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VMDA submission to the Productivity Commission

Regulation of Australian Agriculture

March 2016

Summary:

The importance of veterinary medicines to Australian agriculture and therefore to the Australian economy and our community, cannot be overstated.

The continued availability of safe, innovative and effective animal health products across the farming (extensive and intensive), equine and companion animal sectors, depends upon a robust regulatory system that supports the development of such products and their timely introduction to the market.

With long lead times in product development and the subsequent evaluation of registration applications, it is vital that the process is transparent and the service to the animal health communities is delivered in an efficient and effective manner.

The VMDA liaises closely with the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Department of Agriculture, and other relevant bodies involved in the regulation of this sector. It is our position that in recent times the regulatory activities of the agencies involved have become overly complex, less transparent, and significantly inefficient. Further, while costs have risen and are proposed to increase again in the immediate future, service delivery has not kept pace with these costs, resulting in unwarranted costs for manufacturers and registrants that eventually have an adverse impact upon the users of products, including of course, farmers.

This submission will address those aspects of the regulation of veterinary medicines that we believe require remediation, as well as commenting upon the approach of the regulator to its functions and the perceived lack of understanding of the adverse consequences of some of its actions, including the increasing tendency to 're-interpret' its legislation and/or regulations and guidelines, and its aversion to genuine risk assessment and management.

Risk Assessment and Management:

The APVMA has long had an aversion to accepting and managing risk, even for products that have been clearly identified as 'low risk' in many sectors including human medicine (e.g. nutraceuticals such as glucosamine, chondroitin etc.).

While the APVMA has developed a Listed Registration scheme for some of these products, its approach and that of the Department of Agriculture has been inconsistent and impractical. The current work with the University of Melbourne **Centre for Excellence for Biosecurity Risk Analysis (CEBRA)** to develop a risk assessment tool is a positive step, but has been bound up in the APVMA's historically risk averse attitude. So far 18 months of allocation of resources to this project has produced only simplistic examples of what may be achieved in this area and a positive approach is needed to develop a genuine risk management process that will result in the ready availability of low risk products to the community with a cost-effective approach to evaluation and registration.

Recommendation:

That the APVMA and CEBRA accelerate their process and in particular:

- Utilise 'Generally Recognised As Safe (GRAS) lists available from trusted regulators around the world including in the human health field.
- Develop Standards with the assistance of industry, to identify safe and effective formulations that can be utilised for formulation of products containing known active ingredients that have a history of safe and effective use. Examples include tablet and paste formulations that would avoid the need for extensive assessment and evaluation by the APVMA.
- Include Self-Assessment for products that meet the above criteria.

Office of the Gene Technology Regulator:

The assessment of veterinary vaccines by both the APVMA and OGTR is a genuine example of double regulation for no benefit, and incurs substantial unnecessary costs and delays.

The VMDA provided a submission in September 2014 to the Legislative and Governance Forum on Gene Technology regarding overlap in the regulation of veterinary vaccines produced using gene technology. A copy of this submission is attached.

The VMDA proposes that veterinary vaccines be excluded from regulation under the *GT Act* and be assessed and approved once under the *Agricultural and Veterinary Chemicals Code Act 1994* by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The Department of Health, the Department of Agriculture, and the APVMA have indicated that they would support this approach. The OGTR is opposed.

There is no clear dividing line between GM and non-GM vaccine organisms that can be formalised in legislation. Regulation based on the method used to create the vaccine organism is not necessary. All veterinary vaccine organisms, whether captured by the *GT Act* or not, are subject to assessment and registration by the APVMA under the *Agricultural and Veterinary Chemicals Code Act 1994*. Assessment by the APVMA includes assessment of risks to the environment and to people that are also assessed by the *Gene Technology Regulator* under the *GT Act*. Safety in these areas must be demonstrated experimentally following established international guidelines before any approval may be issued for field trials or for commercial release. The overlap between the issues assessed under the Gene Technology Act 2000 and the Agricultural and Veterinary Chemicals Code Act 1994 are described in detail in the attached paper titled ***Submission to the Legislative and Governance Forum on Gene Technology Regarding Overlap in the Regulation of Vaccines Produced using Gene Technology.***

The process of embarking on field trials and proceeding to an application for registration of a veterinary vaccine is long and entails significant investment. It is estimated by one of our members that to comply with the OGTR DIR requirements over and above the cost of APVMA requirements is > A$2 million/product for a vaccine used in intensively farmed food animals. Even more critically, it unnecessarily adds years to the regulatory process which equates to both a financial cost and project risk. To require assessment and approval by a second authority introduces a level of uncertainty that discourages manufacturers from proposing products that would be subject to this double assessment and approval, stifling innovation and reducing the number and range of products available to Australian primary producers. This is attested to by the fact that at present there are no veterinary vaccines captured by the *Gene Technology Act* that have been licensed for sale in Australia, while such vaccines form the majority of live vaccines currently in use in the USA and in Europe.

Recommendation:

To reduce uncertainty and the cost of developing and registering in Australia new GM vaccine products, the VMDA proposes that veterinary vaccines be excluded from regulation under the *GT Act* and be assessed and approved only once under the *Agricultural and Veterinary Chemicals Code Act 1994* by the Australian Pesticides and Veterinary Medicines Authority (APVMA). This would not result in increased risk of harm to people or the environment, as these risks would still be managed via a scientifically rigorous assessment process.

Alignment with New Zealand:

The agricultural, equine and companion animal markets in Australia and New Zealand are mostly similar, with the exceptions of certain diseases and pathogens that can be clearly identified.

The APVMA and New Zealand's regulator (ACVM) have regular contact and most registered products are common to both. There is however a significant difference in the attitude, processes and efficiency of the two regulators.

NZ for example has a target for assessments of 40 business days (currently averaging 65 days and the ACVM advises that it is 'embarrassed' by this failure to meet targets), whereas the APVMA's minimum statutory period is 90 days plus one month preliminary assessment for a simple 'repack' (that is a direct copy of an existing product manufactured by the same company in the same facility with an identical label). Even a closely similar' product under Item 6 with approval from the original registrant to access and use their formulation is an 8 month period plus the one month preliminary assessment period. More complex applications of course take much longer and the APVMA consistently fails to meet even these targets. 'Embarrassment' does not appear to be in the APVMA's lexicon.

New Zealand also has positive and progressive attitudes in the following areas of regulation of veterinary medicines:

- Low risk products where they look only at those aspects that are of concern and have blanket exemptions in place for a range of product categories.
- Clear legislation compelling the regulator to use all information at their disposal for the purposed of assessing a product.
- Negotiated MRA with EU whereas the APVMA claims that this is 'difficult' and may take 10 years, adding impediments and costs for local registrants attempting to export to Europe.
- Application costs in the range of $2-10k, significantly lower than Australia.
- Use of contract external assessors selected and paid for by applicants from an approved panel. The APVMA has been 'talking' about this for several years without any progress to implementation.

Add to these points the positive attitude of the New Zealand government in assisting their export-involved industries, rather than acting as a 'gatekeeper' as the APVMA does.

Recommendation:

That the New Zealand model for veterinary medicine registration is applied where applicable to the activities of the APVMA and that the APVMA be required to demonstrate reasons why the more progressive and cooperative cannot be implemented in Australia, rather than to constantly search for and put in place 'roadblocks'.

AgVet Chemical Legislative Reforms:

There are important reforms needed immediately to streamline the assessment of agricultural and veterinary chemical products and active constituents in Australia that are not currently included in the reforms proposed and progressed by the Department of Agriculture and Water Resources (the Department). These reforms generally have the support of industry.

Annual Return on Active Constituents:

The APVMA on behalf of and at the direction of the Department will require registrants and holders to report on amounts of active constituents imported, manufactured and exported each financial year, commencing with the financial year 2015–16.

This is as a result of section 69E of the Agricultural and Veterinary Chemicals (Administration) Act 1992 which has been in place since 1995, but has not been enforced by the APVMA since 2006. Data to be passed to the Department by the APVMA will not specifically identify holders or intentionally disclose confidential commercial information. However, considering the limited number of manufacturers in Australia, Industry believes that it may not be possible to achieve this.

Industry contends that this is an unnecessary regulatory burden and should be removed immediately. Further, because of the lack of accurate 'starting' data due to the APVMA not regulating many companies involved in the chain of importing and distribution, subsequent data are meaningless. The information has not been collected by the APVMA since 2009, signifying that it is not relevant or useful and even if a reasonable justification for its collection can be manufactured, there are vastly better alternative sources of information that are readily available, such as sales data already generated annually by the APVMA.

Mechanisms to facilitate participation by all registrants and/or holders in generating data for active constituents and registered products that are placed under reconsideration:

Industry supports measures to facilitate a more effective reconsideration process and key to this is the introduction of a mechanism to encourage all approval holders and product registrants to participate in data generation activities at an early stage of the reconsideration process. This will ensure those that benefit from the potential continued registration of an active constituent or chemical product are invested into the outcome. Removing incentives to delay decisions to generate additional data would also provide additional benefit.

Provisional registration:

The introduction of provisional registration would enable Australian farmers' access to vital tools to control weeds, pests and diseases while outstanding data requirements addressing lower regulatory risk requirements are completed.

As it is currently legislated, all data in support of an application for registration must be submitted at the time of application. This forces the situation where all data generation must be completed before an application can be submitted resulting in lengthy delays to the introduction of desperately needed tools for Australian farmers. Legislative amendments to enable provisional registration would allow certain lower regulatory risk data, such as stability data to extend shelf-life, to be generated and

submitted after the product has been introduced to the market and the benefits realised by Australian farmers and the community in general.

Cost Recovery:

The 2012 First Principles Cost Recovery Review (as yet not finalized) is focused on 'tweaking' the previous arrangements. Currently 100% recovery of the operating costs of the APVMA is from industry with the exception of minor amounts allocated for 'public interest' activities.

The present structure provides for 40% recovery via up front application fees and other specific fees such as Manufacturers Licensing, with the sales levy providing the balancing revenue.

It has been suggested that there should be 100% recovery of costs from application fees either upfront or via progressive payments spread over several years.

This approach risks stifling innovation, especially by local manufacturers and registrants because of the inefficiency of the regulator and the consequent excessive costs applied unnecessarily to assessments. The costs for product development are already high, and a subsequent full upfront fee would be an imposition that local industry will have difficulty in sustaining.

This approach also ignores the ongoing costs associated with the maintenance of the regulatory system, the involvement of the APVMA in stewardship of AgVet Chemicals throughout their lifetime, and the extensive public interest and overall economic benefits to Australia from its agricultural and animal health activities.

Recommendation:

That the Cost Recovery framework is reconsidered so as to spread the costs across the lifetime of products, and across the wider Australian economy, to reflect a genuine 'user pays' approach.

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