



Submission on Streamlining Regulation of Agricultural and Veterinary Chemicals

Section A: General information

Purpose of this form For individuals and organisations to provide submissions on streamlining regulation of agricultural and veterinary chemicals.

Use this form to provide a submission or to write a long-form response. You can also attach a separate response.

Before applying See [Agriculture and Veterinary Chemicals Legislation Amendment \(Streamlining Regulation\) Bill 2018](#).

Closing date 22 August 2018

To complete this form Save the document to your computer.

Your submission must include a completed and signed submission form
 where relevant, supporting information from organisations, written on their official letterhead.

Post or email (preferred) your submission Agvet Chemicals
Sustainable Agriculture, Fisheries & Forestry Division
Department of Agriculture and Water Resources
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Email agvetreform@agriculture.gov.au

Section B: Applicant

1 Organisation name (if applicable) Australian Veterinary Association

2 Contact address

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3 Contact person

Given name(s) Melanie_____ Family name Latter_____

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Section C: Confidentiality

4 Is all of your submission confidential?

No

Yes Clearly mark the submission 'In confidence'

5 Is part of your submission confidential?

No

Yes Clearly mark the relevant section(s) 'In confidence'

Section D: Publication of submissions on the department website

Unless you request otherwise, the department will publish your name, organisation and the title of your submission on its website. Your contact information will not be made available.

6 Do you agree to your submission being made publicly available?

No Go to question 8

Yes Go to question 7

7 Do you agree to your name and state/territory being listed?

No

Yes

8 Do you agree to the department contacting you about your submission if required?

No

Yes

Section E: Submission type

9 What type of submission are you making? (select one box only)

Response to key topics in the draft report → Go to section F

Long-form response to the whole draft report → Go to section G

Separate response in an attached document → Go to section H

Section F: Response to key topics in the consultation paper

Support your answers with references.

10 Comment on provisional registration of chemical products

AVA supports the principle of provisional registration. This can have an important role in expediting the delivery of safe and effective veterinary medicines to the Australian market.

This risk mitigation approach would be applicable to data requirements where the target animal, environmental and human safety of the product have been established, and where the efficacy of the product for the proposed use could be reasonably predicted based on overseas data and / or scientific argument.

The AVA also submits that there are major issues of implementation in respect to veterinary chemicals.

A. General considerations

The management of risk from veterinary chemical use to animal health, welfare and safety, to human health and safety, or to trade requires a different approach to that relevant to agricultural chemicals.

Veterinary chemicals comprise multiple pharmacological classes with diverse risks including:

- a very high likelihood of variation in response to veterinary chemicals being used across Australian livestock species and husbandry systems defined by:
 - Species, breed, nutrition, and pathophysiological state, or
 - Exposure of animals through feed or the environment to bioactive (including toxic or other) substances likely to modify pharmacokinetic properties of veterinary chemicals, and
- that consequences may be moderate to high for animal health or welfare and for human health from inappropriate use or misuse.

In the first instance, provisional registration would be applicable to current requirements for Australian field efficacy studies. When dose titration, target animal toxicity and overseas efficacy data exist, it is frequently possible to make a balanced risk assessment as the likely efficacy of the product which could be confirmed during a period of provisional registration.

Stability data is also important. The current APVMA guidelines are inconsistent with the VICH guidelines (which allow data to be provided at a later time). We view that we need to strongly support that adaption of the VICH guidelines as this will:

- Facilitate the timely introduction of new products as well as new presentations (pack sizes etc) of existing products.
- Bring Australia into alignment with all other competent regulatory authorities
- Be consistent with the APVMA's stated position of adopting international standards where they exist
- Expediate the introduction of products to the Australian market as all overseas manufacturers construct stability data study timelines according to the VICH guidelines.

If provisional registration is approved for a new registration, it also affords the opportunity for the collection of field data by veterinarians, particularly for veterinary chemicals requiring veterinary prescription, supervision or monitoring. This could provide a cost-effective alternative to at least some of the current data requirements but may require the acquisition of specialised expertise.

B. Alternative approaches to extending label claims for veterinary chemicals

For veterinary chemicals registered for production animals, current regulation of Control of Use by the respective jurisdictions already establishes the circumstances under which the administration of veterinary chemicals to trade species other than according to label is permitted on the authority of a veterinarian, requires records to be made and retained, and authorises veterinarians to extend withholding periods (WHP). The relationship of those regulations to these proposals is relevant.

AVA acknowledges and affirms support for this unique role of veterinarians in the national framework for managing risk arising from of veterinary chemical use in trade species.

Indeed, the role of veterinarians should be affirmed by stakeholders as enabling access to appropriate treatment and as a significant mitigator of risk associated with the use of veterinary chemicals in animals, including to ensure sustainability in currently identifiable areas of major consequence including antimicrobial or anthelmintic resistance, and animal welfare.

Harmonised Control of Use regulation would enable more efficient access to a diverse range of treatments to ensure animal health and welfare as well as mitigating risk. This would be further enhanced if it were linked to a national registration of veterinarians.

C. Special consideration: resistance to antimicrobial and anti-parasitic chemicals

Resistance may have major consequences for animal and/or human health as well as productivity.

Considering the critical state of antimicrobial and anthelmintic resistance, AVA supports mechanisms which facilitate the early availability of and access to innovative treatments (as new registrations or new uses). Consideration should be given to provisional registration in such circumstances including any requirement for veterinary prescription, supervision and/or monitoring.

D. Access to appropriate treatments on grounds of animal health welfare and productivity

Applicability of provisional registration of veterinary chemicals requires consideration of very different expectations and risk from the administration to different classes of animals including to trade species, and to companion, performance or recreational animals.

It is noted that the parallel TGA provisional approval pathway for human registrations relates solely to prescription medicines with well-defined eligibility criteria. Such an approach may be applicable to veterinary chemicals intended for some animal classes.

However, the implications are more complex in veterinary medicine because of the special requirements for trade species or performance animals.

AVA strongly supports the registration and availability of veterinary chemicals for common, high-impact animal health problems which are easily recognised by owners of production animals and/or which require strategic management for which such treatments provide an appropriate solution.

AVA supports facilitating registration of veterinary chemicals or access to permits to manage common conditions across regions or zones associated with local livestock, environmental or climatic factors (EXAMPLES: nitrate or copper poisoning of ruminants) or to ensure urgent access or availability following the incursion of an Emergency Animal Disease. Such situations invariably involve a veterinary diagnosis having been established.

The streamlining of processes to ensure early availability and uptake of appropriate treatments is supported. Consideration should be given to circumstances under which provisional registration should be on veterinary prescription and/or require veterinary supervision or monitoring.

Application for provisional registration of variations should also be considered. From a risk management perspective, variations often pose low risk as there is information available on the relative efficacy of the product under Australian conditions, established use of the active ingredient and a history of the development of issues such as resistance. In such circumstances, provisional registration is likely to be influenced by the nature of the product, its use, formulation and the disease state rather than whether it is a variation or new product.

E. Apparent failures of the current registration process

AVA questions whether current policies and application of the process for registration of veterinary chemicals is consistently achieving the best outcomes in terms of enhanced animal health and welfare, and productivity.

For trade species, the current system may be failing to adequately manage risk to animal health and welfare or to productivity from conditions with low to moderate likelihood or frequency of occurrence but major consequence for individual flocks or herds and thus their owners or the animals within them.

The current system imposes substantial barriers to the registration of appropriate veterinary chemicals for trade species which are often available, often on veterinary prescription, in equivalent countries such as NZ, UK (including EU)- particularly as the result of the costs imposed in Australia to meet current requirements, relative to the small market for specific veterinary chemicals or approved uses.

Consideration should be given to not only provisional registration of such treatments as prescription animal remedies, but also to developing a protocol to enable field data to be derived by veterinarians in support of ongoing registration and/or availability. Some of these issues may be resolved by the implementation of VICH, but there may be special cases for some products including limited-use vaccines.

F. Efficacy failures

Sub-optimal efficacy may represent a significant risk to animal health and welfare.

The AVA view is that this will need to be resolved in the detail of the implementation of provisional registration.

It is desirable that the likelihood and consequence (as independent components of risk) of clinical or sub-clinical treatment failures should be assessed in justifying whether a veterinary chemical should be provisionally registered.

It is also suggested that matters related to the product's efficacy and safety that are subject to provisional registration should be identified clearly on the label as a precautionary statement. Standard wording should be developed to minimise end user confusion. The role of veterinary advice or intervention should be included as an important risk minimisation tool.

G. Overt failure of efficacy / Adverse Experience Report (AER)

Overt treatment failures in flocks or herds may be associated with considerable animal welfare implications, including distress to a significant proportion of an animal population. This creates urgency for the owner or person-in-charge and frequently results in inappropriate decisions on further treatment.

The experience of individual veterinarians and anecdotal evidence suggests that a common response of some individual farmers to overt treatment failures may be to adopt high-risk treatment protocols which are not in accordance with registered labels. There is a risk to animal health and welfare, as well as to human health and safety or to trade from inappropriate treatment decisions by users in the face of urgent animal health or welfare problems.

AVA supports the principle that overt treatment failures must be investigated, and an AER submitted. A mechanism is required to ensure that overt treatment failures are adequately investigated as a requirement of provisional registration. This could include a label direction.

It is noted that APVMA has previously required label changes for individual veterinary chemicals informed at least in part by the reporting of adverse experiences. It is submitted that such an approach may be applicable following the submission of AER's related to a provisional registration.

H. Circumstances where extended label uses may not be appropriate

In many circumstances, access to treatment is already ensured through veterinary authorisation under Control of Use regulations. Extending label directions (new uses) may have a negative impact by reducing the likelihood of veterinary intervention or investigation in circumstances where it may be desirable or necessary, including for low frequency or emerging diseases for which surveillance is desirable.

In veterinary medicine there is also a consideration that for some classes of chemical the extension of use to other species or disease condition may not be desirable because of risk- including the likelihood of misuse or that chemical resistance will increase and reduce the sustainability of treatment with the chemical for its principal use. (EXAMPLE: The extension of registration of some anthelmintic chemicals for use in goats).

I. Timeframe of provisional registration

It is likely that the type of data that could be provided over time as part of a provisional registration would be the final steps in an efficacy package (confirmatory field studies) and as such applicant may still have to generate a not insubstantial volume of data prior to provisional registration.

It is noted that the proposed provisional approval pathway for human prescription medicines by TGA includes an eligibility criterion of 'evidence of a plan to submit comprehensive clinical data'. The concept of a project plan is supported.

The imposition of, and strict adherence to, a tight timeline for the provision of data (including time for assessment) for veterinary chemicals will in part address any disadvantage to existing registrants in the same market.

The AVA supports the needs for limited flexibility. While the time needs to be short enough not to significantly disadvantage existing registrant there are situations where the ability to complete studies is outside the registrant's control, including weather, seasonal or unrelated disease events. (EXAMPLE: Fly strike field studies are weather dependant.)

J. Offer of Provisional Registration

The practical application of provisional registration might include the following:

- In the course of the assessment of an application for either a variation of new product it may be considered that the data provided was not adequate to meet the legislative requirements but was adequate to allow for a provisional registration. In this case the authority should be able to offer provisional registration, OR
- An applicant may consider they have sufficient overseas data and scientific argument to allow for a provisional registration whilst other data is being generated and should be able to ask for the application to be reviewed on that basis.

K. Reference product

For scientific, market equity, and logistical reasons, AVA has strong reservations about permitting provisionally registered products to be used as reference products.

L. Additional safeguards

There is an argument to be made in favour of one of the decision points about provisional registration being the history of the holder, as this would add additional enforcement capacity and prevent entities repeatedly applying for provisional registration but never delivering the data. However, AVA would be cautious of penalising well intentioned first-time entrants or those previously dealing with complex data requirements.

There needs to be the ability to cancel or suspend registrations to prevent unscrupulous holders using the process to access markets without intending to provide the data.

11 Comment on accreditation of assessors

AVA supports the use of 3rd party assessors for veterinary chemicals working in collaboration with the registrant.

This would provide the opportunity to:

- enhance transparency and efficiency of the review process,
- engage industry in pre-emptively identifying and managing some aspects of risk currently delegated to or assumed by APVMA (including under a TQM framework),
- utilise a wider range of expertise to manage risk which would seem highly desirable in being able provide confidence in the robustness of the process, and
- enable prospective assessors to develop and maintain relevant expertise.

However, there are matters which should be considered in developing any accreditation program or associated code of conduct.

- AVA advocates caution to avoid registrants who have used an external reviewer having the data reviewed again by the regulator. The system should take account that irrespective of accreditation, the opinion of an accredited reviewer would still be subject to the delegate's decision but on the basis of determining whether the legislated criteria have been met.
- It is important that there are opportunities to clarify issues before an application if the use of an external reviewer is going to significantly expedite the regulatory process. It seems appropriate that accreditation should provide opportunity for the reviewer and the applicant to discuss, consider and resolve any requirement for additional data before the submission is made.
- Any accreditation of assessors should also include consideration of overseas assessors. Such individuals are already used in the USA, NZ, EU and Canada and the APVMA should have the systems to accredit at reasonable cost and effort such assessors to prevent replication of work and to ensure that appropriate expertise is available.

- The use of external experts is widespread globally across regulatory jurisdictions so this concept is well established. Specific guidance would need to be provided to overseas assessors on the specific requirements of the APVMA and every effort should be made to harmonise such requirements where possible to minimise duplication.
- In respect to veterinary chemicals, AVA affirms the professional obligations of registered veterinarians supported by legislation in each jurisdiction as providing additional assurances in respect to activities undertaken if accredited for this purpose. The accreditation of individual veterinarians would be cost-effective, providing an incentive for the enhancement of pharmacological and other relevant expertise within the profession.

12 Comment on approval and registration for prescribed active constituents, products and labels

NIL

13 Comment on data protection incentives (limits on use of information)

It should be confirmed that data supplied during the provisional period would need to attract the same length of data protection as other data, and that the length of that data protection needs to be calculated from the time of approval of the data not the provisional registration.

However, there is concern that extension of data protection would be unlikely to encourage applications for minor uses to be made, as the sales are so small in these areas that the registration fees are more important.

Members with experience in this area suggest that relief from registration costs and/or reduced data requirements would be more likely to drive this decision than limits on use as there is likely to be very little data in these applications that would even attract protection. (See also 10E above)

14 Comment on information to be taken into account in determining applications

This is a very positive move and it is expected to have several important outcomes including to:

- permit APVMA to align with global standard such as the VICH stability guidelines to allow regulators to consider data provided during the course of the assessment of an application.
- increase the flexibility of the regulator and the applicant to ensure that the most current data is considered as part of the assessment process and improve the ability of applicant to respond to questions that arise during over the period of the assessments process.

However, AVA is supportive of the current approach in respect to registrations which require local supporting data, such as for parasiticides.

15 Comment on computerised decision-making

NIL

16 Comment on voluntary recalls

AVA generally supports the principle of proposal 7.

Recalls for issues of product safety or efficacy must be communicated, and currently the term “voluntary recall” becomes a de facto compulsory communication about the recall to the APVMA. More discussion may be required around what APVMA will publish and how this information should be treated legally by consumers.

Notwithstanding this, our view is that the nature of the recall needs to be ranked in some way so that the regulatory response is appropriate to the risk. (EXAMPLE: Voluntary recalls to address issues that do not impact product safety or efficacy should not be discouraged by the publications of recall notices that can be miscommunicated either unintentionally or maliciously.)

However, it is noted that recalls of some veterinary chemicals may have a major disruptive effect on being able to manage disease in flocks, herds etc. This may be considered an animal welfare impact.

Consideration should also be given to a mechanism to ensure that alternative treatments are notified including advising owners of any obligation to obtain written veterinary authorisation (such as a veterinary chemical registered for another major trade species).

17 Comment on notification of new information

NIL

18 Comment on standards for registered chemical products

In principle this has merit, as it has considerable ability to provide flexibility to registrants. However, there would need to be additional consultation on the details.

19 Comment on suspensions or cancellation of approvals and registrations for providing false or misleading information

From a product safety perspective this is a precautionary approach which takes no account of the impact of the misleading information or whether there was intent. This would seem to require further consultation.

20 Comment on addressing an inconsistency in label particulars (supply with unapproved label)

NIL

21 Comment on variation of approval or registration during suspension

This is a practical approach to dealing with this issue and is supported by AVA.

Suspension or cancellation of registrations of some veterinary chemicals may have a major disruptive effect on being able to strategically manage disease in flocks or herds. This should be considered an animal welfare impact.

22 Comment on prescribing matters for the statutory criteria

NIL

23 Comment on removing the need for an annual operational plan

NIL

24 Comment on aligning the 2014 legislation review with the current review of agvet chemical legislation

NIL

25 Comment on other minor and machinery changes to the Agvet Code and the Administration Act

NIL

26 Comment on other amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016

NIL

27 Comment on other minor and machinery changes to the Agvet Code and the Administration Act

NIL

28 Other comments. This could include additional information or relevant issues to be raised.

NIL

→ Go to section H

Section G: Long-form response to the consultation paper

29 Support your response with references. Attach additional sheets if necessary.

Section H: Applicant declaration

To be completed by the person listed in section B of this application.

I understand that:

- the Australian Government reserves the right to refuse to publish submissions, or parts of submissions, that contain offensive language, potentially defamatory material or copyright infringing material
- a request may be made under the *Freedom of Information Act 1982* for a submission marked confidential to be made available. Such requests will be determined in accordance with provisions under that Act
- if I provide personal information about an individual other than myself, I must make that person aware of the privacy notice in [section I](#) of this form and draw their attention to the department's privacy policy.

Signature (type or sign your name) Dr Melanie Latter_____

Date (dd/mm/yyyy) 22-08-18_____

Full name Melanie Latter_____

Section I: Privacy notice

'Personal information' means information or an opinion about an identified individual, or an individual who is reasonably identifiable.

The collection of personal information by the Department of Agriculture and Water Resources in relation to this submission is for the purposes of gathering information on the Exposure Draft of the Agricultural and Veterinary Chemicals (Operational Efficiency) Bill and related purposes. If you do not provide this information, the department will be unable to contact you to discuss your submission.

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