicals (cumulative and synergistic) be feasibly considered in the Australian system, given the limited progress in this area internationally?

   b) Should Australia wait until international methodologies for assessing impacts of chemical combinations have been developed? Or should Australia have a role in assisting in their development?

   c) What skills and tools are needed in Australia to allow consideration of the impacts of synergistic impacts of chemicals?

DISCUSSION

Wait until international standards are available and Australian should take part in setting these. Combination sheep drenches are recommended in Australia as the best method of reducing drench resistant worm development. Australia must have better regulation of existing chemicals.

4.4 Can data mining drive better targeting of effort?

Panel's view

The panel acknowledges these issues would need to be addressed in the implementation of any relevant initiative. If governments are to achieve the benefits that data mining offers it will be essential for them to find a way of enabling access while protecting intellectual property and privacy. Nevertheless, the panel sees considerable potential in more effective data mining arrangements in the regulatory scheme of the future.

Discussion questions

15) What role could data mining and intelligence use play in the regulatory system?

   a) Should governments improve their data holdings and share this data among the jurisdictions to improve the management of agvet chemicals?

   b) Should agvet chemical users be required to mandatorily report chemical use data to the regulator? On what basis, If not, why?

   c) How could data mining and analytics drive better targeting of regulatory effort?

   d) What standards should operate to ensure data integrity, confidentiality and use?

DISCUSSION

There should be sharing of data between government departments – both federal and state & territory departments. Sharing of data between regulators is essential as it can lead to better regulatory actions.

4.5 Should there be greater monitoring of chemicals in produce and the environment?

Discussion questions

16) Do you support the need for a national domestic produce monitoring system and should it be modelled on the National Residue Survey?

    a) Should data on residues in domestic produce be publicly available?

    b) What should core design principles of such a system encompass?

Supermarkets and organic certifiers have data that could be provided to regulators.

DISCUSSION

Discussion questions

17) How could consistency in water and environmental monitoring across jurisdictions be achieved?

    a) Would monitoring systems (for both water and the environment) based on risk priorities be effective?

    b) Are there specific environments that should be a priority for monitoring?

Should monitoring results be published and how often?

DISCUSSION

Chapter 5: HOW CAN COMMUNICATION AND ENGAGEMENT BE IMPROVED?

5.1 Is there a need for more community information on regulatory actions?

Discussion questions

18) What information would consumers like to see more of from the national and state agvet chemicals regulators?

   a) How would consumers prefer to receive information?

   b) What should be the role of regulators in communicating decisions to the wider community?

DISCUSSION

a) Searchable information on websites and emailed newsletters or media statements
b) As above and also all successful prosecutions should be published in a searchable form on the website. Data about total numbers of complaints and their outcomes should also be published.

5.2 Do stakeholders require a formal consultation mechanism with the regulators?

Panel's view

The panel is disposed towards a consultative mechanism, like the UK model, with active functions that give it momentum and a greater likelihood of being sustained over time.

Discussion questions

19) Do you support the establishment of a formal consultative forum in Australia, similar to the UK model? If not, why?

   a) Do you have suggestions on the possible membership and scope for a formal consultative forum in Australia?

   b) If this model is adopted would there be benefits in forum meetings being open to the public?

DISCUSSION

a) Yes a consultative forum to cover both registration and regulation

b) No but the agenda should be publicised along with forum members so that stakeholders can ensure they can inform forum members of their views and a summary should be published after each forum meeting.

Chapter 6: HOW CAN WE SIMPLIFY THE REGULATORY SYSTEM?

6.1 Does a product that is the same as another need its own assessment?

Option 1 Repack applications become a declaration/notification process

Option 2 Link the registration status of repacked products to the pioneer product

Option 3 Continue to assess repack applications as per the current approach

Discussion questions

20) Which of the three repack application options presented do you prefer and why?

   a) Are there likely to be any increased risks with a product if option 1 is adopted?

   b) In option 2, is it reasonable to cancel the registration of all repacks following cancellation of the pioneer product (except in circumstances where the registration holder is in possession of appropriate data and product information)?

   c) Are there alternative options for dealing with repack applications?

DISCUSSION

Repacking needs to be made as easy as possible. Goat owners need smaller packs of vet medicines than those used by commercial sheep and cattle farmers. Option1 is therefore supported.

In addition, veterinarians must be allowed to repack to supply to clients whose goats they have seen or whose property they have visited. Many goats owners have only 1 or 2 goats are use veterinary medicines such as worm drenches, pregnancy toxaemia drenches or obstetrical lubricants in small amounts and hence most of the product goes past the use by dates before used. They must continue to be allowed to access small amounts from their vets as many vet medicines are supplied in large volumes for commercial farmers.

6.2 Who should be responsible for ensuring products work?

Option 1 Removing efficacy from the scope of agvet chemicals regulation

Option 2 Removing the requirement for efficacy data assessment

Option 3 Maintaining the criterion and amending requirements and streamlining assessments

Discussion questions

21) Which of the three options presented for retaining (for specific products), reducing or removing efficacy from the current agvet chemicals regulatory system do you prefer and why?

    a) Do you support applying option 1 to all crop protection products and non-scheduled veterinary medicines? If not, why?

    b) Do you support applying option 2 to scheduled veterinary medicines? If not, why?

    c) Are there unmanageable risks or costs if the efficacy criterion was removed or reduced from the regulatory system? If so, could you provide details?

DISCUSSION

Reducing or removing efficacy would be a disastrous step. Goat owners and vets need to know that vaccines actually work both for animal welfare and for public health e.g. if goats are in a leptospirosis area they need vaccination to protect both the goats and also the goat owners. Enterotoxaemia is a deadly disease of goats and goats already respond poorly to sheep and cattle vaccines and need vaccinations more frequently and if the requirement for efficacy was removed there would be no need to ensure labels have info on them about the need for more frequent vaccinations and many goats would die a painful death.

Option 1 & 2 are definitely NOT supported

6.3 Should there be greater use of standards?

Discussion questions

22) Would the ability to make greater use of standards be beneficial for applicants? If not, why?

    a) Should the use of standards be limited to products of low regulatory concern? Why/why not?

    b) Are there any unforeseen risks with adopting a standards approach like New Zealand that wouldn't require regulation changes each time a standard is created?

    c) Should the development of standards be driven by industry or the regulator?

    d) Are there any other types of standards, or approaches to self-assessment the panel should consider?

DISCUSSION

If standards can shorten registrations time and effort with no increase in risks then standards are supported.

Minor species should be able to use data from major species and overseas. It is unclear if goats are minor species considering the large number of rangeland (feral) goats slaughtered and their meat exported. However pet goats miniature breeds and dairy goat breeds be considered minor species.

6.4 Does Australia need to assess products that comparable regulators already agree are acceptable?

Panel's view

The Australian regulatory system needs to take full advantage of the work of comparable regulators, so that Australian effort is only focused on the issues that are unique to Australia.

Discussion questions

23) Should the regulator utilise prior assessment decisions from comparable regulators to fast track registration where appropriate? If not, why?

   a) Do you support a registration by reference approach as outlined? If not, why?

   b) Is basing the approach on decisions from one or more comparable international regulatory systems sufficient?

   c) Should the approach make it one registration for product, active constituent and label?

   d) Should the approach be used for variations and reconsiderations?

   e) Are the criteria for what constitutes a decision of a comparable regulatory system a policy decision appropriate for the minister, departmental secretary or the national regulator?

   f) What should be the requirements when considering regulatory comparability?

   g) Are there uniquely Australian issues that need to be assessed that have no international equivalence?

   h) How might the assessment of any unique Australian matters be easily managed?

DISCUSSION

The APVMA must consider assessments made overseas.

6.5 Does the existing approach for assessing permits (minor-use and emergency use) meet the needs of users?

Discussion questions

24) Is enough being done to address minor use permit applications, if not what more could be done?

   a) Are there any improvements or changes to the permit system that would be beneficial?

   b) Should permits be expanded beyond the activities they currently cover? If so, what activities would you suggest?

DISCUSSION

It is expensive and time consuming to obtain a permit and goat organisations lack the skilled personnel or the funds to employ them to develop and submit them. Also the basic information is either not available due to lack of research on drugs on goats or lack of public information.

There is however another option and that is to encourage veterinarians to write prescriptions for vet medicines for goats and minor species such as alpaca. This means giving guidance and also default with-holding periods such as is available in the UK i.e. 45 days for milk. Currently if Q drench, Zolvix or Startect is used on a dairy goat by mistake, theoretically its milk can never be used for human consumption.

DO NOT USE statement are more frequently being added to labels and this prevents a vet from writing a prescription. An example is levamisole worm drenches used for sheep. There are with-holding periods for meat and milk in goats in the USA which a vet could use to write a prescription but because of the DO NOT USE statements a vet cannot do so. DO NOT USE statements should only be used for species where they is a known and documented toxicity problem e.g. monensin in horses and donkeys or aspirin in cats.

6.6 Should chemical reviews be timelier and more informative?

Discussion questions

25) Are there changes that need to be made to the chemical review process to accelerate timeframes for completion? If so, what would these changes be?

   a) Should reviews have flexibility to consider specific issues that warrant review rather than a comprehensive reassessment of all aspects of the original approval?

   b) Should chemical reviews be risk-based rather than driven by rolling specified timeframes?

DISCUSSION

Chemical reviews should only be done based on risks to preserve resources for registrations of new agvet chemicals. Veterinarians know how to use adverse experience report and they can be used to determine risks.

An APVMA board could also provide advice.

6.7 Should greater use of technology be used—smart labelling?

Discussion questions

26) Should smart-labels be used, what smart content should they contain and should they be machine readable?

   a) Does control of use legislation limit this approach in any way?

   b) Is mandating labels for containers above a certain volume to be machine readable supported?

   c) Should Australia adopt a comprehensive use database and/or provide access to an exact copy of the label?

   d) Should separate label approvals be removed and instead have label content specified as a condition of registration? Are current labelling requirements excessively prescriptive? Could they be made more outcomes oriented?

DISCUSSION

Chapter 7: HOW CAN AUSTRALIA BUILD NATIONAL AND INTERNATIONAL CAPACITY?

7.1 Are there sufficient international networks of expertise?

Discussion questions

27) How could the regulator and the Department of Agriculture, Water and the Environment best engage and strengthen international networks?

   a) How can parties outside of government become involved in existing international networks?

   b) How can the regulator best expand and use its existing network of international assessors?

DISCUSSION

Most state departments have few staff left with expertise due to retirements and VERs. This is a serious problem and departments & the APVMA should introduce graduate programs and post-graduate tied scholarships to overcome this. Skilled migration will also be needed. Once numbers are regained then staff can be encouraged to redeploy internationally for 6-12 months.

University staff need tenure and access to study leave but Australian universities are suffering from insecure employment and this is unlikely to improve as universities suffer financial loss due to the loss of overseas students.

7.2 Is an operational regulatory working group needed?

Panel's view

The panel sees benefit in an operational group of regulators across jurisdictions focused on addressing and working through issues that need solving. This would assist in building capacity among regulators as they share information, intelligence and skills to progress their regulatory responsibilities. The panel is interested in feedback on whether there would be merit in reinvigorating the Registration Liaison Committee to focus on its original intent.

Discussion questions

28) Do you support the reinvigoration of the Registration Liaison Committee to focus on its original intent? If not, why?

a) Do you support the proposed new formal consultative forum (chapter 5) in Australia including work on regulatory operations and technical working committees?

DISCUSSION

The Registration Liaison Committee needs to be reactivated by the APVMA and all state and territories.

7.3 Should the private sector be able to perform assessment work?

Discussion questions

29) Do you support a third-party accredited assessor scheme? If not, why?

a) Do you support the scheme being based on the model in the lapsed Streamlining Regulations Bill 2019?

b) Should applicants be able to choose their accredited assessor, or should there be a panel of assessors allocated by the regulator?

c) Should persons overseas be able to work as accredited assessors?

DISCUSSION

The APVMA have lost many staff in recent years so third parties can be involved but must be chosen from a panel by the APVMA after a skills based selection process, not the applicant. Whether these applicants are in Australia or overseas based is irrelevant but reviewers must display knowledge of Australia farming systems if going to be used for agvet chemical used on farms (not needed for dog and cat medicines). Payment must come from the APVMA or government, not directly from the applicant.

There should be good communication between the applicant and the APVMA and the vet medicine company should be able to suggest new panel members especially in very specialised areas or for new technology medicines.

7.4 What capabilities may be needed to adapt to future technology?

Discussion questions

30) What additional capabilities may be needed by agvet chemical regulators to assess new technology?

a) Which stakeholders should agvet chemicals regulators consult with to stay abreast of current and emerging technologies?

b) What horizon scanning activities should be undertaken by agvet chemicals regulators?

DISCUSSION

The APVMA should have a Chief Scientist with suitable expertise and who would be available to help regulators and assessors with major technical queries and guide both the APVMA and regulators.

Chapter 8: HOW WILL A NEW REGULATORY SYSTEM BE SUSTAINABLY FUNDED?

8.1 Are all system users paying their fair share of costs?

8.2 Are fairer cost recovery arrangements needed?

Discussion questions

31) Which proposed cost recovery options presented do you support and why?

   a) Which combinations of the proposed options work best together and why?

   b) Are there other options that the panel should consider?

DISCUSSION

8.3 Are there 'public goods' government should fund?

Discussion questions

32) Which regulatory activities outlined do you think represent a public good and why?

   a) Are there other activities not mentioned that could represent a public good? If so, what are they?

DISCUSSION

Chapter 9: APPENDIX A: INDEPENDENT REVIEW: AGVET CHEMICALS NATIONAL REGULATORY FRAMEWORK

OTHER ISSUES FOR CONSIDERATION

Special case of products where the target changes with product use and the dosage regimen needs periodic adjustment. This is the case of antimicrobial resistance and antiparasitic resistance (lice, coccidia, gastro-intestinal parasites, flukes). There will be an impact of changing dose rates on withholding period determination. A system is needed that allows data collection on residue concentrations in food producing animals treated off-label. Such data could lead to evidence-based recommendations on future uses. Also residue surveys need to recognise that where there is no maximum residue level (MRL) for goats as the product is not registered for goats the MRL for sheep should be used. Currently residues must be below the level of detection for goat meat and milk for any non-registered veterinary medicine, which with today's advanced laboratory techniques can be levels of parts per billion or lower.

Registration will only ever apply to a small number of the veterinary medicines used by veterinarians. The regulatory system needs to recognise this and the role of veterinarians in using medicines that are essential but not-registered. Veterinarians need to be able to prescribe new veterinary medicines for goats for pain relief but new releases such as Trisolfen and Buccalgesic are only registered for sheep and cattle. Access to these pain relief products is essential for the welfare of goats and for Australian's reputation. Veterinarians must be able to prescribe these products with ease e.g. by telemedicine and without the need for 3 monthly farm visits in rangeland and pastoral areas.