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19 February 2016

Mr Paul Lindwall
Presiding Commissioner
Regulation of Australian Agriculture
Productivity Commission
Locked Bag 2, Collins Street East
MELBOURNE Victoria 8003

By email only: agriculture@pc.gov.au

Dear Mr Lindwall,

Re: Regulation of Australian Agriculture

On behalf of Animal Medicines Australia, the peak industry body representing the animal health industry in Australia, I provide the following submission to the Productivity Commission Inquiry into the Regulation of Australian Agriculture.

Veterinary chemicals are important tools for agricultural productivity. It is important that the veterinary chemical regulatory system is supportive of their continued availability and their responsible use by Australian producers.

As Australian farmers compete for market share with overseas producers, access to the productivity gains associated with veterinary chemical products is absolutely critical to securing a competitive, profitable and sustainable future for this important pillar of our economy.

Our submission will refer to just some of the areas in which improvements may be made to the system which will maintain vital safeguards while improving the operation of the system. We look forward to further engagement to assist in the Commission's work on this important inquiry.

Please do not hesitate to contact me should you wish to discuss any aspect of this submission.

Yours sincerely,

Duncan Bremner
Chief Executive Officer

SUBMISSION TO THE

Productivity Commission Inquiry into Regulation of Australian Agriculture

19 February 2016

Animal Medicines Australia

INTRODUCTION

Animal Medicines Australia is the peak industry body representing the animal health industry in Australia. Animal Medicines Australia member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors. Animal Medicines Australia works closely with a variety of industry organisations to promote an evidence based approach to public policy. Animal Medicines Australia is a member of Health For Animals (formerly the International Federation for Animal Health), an official observer on VICH, and a member of the National Farmers' Federation (NFF).

Veterinary chemicals are important tools for agricultural productivity. It is important that the veterinary chemical regulatory system is supportive of their continued availability and their responsible use by Australian producers. As Australian farmers compete for market share with overseas producers, access to the productivity gains associated with veterinary chemical products is absolutely critical to securing a competitive, profitable and sustainable future for this important pillar of our economy.

In order to ensure that Australian farmers continue to have access to innovative animal health technologies, it is essential that inefficiencies in design and/or operation of the regulatory system be addressed.

In broad terms, it is our submission that there are a number of areas in which regulatory effort is incommensurate with the risk being managed, with the result that resources of government and industry are not being efficiently utilised. By achieving greater alignment of effort to risk, regulatory objectives can be achieved in a manner that will make Australia a more favourable place for companies to make the investment that is necessary for farmers to have access to existing and future animal health products.

SUMMARY

ALIGNING EFFORT TO RISK

CEBRA Risk Profiling Tool

Issue: Current regulation of veterinary medicines characterised by heavy reliance on direct technical engagement for evaluative purposes by APVMA. Approach taken regardless of where the application sits on the spectrum of risk.

Recommendations: (1) The Risk Profiling Tool being developed by CEBRA be utilised to identify products that are suitable for alternative regulatory approaches;

(2) Legal mechanisms be established to enable CEBRA profiling to be swiftly implemented.

(3) Additional funding be provided to APVMA to develop standards for a range of chemicals in order to streamline all future applications for registration of that product class.

USE OF INTERNATIONAL ASSESSMENTS AND STANDARDS

Reduction of duplicative regulatory effort

Issue: Cost of obtaining and maintaining access to Australian market is increased where technical requirements diverge from normative international standards.

Recommendation: (1) APVMA complete its project of reviewing all guidelines to ensure that where additional requirements are imposed, they are defensible from a scientific perspective.

(2) Data requirements must be consistently scrutinised to ensure that they materially contribute to risk management.

IMPACT OF TRADE RISK MITIGATION STRATEGIES

Export Slaughter Intervals (ESIs)

Issue: Conservative approach results in longer finishing periods for Australian producers than international counterparts. Longer

interval between last administrations of product to animal prior to slaughter lowers efficiency of production process.

Recommendation: A robust analysis be conducted of the cost to the producer of our current approach to ESI setting, and alternatives explored.

OPERATION OF PARALLEL LABELLING SYSTEM

Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Issue: Compliance with additional labelling requirements of GHS adds nothing to the management of risk but adds regulatory cost.

Recommendation: Relevant WHS laws be amended to reinstate a previous (and sensible) recognition that APVMA-approved labels arm workers with superior information to that which is provided under GHS requirements.

COST RECOVERY POLICY

Myopic approach to reviewing cost recovery arrangements

Issue: Periodic review of APVMA cost recovery arrangements fail to engage with broader questions of the relationship between APVMA, the success of Australian agriculture and the interests of the nation.

Recommendation: A holistic approach be adopted to ensure that cost recovery arrangements further the national interest.

ALIGNING EFFORT TO RISK

The current system of regulation of veterinary chemicals places a heavy emphasis on pre-market technical assessment aimed at safeguarding human and animal health, and ensuring that potential risks to the environment and to trade can be acceptably managed. These outcomes are of paramount importance. The task of aligning regulatory effort to risk begins with an acknowledgment that regulatory objectives can be achieved in a number of different ways, some of which may be more cost effective than others.

At the time of writing there is considerable work being conducted in this area by industry and government with the aim of achieving proportionate approaches to regulation.

At the outset, it is stressed that the existing deficiencies in the system do not require a radical new approach to regulation. Rather, targeted improvements should be implemented to obtain rapid efficiency gains while ensuring the integrity of regulatory safeguards and promoting stability for industry and the regulator.

PRIORITIES FOR LAW REFORM

On that basis, Animal Medicines Australia considers the following to be priorities for law reform in 2016:

1. Amending the *Agvet Code* to allow for streamlined processing of routine updates or variations to product and active constituent particulars;

2. Amending the *Agvet Code* to allow for provisional registration of chemical products;

3. Amending the *Agvet Code* to remove the requirement to make annual returns to the APVMA of the quantities of active constituent manufactured, imported or exported.

4. Amending the WHS regulations of each state and territory to recognise APVMA labels as being an equivalent or superior method of communicating information to chemical handlers and users to help them to handle or use products in a safe manner.

CEBRA RISK PROFILING TOOL

The APVMA is currently undertaking work with the Centre for Excellence for Biosecurity Risk Analysis (CEBRA) aimed at the development of a Risk Profiling Tool to determine how best to achieve an alignment of regulatory effort with risk.

It is anticipated that a range of options for streamlined regulatory engagement will be recommended. It is important that government and industry focus efforts to ensure that the

recommendations have sufficient legal and financial support to be implemented in a timely fashion. These efforts have already commenced, with policy proposals in an advanced stage of development following consultation on agvet reform during the previous calendar year. It is convenient to draw attention to some of the more important mechanisms that Animal Medicines Australia considers necessary to ensure that the CEBRA work results in the alignment that we seek.

MECHANISMS TO FACILITATE ALIGNMENT

New mechanisms required to achieve alignment

Self-assessment pathway

Animal Medicines Australia supports the creation of self-assessment pathways to apply to certain products where the risks posed are well defined and do not require direct regulatory engagement prior to registration. It is anticipated that such an approach would define eligibility requirements for registrants to clearly identify whether their product meets requirements or not. AMA views self-assessment as a mechanism that is appropriate for certain low risk products. However, it is considered necessary that upon a self-assessment decision being made by an applicant, they would be required to notify APVMA. Depending on the risk profile, an application might take effect upon notification or might require a level of APVMA review. For either pathway, it is important for system integrity that the APVMA supports the process by auditing a sample of products registered or varied using the process. This is considered essential for compliance and monitoring purposes as well as the funding of these important regulatory functions. It would make sense for APVMA to host the self-assessment tool within the existing application portal, thereby removing the requirement for a separate notification system to be created.

Provisional registration

Faster access to chemistries would be facilitated in certain circumstances if provisional registration was available. Such an option would be appropriate where health and safety-related aspects of evaluation are completed, and additional efficacy or stability data is requested. In these circumstances, the product could be provisionally registered, with the proviso being that the relevant data be submitted to APVMA by a certain time in order to transform the registration into an ordinary registration. This would potentially be a useful mechanism for granting longer shelf life for products, with the condition being that sufficient stability study data be provided within a relevant time period. Introducing such a mechanism would have the potential to dramatically accelerate the arrival onto market of certain medicines, enabling farmers to have access to the tools faster than is currently the case.

Existing mechanisms that should be better utilised

Listed chemical products

Provisions already exist within the *Agvet Code* which, if utilised, would facilitate streamlined evaluation. For example, if a standard is developed for a listed chemical product, the pre-market regulatory engagement of APVMA is focussed on establishing that the product complies with the standard. Compliance with the standard is sufficient to satisfy APVMA that the product meets the safety, efficacy and trade criteria.

The listed chemical provisions are underutilised. Currently, there is only one standard for a listed veterinary chemical product.[1]

Animal Medicines Australia is supportive of the increased use of these standards but notes that the development of standards is resource intensive. At current resource levels and with performance of the Authority beneath expectations, it is submitted that capitalising on the gains of the listed chemical approach will require an investment of government funding. We are concerned that absent an investment by Government in the development of a range of these standards, the provisions will continue to lie more or less dormant.

USE OF INTERNATIONAL ASSESSMENTS AND STANDARDS

In a globalised market, the manner in which APVMA treats information generated and/or analysed in places other than Australia will only become more relevant to its ability to achieve effective regulatory outcomes in an efficient manner.

Harmonisation of pre-market technical requirements and post-authorisation monitoring schemes can reduce the cost of obtaining and maintaining access to the Australian market.

The issues paper asks whether there is scope for Australian regulators to recognise the tests and standards developed by their overseas counterparts. The short answer is yes, but explanation is required in order to ensure that the reader does not gain the mistaken impression that there is not already a level of engagement by APVMA with "international information".[2]

As with other areas, there is work in progress on the APVMA's use of international information. In 2015, the APVMA released a draft policy document entitled *APVMA's*

[1] *Agricultural and Veterinary Chemicals Code (Listed Chemical Product – Joint Health Products for Dogs and Horses) Standard 2014.*

[2] In this submission, we will use "international information" as a neutral term to refer collectively to international data, standards, guidelines, assessments and decisions.

approach to the use of international data, assessments, standards and decisions.[3] The document outlines how the agency treats international data, assessments, standards and decisions in the course of performing its statutory functions. For the most part, it is declarative of existing operational approaches to engagement with international information. It also contains a number of statements of intent regarding future practice. For example, the document states that APVMA will accept normative technical standards unless there are compelling reasons to not accept them. Importantly, APVMA has committed to publish these reasons if and when they are said to exist. Animal Medicines Australia welcomes this statement of intent. It is essential that divergences be open to scrutiny to enable a continuous evaluation of whether they are in fact required for risk management purposes.

To summarise the key points of the APVMA's draft document:

(a) **Data**

Data is generally accepted if it is scientifically relevant to the risk assessment exercise for which it is submitted. In and of itself, the geographic origin of the data is irrelevant to APVMA's approach.

(b) **International standards and guidelines**

The Australian Government's *Industry Innovation and Competitiveness Agenda 2014* ("**IICA**") forms an important element of the context for the draft APVMA policy document on its approach to international information. In particular, one principle articulated in the IICA is as follows:

> "If a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is good reason for doing so."

The IICA principle is clear in the requirement for regulators to justify openly any requirements they impose which are additional to those which are imposed under a trusted international standard. In essence, alignment with IICA policy requires that there be a rebuttable presumption that an international standard is acceptable. The presumption may be rebutted, but only by compelling scientific evidence and argument and such argument must be accessible.

The IICA principle also highlights the need for scientific justification for the imposition of unique Australian requirements which impose obligations that exceed those that are required in other jurisdictions. For example, where APVMA maintains some Australian-specific requirements such as Australia-specific flea or coccidian trials, and these trials are not required

[3] APVMA, *APVMA's approach to the use of international data, assessments, standards and decisions* (April 2015) [draft] <http://apvma.gov.au/sites/default/files/images/node-14181-use-of-international-data-consultation.pdf> accessed 1 February 2016.

of the global data package which supports approval under a trusted overseas risk assessment, the APVMA should provide scientific evidence that the continuation of these additional requirements is necessary to appropriately manage risk.

As stated above, APVMA has adopted a default position of accepting international standards and guidelines unless there are compelling reasons for not doing so. Incorporated within that default position is a commitment only to impose Australian-specific requirements in circumstances where a scientific justification exists for their imposition and the justification is made public. Animal Medicines Australia understands that APVMA is currently reviewing all of its guidelines to ensure that any departures from normative guidelines are consistent with this policy. Over time, continual assessment of the relevance of risk management requirements will ensure that our system features only those things that actually contribute in a material way to the quality of Australia's regulatory scheme.

(c) **International assessments**

APVMA's document states that it will accept certain assessments performed by a limited range of overseas or international regulatory authorities. It adds that this acceptance will not be unconditional. APVMA states that in most cases it will require submission of underlying data relied on by the author of the assessment to facilitate some form of "peer review" of the assessment by APVMA evaluators. We observe that this requirement implies a lack of trust in the content and conclusions of the overseas regulator. A proper purpose and genuine need for the underlying data should be demonstrated to support the requirement to provide underlying data.

Animal Medicines Australia does not object to the list of agencies contained in the report. However, as we have commented in our submission in response to the draft document, the underlying criteria according to which APVMA determines the acceptability of one regulator's approach versus another has yet to be published, and this diminishes the utility of the document for industry. AMA understands the APVMA intends to publish a draft of this more detailed document in the near future. This should provide greater insight into how overseas methodologies are compared. Of equal importance will be detail regarding the precise nature of "peer review". The concept appears to suggest a lighter touch than a complete technical evaluation. Greater clarity is required to ensure this aspect operates predictably and does not unnecessarily duplicate work that has already been conducted by competent overseas regulators.

(d) **International decisions**

An approach which would place the greatest reliance on the competence of overseas regulatory agencies would be to adopt their final regulatory decisions as to whether a product should or should not be permitted on the market. Under such a model, a decision of a foreign regulator to approve a product for specific uses would form the basis for an identical registration in Australia.

In 2015, the Department of Agriculture & Water Resources published a discussion paper on the use of international decisions which set out a variant of the above model. The idea floated was that in the case of certain products, automatic registration in Australia would be provided for if the identical product had been approved for identical uses in at least two jurisdictions following a scientific assessment by a competent and comparable regulatory authority. While not employing these terms, the scheme would operate in a manner akin to provisional registration, whereby a product is registered in Australia on the proviso that it has previously obtained, and retains, regulatory approval in two trusted jurisdictions. The proviso would cease to operate if an application to register that product is granted in Australia following "long form" evaluation overseen by APVMA.

Animal Medicines Australia will not support any reform that would compromise the integrity of the Australian veterinary chemical regulatory system. A measure would compromise systemic integrity if an alternative approach is not suited to deliver safe, effective chemicals.

At present, the absence of alignment between regulatory systems reduces the opportunities to register products in Australia based solely on the decisions of overseas regulators due to lack of uniformity of regulatory approach. Greater harmonisation of pre-market and in-market regulatory approaches over time should increase opportunities for adoption of overseas regulatory decisions. Animal Medicines Australia would only support registration in these circumstances if the outcome of regulation (safe, effective chemicals) could be assured. This is most likely in cases where the environmental and exposure risks of the product are equivalent to the risks posed in overseas jurisdictions. At the present time it would appear that the proposal is suitable for adoption only in relation to companion animal products, however if suitable constraints can be identified the model might be applicable in food animal products.

Preferred method for improving utilisation of international information

Part of the CEBRA work is to identify circumstances in which international information may be better utilised. Generally speaking, it is expected that those product classes deemed to be of lower regulatory concern would warrant greater reliance being placed on international information. This is not to be equated with a reduction in risk management. Rather, it is an acknowledgment that the risk management outcome being sought by regulation can be achieved using work that has been done elsewhere, and that by doing so, the system as a whole is improved because resources can be allocated in a more efficient manner.

Animal Medicines Australia would therefore recommend that APVMA be allowed to complete its risk framework project prior to any radical changes in this area of regulation.

IMPACT OF TRADE RISK MITIGATION STRATEGIES

One of the risks that the Australian regulatory system seeks to manage is the potential for residues of veterinary medicines to be present in food products at levels which exceed the

import thresholds imposed by our overseas trade partners. The most severe consequence in the event that this occurred would be a removal of market access in relation to that commodity. In certain circumstances this could have severe economic consequences for the nation. Animal Medicines Australia acknowledges the importance of our export markets to the success of Australian agriculture, and seeks effective means of managing the risks to trade while ensuring that the benefits of innovative veterinary medicines can be enjoyed.

At the moment, there are certain respects in which we submit the mechanisms to manage trade risk are not achieving the appropriate balance between managing risk and maximising benefits. This undoubtedly impacts on the profitability of certain veterinary medicines products. More importantly for Australian agriculture, it impacts on the extent to which Australian producers can utilise the latest technologies to address food production challenges and to increase their competitiveness.

Specifically, problems arise in the operation of Export Slaughter Intervals. Export Slaughter Intervals are used to advise of the minimum period of time between the last administration of a veterinary chemical and export. The time period is designed to ensure that residues of the veterinary chemical have depleted sufficiently to comply with the standards for residues set by Australia's overseas trading partners. They are used when the Australian Maximum Residue Level is higher than the MRL/import tolerance of a trading partner, or where the trading partner has yet to set a MRL or tolerance for the particular chemical. Importantly, they are set in accordance with the strictest requirements imposed by a list of major trading partners, such list being set in relation to each major commodity. Therefore, it would only require one major trading partner to have a zero tolerance to residues of a molecule for the ESI to be set with a view to ensuring that the residues have depleted below the level of quantitation. This will lead to a longer ESI than would otherwise be the case for some major trading partners and an ESI that could potentially increase as analytical improvement decrease the level of quantitation.

This is part and parcel of managing trade risks, and if a trade partner applies its requirements uniformly, this would not lead to a competitive disadvantage for Australian producers. However, there are circumstances in which a product is registered in Australia as well as in another jurisdiction, and the product is used in the production of the same commodity being sold by both countries to an overseas destination, and Australian ESIs are longer than those that apply in the other jurisdiction. Very clearly, the overseas jurisdiction is achieving a more efficient approach to managing the balance between risks to trade and exploiting innovation. This means that overseas producers have greater flexibility to use the product than Australian producers.

The source of discrepancies in approach must be investigated and more effective mechanisms adopted to ensure that Australian producers do not suffer a competitive disadvantage as a result of inefficient Australian policy.

PARALLEL LABELLING REGIMES

AMA supports a risk management approach to the regulation of veterinary medicinal products as a superior way of mitigating the risks associated with their use. The product label for a veterinary chemical product reflects the hazard assessment, exposure assessment, risk characterisation, risk management and risk communication processes applied to each product by APVMA. From 1 January 2017, veterinary chemical products will need to bear labels that comply with Globally Harmonised System of Classification and Labelling of Chemicals (GHS) requirements as reflected in the Work Health and Safety regulations of several of the states and territories. AMA will always advocate for whatever scheme provides greatest protection to the safety of humans, animals and the environment. The evidence available to us at this point in time leads us to conclude that the risk-based system for agvet chemical regulation provides superior protection.

Animal Medicines Australia submits that these impose an unnecessary regulatory burden that contributes nothing to worker health or safety. The provisions should be amended to recognise that the APVMA labelling process achieves the purported aims of GHS.

COST RECOVERY ARRANGEMENTS

A first principles review of cost recovery arrangements at the APVMA was commenced by the Department of Agriculture in 2012. It has yet to be completed. The methodology employed to date leaves much to be desired and Animal Medicines Australia joins with other stakeholders in urging a more holistic approach to the determination of cost recovery and funding arrangements at the APVMA. We argue that a narrow sighted focus on simply balancing revenue with expenditure leaves unaddressed the anterior question of what broader objectives the system seeks to promote. Australia will benefit from a system that safeguards health and safety in a manner that also promotes investment in innovation. To deal with cost recovery arrangements as if they were a distinct and self-contained policy area with no impact on the operation of the broader system appears to be a sub-optimal approach to the task.