

Veterinary Manufacturers and Distributors Association Ltd.

SUBMISSION

**Consultation on Streamlining Regulation of Agricultural and Veterinary
Chemicals Bill**

August 2018

As a peak body representing the animal health industry, and with a majority of members actively involved in the manufacture of veterinary chemical products here in Australia, the VMDA takes a keen interest in all aspects of the regulation of animal health products.

Our members also contribute significantly to Australia's export effort and the extent to which the legislation covering our industry has an impact on the ability of registrants to export is of significant interest.

From a general perspective, the VMDA is supportive of the ongoing efforts of the DAWR to clarify and amend the relevant legislation in order to better facilitate the regulatory process. We commend the Department for the extent to which it consults key stakeholders, and offer our comments on these latest proposed legislative amendments in a spirit of cooperation that we trust will assist in achieving positive outcomes.

Proposal 1 –

Provisional registration or variation with conditions for efficacy (provisional registration of chemical products)

Provide the APVMA with discretion to provisionally register products, or provisionally register new uses of existing chemical products (vary product registrations), by allowing information about the efficacy of a product to be provided after registration, as a condition of registration.

The VMDA supports this proposal while noting that in many cases the applicant will have generated efficacy data as part of the process of establishing safety, stability and trade criteria where applicable.

However, where the lack of efficacy data is due to a requirement for generation of such data specific to Australia, the VMDA notes that it will be necessary to consider whether

subsequent lack of efficacy would compromise the health of the treated animal (e.g. a product for the eradication of Paralysis Tick (*Ixodes holocyclus*)).

Where the consequences of subsequent lack of efficacy would not have a significant impact upon the health of the treated animal, the VMDA supports the proposal and the principle of allowing commercial considerations to determine the fate of the product (i.e. if it doesn't work consumers will not buy it).

We also note that, for all applications where this approach is practical the principle could be applied, including medicated shampoos, simple worming tablets, etc. Where the active constituent/s are in common use and the formulation is 'routine', the VMDA supports the development of Standards for these types of products so that both Safety and Efficacy data would not be required at all.

We support the 'fit and proper person' test and also suggest that the applicant should be required to explain and justify the circumstances of the lack of efficacy data and provide a proposal that outlines the process for providing the data within the 3 year period, especially where this is for a new product. For an extension of use (e.g. new species), the requirements for this element could be less onerous.

Application or offer? We suggest that this option is available on request by the applicant or offered by the APVMA during a Pre Application Assistance process, and that there should be no need for an additional Item Number. If it becomes apparent during a PAA meeting or correspondence that there may be a delay in providing efficacy data or that the proposed data are considered insufficient by the APVMA, this option could be canvassed by either party.

Stability data: The VMDA supports a general proposal for stability data to be provided and updated during the registration process so as to allow continued generation of the data while the application is being processed. This would represent a significant saving for applicants in terms of 'time to market' while not affecting the assessment of the application to any extent.

Extension of time to provide or correct data: Where an initial three year period has passed without suitable efficacy data being provided, the VMDA proposed that a further period could be allowed, provided that the applicant can:

- a) Demonstrate that there have been no reported incidences of lack of efficacy while the product has been sold with the provisional registration.
- b) The applicant can demonstrate that there is sufficient evidence to show that it is likely that subsequent data will justify efficacy.

Other products could use the provisionally registered product as a reference product, provided that those products meet similar conditions, and that the applicants provide their own arguments and evidence to support the request, since any information and efficacy data submitted by the first product would be Protected Information.

Proposal 2 –

An accreditation scheme for assessors in the future (accreditation of assessors)

Provide for a disallowable APVMA legislative instrument to prescribe an accreditation scheme for assessors in the future, including charges for accreditation, and provide for sanctions for contravening conditions of accreditation.

The VMDA supports this proposal, with the following comments:

- Once accredited, the external assessors' work would be peer-reviewed by the APVMA, but not duplicated by APVMA staff. VMDA members are prepared to pay for a more efficient process and that must include faster processing of applications.
- Fees paid to external assessors by applicants should have no element of APVMA administrative fee overlay.
- Management or administrative costs incurred by the APVMA should be recovered by the regulator from the external assessors, whether as an annual fee or some other mechanism that also recovers the cost of compliance action by the APVMA.

Proposal 3 –

Prescribed approvals and registrations (approval and registration for active constituents, chemical products or labels).

Provide for prescribed approvals and registrations to simplify the approval of active constituents and labels, and the registration of certain products (to be set out in regulations or other instruments).

The VMDA broadly supports this proposal, noting that this has been a long-standing issue that has been proposed to be addressed over many years, and has at times been subject to ineffective action by the APVMA (viz the CEBRA project in recent years).

We do not support the 'deemed refusal' provisions being removed and do not see how and why any lack of action on the part of the APVMA to formally approve products under this procedure should not be treated any differently from the current arrangements. The 'reputational damage' for an applicant would be no different under these provisions than under the current arrangements. Should this proposal remain the VMDA seeks a further explanation of the rationale. We do not accept that inappropriate delays by the regulator should not allow the same access to the AAT as they do now.

We accept that the 'deemed approved' option should not apply for the reasons stated.

We do not support the harsh application of the 'disqualifying criteria' in these circumstances, as we do not support those same criteria currently. It is possible that an innocent person in a position of responsibility in a company could be banned from e.g. holding a manufacturing licence in circumstances where he or she had no involvement in or control over the offence committed. The VMDA believes that a more appropriate approach would be a 'show cause' notice so that the 'accused' person has the opportunity to demonstrate that their circumstances have changed or that they were not directly responsible for a previous offence.

Proposal 4 –

Data protection incentives for certain uses of chemical products (limits on use of information).

Provide for extensions to limitation and protection periods (to be set out in regulations or other instruments) as an incentive for registration holders to include certain uses of chemical products on labels and reduce the need for permits.

The incentives would operate by providing for any existing limitation and protection periods to be extended for up to five years if certain conditions are met.

The regulations would prescribe circumstances where the limitation periods in section 34M of the Agvet Code may be extended—that is, the extension would apply to the information used for the initial registration, and not only to the information for the additional use(s)

The VMDA is implacably opposed to this measure being applied to further extend the original Protected Information period, even when the application is required to be made with 3 years still left on the protected period.

There is no justification for this principle to be applied to veterinary chemical products. Extension of use to another species or another pathogen is of benefit to the animal and protection is warranted, but only for the extended claim.

If our suggestion is applied then the 3-year caveat need not apply and a normal period of Protected Information can apply to the new claim, regardless of the status of the original product and Protected Information period.

Whether the incentives should be limited to agricultural chemical products, with alternative approaches to apply for veterinary chemical products (for example, extending the current three year limitation period for information used for a variation to five years instead of extending the limitation period for information used to register the product).

The VMDA asserts that the incentives as proposed should only be applied to agricultural chemical products.

The current three year limitation period for information used for a variation should remain at 3 years for veterinary chemical products. There is no justification for an extension to 5 years for this existing period. Any change to this will be a further impost on farmers and consumers with a delay in introduction of generics with the same claim.

Applying the extended protection period to the whole of the product is an artifice that is tantamount to artificial data protection/patent extension and is open to abuse.

The principle of acceptance of generic products into our Australian market (both human and veterinary), is highly beneficial to our society, well established, and provided for in legislation that has been tested on multiple occasions in court. It is a principle that should be accepted and maintained.

Proposal 5 –

Prescribe certain information that can be taken into account if provided during an assessment (information to be taken into account in determining applications).

Provide the APVMA and industry with more flexibility to deal with certain prescribed types of information (to be set out in regulations or other instruments) given while the APVMA is determining an application.

Shelf-life extension may require extensive technical assessment—the APVMA has advised that it prefers that new information requiring technical assessment not be accepted and considered under this mechanism. The government is separately exploring greater use of the existing ‘timeshift’ applications to provide the APVMA and industry with more flexibility to deal with information relating to extensions of the shelf-life of a product but notes that this may add administrative burden to both the APVMA and applicant.

The VMDA believes that this is an excellent proposal that would simplify the process of managing an application and would avoid some of the long delays that frustrate both industry and the regulator.

We do however, believe that additional information related to shelf life should be included in this provision. That would allow for applications to be commenced and additional shelf life information to be provided as it becomes available to support the final shelf life of the product. Assessment of continuing shelf life studies is not an onerous technical exercise and cannot be considered to be the same as a deficiency in efficacy data, for instance.

We applaud the change in attitude that this proposal represents and would support if fully with the addition of an option so supply shelf life and other simplified data that may be required by the APVMA to properly assess the application, rather than to reject it. Our members would look favourably on such a proposal, even at an additional cost.

Proposal 6 –

Provide for computerised decision-making (computerised decision-making).

Modernise the Agvet Code by providing for the APVMA to use computerised decision-making.

The VMDA supports this initiative.

Proposal 7 –

Improve the transparency of voluntary recalls (voluntary recalls).

Improving transparency about recalls of agvet chemicals by requiring persons to inform the APVMA when they are undertaking certain voluntary recalls and requiring the APVMA to publish such recalls.

The VMDA supports this initiative.

Proposal 8 –

Require relevant information to be provided in relation to label approvals and variations (notification of new information).

Ensure that obligations to provide relevant information apply to holders of label approvals, and applicants for both label approvals and variations to

approvals or registrations; as they do in relation to active constituent approvals and product registrations.

The VMDA supports this initiative.

Proposal 9 –

Standards for registered chemical product constituents (definition of registered chemical product).

Reduce the regulatory burden on industry and the APVMA by allowing defined variations to the constituents in chemical products.

Proposed approach

The government proposes to amend the Agvet Code to provide for the regulations to prescribe standards for ranges of constituents in chemical products. These standards would apply for all offences and civil penalty provisions in the Agvet Code. This would allow for reasonable variations; for example, those that reflect manufacturing processes for chemical products. Holders would therefore not need to apply to the APVMA to amend the relevant particulars of their registration to ensure the register reflected an appropriate concentration range for constituents in chemical products.

The VMDA supports this initiative and looks forward to the details of the types of variations that will be proposed to be included.

Proposal 10 –

Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval (suspension or cancellation of approval or registration for provision of false or misleading information).

Include more comprehensive grounds for suspending or cancelling approvals or registrations where false or misleading information is provided, including in a variation application or an application for label approval.

The VMDA supports this initiative.

Proposal 11 –

Addressing an inconsistency in label particulars (supply of registered chemical products with unapproved label).

Address an inconsistency in the Agvet Code by clarifying what information must be included on a label.

The VMDA supports this initiative and looks forward to the opportunity to provide input as to the label requirements.

Proposal 12 –

Improving dealings with suspended approvals and registrations (variation of approval or registration during suspension).

Introduce practical measures to deal with suspended approvals and registrations, to address the reason for a suspension and to allow holders to request a suspension.

The VMDA supports this initiative.

Proposals 13 through 17:

The VMDA supports these initiatives.

Conclusion:

The VMDA congratulates the DAWR on a comprehensive and thoughtful approach to these proposed legislative changes.

We trust that our comments and contributions will be considered and taken into account when the drafting of the legislation is finalised. As always we are available to provide further explanation in respect of our comments.

The Veterinary Manufacturers and Distributors Association.

August 22nd, 2018.