VMDA
The Veterinary Manufacturers and Distributors Association Ltd
ABN 29 819 231 380
PO Box 789 Bowral NSW 2576
Telephone: 0447 715 515
Email: vmda@vmda.com.au Website: www.vmda.com.au

Operation of amendments to Agvet Chemical Legislation Inquiry: ACIL Allen Consulting on behalf of DAWR VMDA Submission – March 2019

Theme 1. Application assessment and efficiency and effectiveness:

- **Timeframes for assessments: Despite claims to the contrary from the APVMA, performance against timeframes for applications for new products have not improved. Timeframe performance improvements as indicated by the quarterly statistics, relate to minor assessments such as active constituent approvals, notifiable variations, and other assessments with little or no technical evaluation component. Timeshift applications have the potential to assist with making timeframes practical.**
- **Amendments requiring refusal of incomplete applications: This appears on the surface to be a laudable aim, but in practice there are often minor issues that practically could be dealt with by APVMA staff without requiring significant additional work or delays. It is the role of the APVMA to register safe and effective products, and it is not the role of the APVMA to only consider 'perfect' applications. Fortunately the APVMA has worked hard at dealing practically with this aspect of the legislative change and has largely limited what could have been a damaging outcome for industry. The VMDA supports the operation of this innovation as handled by the APVMA in its implementation.**
- **Operation of the 'anti-drip feeding' aspects of applications: This has created more work for applicants where the APVMA staff have 'identified' errors and/or omissions by way of issuing a '159 notice', that could have and should have been information that the APVMA staff should have as a matter of course by virtue of the role that they occupy. An example of this is to query the pH of a product when it is different from that of the reference product, whereas the APVMA assessor/risk manager should be aware of the safe and effective pH range of injections for all species and could and should therefore make the assessment without the need for the 159 notice.**
- **Amendments to preliminary assessment so that it dealt only with administrative matters: The operation of this aspect of the amended legislation has not been successful and there are now proposals to further amend the regulations to allow for a range of technical Pre Application Assistance (PAA) options with a commensurate fee to be charged.**
- **Overseas data and assessments: The operation of this aspect of the legislation has not been widespread and the APVMA continues to be 'overly risk averse' when considering external information and data in the process of considering an application.**

- **Electronic communication: Because the APVMA's IT systems are archaic and do not interact well with applicants and do not work well for APVMA staff, the operation of these amendments is not yet efficient. The changes underway as part of the relocation to Armidale are expected to resolve these issues.**
- **Guidelines: The APVMA has not had the resources to properly implement this aspect and so its operation has been correspondingly adversely affected.**
- **Pre-Application Assistance: This has operated moderately well, but APVMA staff with inappropriate 'risk averse' attitudes are still not able to commit in some cases to an agreement during the PAA process that will be guaranteed to be followed during the assessment of the application.**

Theme 3. Compliance and enforcement:

- **The VMDA agrees that simplifying the Agvet Code further with greater use of conditions of registration to regulate labelling, and also agrees with the possible future scope to include more measures in disallowable legislative instruments, including the example of a licensing scheme.**

Theme 4. Data protection:

- **Consolidation of 'protected information' and 'information with limits on its use' would require greater detail as to the practical operation of such a suggestion.**

Theme 6. Variations to relevant particulars and conditions:

- **The VMDA supports the use of notifiable variations for the particulars noted.**
- **The VMDA would need understand what conditions would be proposed to be amended by 'notifiable variation'. Clearly these could not be any that would require significant technical assessment, but could perhaps be those that require 'supporting information' for technical changes, and for the applicant to be required to submit such information and for the APVMA to assess this on an 'ad hoc' basis. Penalties would apply for applicants that used this process and did not supply suitable supporting information, and a requirement for the variation to be rescinded. Any decision such as this would need to be appealable through a timely process.**

VMDA 29 March, 2019.