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14 November 2018

Committee Secretary
Senate Standing Committees on Rural and
Regional Affairs and Transport
Parliament House
Canberra ACT 2600

By email only: rrat.sen@aph.gov.au

Dear Standing Committee Members

The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

I am pleased to provide comments from Animal Medicines Australia (AMA) that may assist the Standing Committee in its deliberations in this inquiry.

AMA is the peak industry body representing the leaders of the animal medicines industry in Australia. AMA 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.

AMA works closely with its members, a variety of organisations, and governments to promote an evidence-based approach to public policy. Additionally, AMA advocates for the responsible and judicious use of all animal medicines to improve and protect animal health and welfare.

The Australian animal medicines industry is engaged with a broad range of regulatory agencies at State/Territory and Commonwealth levels. A key agency is the APVMA.

The essential and rigorous work done by the APVMA, in making independent, scientifically valid, and credible decisions, critically underpins positive outcomes for animal health, animal welfare, the environment, human health, worker safety, productivity, public health, food safety, and importantly gives confidence to Australian consumers, governments and the publics of Australia's trading partners.

Notwithstanding, AMA contends that APVMA needs to improve its business management with regard to the predictability and efficiency of its processes and operations.

If I can provide additional information please do not hesitate to contact me.

Yours Sincerely

Ben Stapley
Executive Director

Submission to the Senate Standing Committee on Rural and Regional Affairs and Transport on:

The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

14 November 2018

Animal Medicines Australia

1. About Animal Medicines Australia

Animal Medicines Australia Ltd (AMA) is the peak industry body representing the leaders of the animal medicines industry in Australia. AMA 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.

AMA supports the global 'One Health' concept which forges collaboration between human and animal health, to achieve better health outcomes for people, animals and the environment. Thanks to animal vaccinations, medicines and other health products, we and our animals are protected against many diseases, including some that are life-threatening, meaning better health and welfare for everyone**.**

In the Australian livestock sector, AMA member company products increase farm productivity and deliver improved environmental, health, safety and animal welfare outcomes. These animal medicines also underpin the quality and safety of Australian livestock products for local consumption and for export.

In the companion animal sector, veterinary medicines produced by member companies are facilitating longer and better quality partnerships between humans and animals.

AMA works closely with a variety of industry organisations, Commonwealth, state and territory governments and other stakeholders to **promote an evidence-based approach to public policy**.

AMA is a significant stakeholder in this review and welcomes the opportunity to provide this submission.

2. Animal medicines add value to Australia's livestock industries

A recent report[1] commissioned by AMA confirms the essential role of animal medicines in supporting Australia's livestock industries.

The report has, for first time, quantified the additional economic value of animal medicines in key livestock industries. It considers the value added through the use of animal health products in seven key production industries including beef, dairy, wool, sheep meat, pigs, and chicken meat and eggs. Importantly, the report puts a dollar figure on the benefit that is supplied by animal medicine products.

The analysis and report, undertaken by ACIL Allen Consulting, showed that animal medicine products:

- contribute **$2,668 million to the Australian economy;**
- create **9,898 full time jobs;**
- generate more than **$578 million in wages; and**
- resulted in costs savings on an average grocery bill of **almost $270 per annum**.

Consumers are beneficiaries of increased production as a result of animal health products. The responsible use of these products results in healthier animals, higher production for farmers and a reduced grocery bill. The estimated productivity attributable to animal health products ranged from **14%** for poultry meat to **28.5**% in dairy farming. This is a considerable productivity gain for farmers, which in turn benefits consumers.

Figure 1 identifies the economic and employment contributions attributable to animal medicine products in 2015-16.

[1] Acil Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries, 2015-16, June 2018

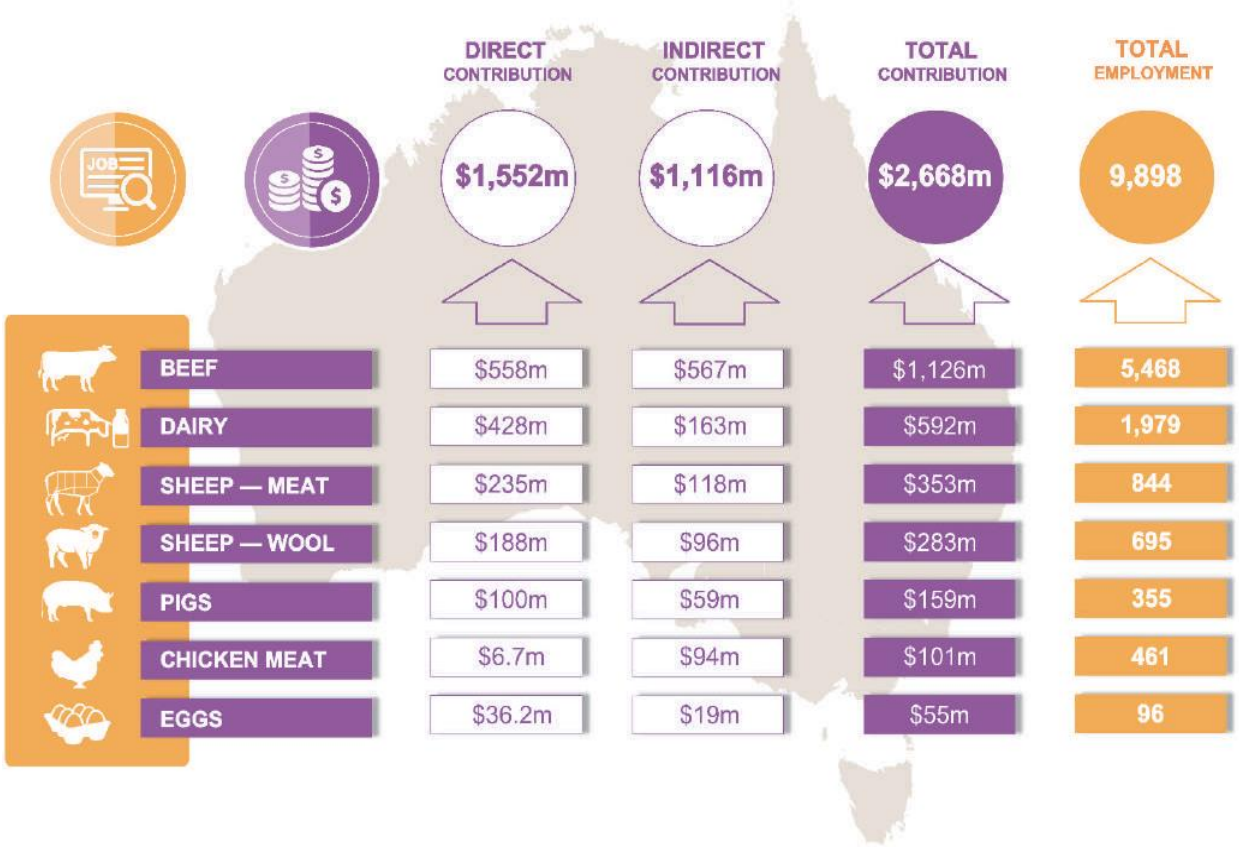

Figure 1: The total economic and employment contribution attributable to animal medicines in 2015-16

3. *Scope of response*

Animal medicine products are highly regulated with controls directed to pre-market approvals, manufacturing, marketing, transport, distribution, storage, workplace safety, the environment, consumer affairs, sales, advice, recommendations, use and disposal at Commonwealth and State/Territory levels.

AMA members are also participants in the key industry initiatives of:

- **AgSafe:** *accreditation and training to support safe storage, handling, transport and sale;*
- **DrumMuster:** *a recycling pathway for eligible empty agvet chemical containers; and*
- **ChemClear:** *collection and end-of-life disposal of unwanted chemicals.*

For the purposes of this submission AMA is pleased to provide background information and will focus its principal comments on the matters directly referred to the Senate Standing Committees on Rural and Regional Affairs and Transport (RRAT)

AMA also notes recommendations of the 2017 Australia 2030 Report[2] particularly toward addressing aspects of the Review of the Australian Public Service (APS) that serve to:

- drive innovation and productivity in the economy;
- tackle complex, multi-sectoral challenges in collaboration with the community, business and citizens; and
- improve citizens' experience of government and delivering fair outcomes for them.

[2] Innovation and Science Australia 2017, Australia 2030: prosperity through innovation, Australian Government, Canberra

4. Guiding Regulatory Principles

Given the wide range of regulatory systems and regulators that are relevant to the animal medicines industry it is instructive for AMA and its members to consider its interactions and regulatory positions to be based on clear regulatory principles.

A number of government policy and guidance statements provide helpful direction to the development of regulatory proposals. These are identified at Attachment 1 to this submission and provide some clarity on approaches to the government's Deregulation Agenda[3].

Since the introduction of requirements for regulatory impact analysis and regulatory impact statements in the 1990s there has been continuing evolution of the understanding of their critical importance and role by governments and its stakeholders. For some, one of the more significant advances has been in the need to clearly elaborate a *problem definition* and what policy objectives needed to be addressed.

Recognising the important work done by governments, AMA strongly supports regulatory processes and outcomes that conform to the following regulatory principles:

- be evidence-based
- be science-based
- be the minimum required to achieve the stated objectives;
- be predictable, efficient and effective;
- adopt a risk management approach to forming and administering regulation;
- minimise the impact on competition;
- be nationally consistent in content, implementation, interpretation and timeframes;
- be compatible with international standards and practices, where appropriate;
- not unnecessarily restrict trade;
- be developed in consultation with the groups most affected and be subject to regular review;
- be flexible, not prescriptive and be compatible with the business operating environment;
- standardise the exercise of bureaucratic discretion;
- have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms; and
- apply Regulatory Impact Analysis including clear identification of costs and benefits

5. AMA's desired outcomes

AMA recognises the important role of regulation in proving a framework to promote positive behaviours by members of the regulated community leading to benefits to the Australian community. In this sense, such frameworks provide means for managing risks that are acceptable to the Australian community.

AMA and its members shared view is that we want the industry's regulators to **be successful** by meeting agreed principles and outcomes. This will promote key system certainty and stability attributes for industry of predictability, efficiency and effectiveness. It also supports confidence in the schemes.

AMA's experience across the regulatory spectrum is that regulatory systems are generally effective but not efficient. Indeed, this was also a finding of the 2008 Productivity Commission Research Report on Chemicals and Plastics Regulation[4]

[3] https://www.jobs.gov.au/deregulation-agenda

[4] Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne

6. Previous reviews of the APVMA

The APVMA (and its NRA predecessor) has been subject to almost continuous review since the 1996 Charlie Bell Report, Time for Business[5]. Subsequently there have been reviews under the Chemicals and Plastics Action Agenda, Banks Regulation Taskforce, Ministerial Taskforce, Productivity Commission, COAG Commitments, COAG 'Hotspots', Australian National Audit Office (various), Cost-Recovery Reviews (various), Reform Programs, Auditor General Report and others.

Despite the expenditure of considerable government and stakeholder resources in these reviews many common and underlying issues for system improvements remain. In recent times efforts for improvements have been frustrated by the impact of the APVMA relocation to Armidale with a Canberra office.

On 27 February 2018 AMA submitted comments to the Standing Committee on Agriculture and Water Resources on the inquiry based on the Auditor-General Report No.56 (2016-17): Pesticide and Veterinary Medicine Regulatory Reform.[6] A copy of AMA's letter is provided at Attachment 2 to this submission. In general, the comments demonstrate the slow adoption of reforms which hinder potential gains in APVMA efficiencies.

7. Matters referred to RRAT

The independence of regulatory decisions made by the APVMA with particular reference to:

7.1 the responsiveness and effectiveness of the APVMA's processes for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators

The APVMA has legislative powers to reconsider the approvals of active constituents, the registration of products and their labels and to require registrants to provide information.[7]

AMA understands that APVMA may initiate actions to consider new data or information to determine whether of not a formal reconsideration process should be triggered.

AMA is conscious that APVMA monitors international developments and reviews by authorities with comparable regulatory standards.

AMA does not have current information or data to provide a comparison of *review performance* with comparable international regulators. In any case, the question should be whether the APVMA has appropriate processes in place to ensure protections required by the Agvet Code.

7.2 the funding arrangements of the APVMA, comparisons with equivalent agricultural chemicals regulators internationally and any impact these arrangements have on independent evidence-based decision-making

The current APVMA cost recovery arrangements were implemented in 2013 following a Cost Recovery Impact Statement process.

> "The cost recovery policy is administered by the Department of Finance and Deregulation and outlined in the Guidelines and Finance Circulars 2005/09 and

[5] http://daf.asn.au/wp-content/uploads/2014/09/time_for_business.pdf
[6] Standing_Committee_on_Agriculture_and_Water_Resources/AGreportNo562016-17
[7] https://apvma.gov.au/node/10816

> 2008/08. The underlying principle of the policy is that agencies should set charges to recover all the costs of products or services where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group, and where charging is consistent with Australian Government policy objectives." [8]

AMA seeks APVMA performance and service delivery based on the regulatory principles identified in Section 4 above.

AMA sees no evidence that APVMA processes are influenced by its source of funding.

Indeed, should the Government wish to change the APVMA funding arrangements, AMA would be very pleased to enter into a dialogue.

7.3 *the roles and responsibilities of relevant departments and agencies of commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals*

AMA notes that the APVMA is an Australian government statutory authority established in 1993 to centralise the registration of all agricultural and veterinary chemical products into the Australian marketplace. Previously each State and Territory government had its own system of registration. The APVMA was previously known as the National Registration Authority (NRA). The authority's principal responsibilities are described in the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals Code Act 1994*. The APVMA's history and *raison d'être* is well documented.[9]

Maintaining the confidence of consumers, at the local and trade destination levels, is crucial to the ongoing success of Australian livestock production and the Australian economy. It is important to stress the standing of bodies/functions such as The National Residue Survey in facilitating information to both domestic and export markets.

> *"The National Residue Survey (NRS)[10] is a vital part of the Australian system for managing the risk of chemical residues and environmental contaminants in Australian animal and plant products. The NRS supports Australia's primary producers and agricultural industries by confirming Australia's status as a producer of clean food and facilitating access to domestic and export markets."*

AMA suggests that the RRAT Inquiry into independent decision-making by the APVMA considers outcomes and focussed approaches, including partnership or facilitations that lead to benefits to the Australian community and the economy. In essence, the NRS is an example that provides strong validation for the science-based decision making by the APVMA. Additionally, the NRS is highly respected by Australia's trading partners.

7.4 the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products

As identified in Section 2 of this submission, animal medicines make significant contribution to the Australian economy, including through jobs, wages, and reduction in costs for Australian family shopping baskets. Animal medicines also underpin animal health and welfare standards, as well as confidence in safe foods for local and export consumption.

[8] https://apvma.gov.au/sites/default/files/publication/15791-apvma-cris-2013-15.pdf
[9] https://apvma.gov.au/node/1063
[10] http://www.agriculture.gov.au/ag-farm-food/food/nrs

Businesses do not favour uncertainties. Predictability (requirements, costs, assessments, timing etc.) is key to providing a favourable environment for investment in product development and marketing in Australia.

Additionally, the animal medicines industry is facing management of a range of issues, including antimicrobial resistance, impacts of export slaughter intervals (compared with trade competitors), trading partner restrictions such as recent reciprocity measures in Europe and others.

These and other factors highlight the need for a responsive regulatory regime.

7.5 *the impact of APVMA's relocation on its capability to undertake chemical review in a timely manner*

In November 2016 the Government announced that the APVMA would be relocating it operation to Armidale in 2019.

In September 2017, AMA made a submission[11] to the Inquiry into Regional Development and Decentralisation. AMA highlights the following comments and recommendations:

"AMA believes that Commonwealth entities should be located where they may be most effective and efficient. In considering where an agency may best be located, key considerations should include:

- *Its human resources, financial and infrastructure requirements;*
- *Its accountability responsibilities and governance structures; and*
- *Its need to engage with key stakeholder groups."*

and

"In summary, AMA does not oppose the decentralisation of government agencies, provided that any relocation is:

- *Based on a clear understanding of the purpose and functions of the agency, and its key stakeholders. This must include early engagement with stakeholders to identify issues that may not be apparent from the Government perspective; and*
- *Supported by a comprehensive and transparent cost-benefit analysis that demonstrates clear benefits from relocation* for all stakeholders, including industry stakeholders."

In the APVMA's case, decentralisation and relocation is resulting in high levels of staff turnover. This is, in turn, is providing challenges to the APVMA as it seeks to deliver on its regulatory functions.

Comprehensive analysis of relocation proposals must include an objective analysis of all costs and benefits, especially those incurred by the regulated community.

AMA is yet unable to evaluate when APVMA will be in a normal business mode and meet the expectations of its range of stakeholders.

[11] https://www.aph.gov.au/DocumentStore.ashx?id=ab7c99c2-eb59-4ff0-a588-a2530c37a123&subId=516107

8. Recommendations

That the *RRAT* Inquiry into decision making by the APVMA:

8.1 highlights and supports the importance of the principles of Best Practice Regulation as critical in the cultural development of:

- the APVMA in its delivery of its regulatory processes and programs; and
- the Department of Agriculture and Water Resources in developing and delivering policy advice, regulatory oversight and administration.

8.2 undertakes to identify the reasons, despite a large number of reviews, why reforms are slow to be implemented;

8.3 recognises the statutory and scientific independence of the APVMA;

8.4 suggests refreshing the Minister's Letter/Statement of Expectations with the APVMA; and

8.5 reviews the APVMA's performance criteria and measurement

Attachment 1

Best Practice Regulatory Principles

A number of government policy and guidance statements provide helpful direction to the development of regulatory proposals. These are identified briefly below and provide some clarity on approaches to the government's Deregulation Agenda[12].

Since the introduction of requirements for regulatory impact analysis and regulatory impact statements in the 1990s there has been continuing evolution of the understanding of their critical importance and role by governments and its stakeholders. For some, one of the more significant advances has been in the need to clearly elaborate a problem definition and what policy objectives needed to be addressed.

AMA notes the following principle statements:

COAG Principles of Best Practice Regulation

The Council of Australian Governments (COAG) has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles[13]:

a. establishing a case for action before addressing a problem;
b. a range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;
c. adopting the option that generates the greatest net benefit for the community;
d. in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:
    i. the benefits of the restrictions to the community as a whole outweigh the costs, and
    ii. the objectives of the regulation can only be achieved by restricting competition
e. providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;
f. ensuring that regulation remains relevant and effective over time;
g. consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and
h. government action should be effective and proportional to the issue being addressed.

Ten Principles for Australian Government Policy Makers[14]

a. Regulation should not be the default option for policy makers: the policy option offering the greatest net benefit should always be the recommended option.
b. Regulation should be imposed only when it can be shown to offer an overall net benefit.
c. The cost burden of new regulation must be fully offset by reductions in existing regulatory burden.
d. Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.
e. Policy makers should consult in a genuine and timely way with affected businesses, community organisations and individuals.
f. Policy makers must consult with each other to avoid creating cumulative or overlapping regulatory burdens.

[12] https://www.jobs.gov.au/deregulation-agenda
[13] https://www.pmc.gov.au/resource-centre/regulation/best-practice-regulation-guide-ministerial-councils-and-national-standard-setting-bodies
[14] The Australian Government Guide to Regulation, 2014 Canberra

g. The information upon which policy makers base their decisions must be published at the earliest opportunity.

h. Regulators must implement regulation with common sense, empathy and respect.

i. All regulation must be periodically reviewed to test its continuing relevance.

j. Policy makers must work closely with their portfolio Deregulation Units throughout the policy making process.

These principles are critical to ensure that regulatory responses are properly targeted and proportionate. They are supported by AMA as an essential framework which can be used to assess the merits of any legislative or regulatory proposal. AMA would welcome any measure to reinforce their importance to effective public administration.

The development of a best practice regulatory culture

It is noted that the Independent Review of the Australian Public Service will examine the capability, culture and operating model of the APS and that it will make practical recommendations to ensure the APS is ready, over the coming decades to best serve Australia.

Delivering high quality advice, regulatory oversight, programs and services

AMA sees an important goal is that APS culture embraces and facilitates:

- Fostering innovation;
- Evidence-based decision-making;
- Timeliness;
- Predictability;
- Efficiency and effectiveness;
- Transparency;
- Visible governance; and
- Accountability.

AMA believes that the necessary regulatory policy information and tools exist to facilitate progress. These are supported through COAG and Government statements.

> *"The Australian Government Guide to Regulation is intended to be read by every member of the Australian Public Service involved in policy making—from the most junior member of the policy team to the departmental secretary. It provides the context for regulation and encourages policy makers to think about regulatory impact early in the policy process. The principles in this Guide will be supplemented by regular Guidance Notes from the Department of the Prime Minister and Cabinet, available at www.cuttingredtape.gov.au.*[15]

AMA will actively support RRAT recommendations that highlight the importance of the principles of Best Practice Regulation as critical in the cultural development of the APVMA and DAWR.

[15] The Australian Government Guide to Regulation, 2014 Canberra

Attachment 2

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27 February 2018

Standing Committee on Agriculture and Water Resources
PO Box 6021
Parliament House
Canberra ACT 2600

Submitted by email to agriculture.reps@aph.gov.au

Dear Committee Secretariat,

Regarding the inquiry based on the Auditor-General report No.56 (2016-17): Pesticide and Veterinary Medicine Regulatory Reform

Animal Medicines Australia (AMA) is the peak body representing the leading animal health companies in Australia. AMA member companies are the local divisions of global 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.

Our members engage with the APVMA regularly and have a strong interest in ensuring that the regulator is able to deliver timely, predictable and efficient veterinary medicines approvals. An effective and efficient regulator is critical for the business and strategic planning of our members and ensures that Australian animal have access to the world's leading veterinary medicine products. AMA advocates for the responsible and judicious use of all veterinary medicines to improve and protect animal health and welfare.

Our members note that they have observed some small improvements in the performance of APVMA as some of the 2014 legislated reforms have been implemented. In particular, they note that the ability

to submit applications online has been a useful reform. Pre-application assistance (PAA) has mostly been very useful and informative for our members, however there have been some instances of PAAs being misdirected and poorly handled, which suggests there is scope for further improvement with this measure.

The submission of international data and the consideration of international assessments is also a positive reform measure. However, although some of our members have noticed an improvement in the ability to submit international data, others have reported that the consideration of international data/assessments is inconsistent across different sections, assessors and case managers at APVMA. Inconsistencies in the treatment of international data/assessments has thus reduced the improvements in performance that could have been gained from this measure.

Overall, these reform measures have only conferred small reductions in regulatory burden or improvements in the timeliness of application completions.

A history of ad hoc and individual decision making, in addition to the substantial loss of staff and corporate knowledge, have meant that the consistency and predictability of APVMA decisions has been severely compromised. Countless quick fixes and patches to APVMA operations have accumulated over time, such that the workflow processes and infrastructure have become increasingly complex, haphazard, inefficient and ineffective. For example:

- Only parts of the payment system are online. While online payments are handled efficiently, paper forms are sometimes misplaced, leading to cancelled applications and timeframe blow-outs.
- Pharmacovigilance data must be manually entered into the APVMA database by APVMA staff, requiring significant resource investment in a routine task that could be automated. In other regulatory jurisdictions, pharmacovigilance reports are submitted electronically via a validated database. This also means that electronic dossiers built for another jurisdiction (such as the EU) must be reworked prior to submission to APVMA.
- Data from the supply chain is received by the APVMA in multiple formats (including paper reporting forms), which must also be manually entered into APVMA databases.
- Having an assigned case manager is a positive development, however in practice, it has meant that in many cases, the case manager's role is simply to inform applicants that there are delays. In addition, it gives registrants less access to evaluators, so that simple phone calls to resolve issues are not made, leading to misunderstandings and long timeframes to get small details sorted out.
- There have been breaches of protected data associated with a lack of staff experience and inadequate in-house documentation.
- Changes have been made to guidelines and processes that have not been communicated to registrants, leading to costly packaging changes and delays in registrations that could have been avoided.

Further, the current risk assessment framework and high pre-market authorisation requirements impose a substantial regulatory burden on industry that is often disproportionate to the risks that the products pose. For products that are well known, do not enter the food chain, pose low risks to users and where those risks are already well characterised, there should be a streamlined regulatory assessment to bring such products to the market. Such products may include flea collars, companion animal shampoos, or vitamin and mineral supplements.

Post-market monitoring requirements in Australia are further complicated by the responsibility of individual state and territory governments for control of use, and the overlap of compliance and enforcement activities between APVMA and the individual states and territories, leading to varying degrees of enforcement in different jurisdictions. This has resulted in notable inconsistencies and unpredictability in post-market compliance of veterinary medicines.

The effective and efficient regulation of agricultural and veterinary chemicals is essential to protect the health and welfare of our livestock, horses and companion animals in Australia. The APVMA is a critically important chemical regulator for Australia that supports a $60billion agricultural industry and $12billion pet industry.

AMA believes that comprehensive investment in the regulator is urgently needed to bring its infrastructure, processes and guidelines in line with current global standards, and enable the regulator to meet its legislative obligations. The APVMA must be adequately supported and resourced to allow full implementation of the 2014 reforms (including the recommendations in the ANAO report), meet its legislated timeframes for assessments, and continue efforts to improve overall performance without imposing further disruptions to service delivery.

As a government authority, the onus should be on government to fund these desperately needed improvements in infrastructure, processes and guidelines. The APVMA operates on a cost-recovery basis which, in the current situation, means that industry is paying for an inefficient, unpredictable and untimely regulator. If the government provides an efficient, transparent and predictable regulatory system, then our industry will gladly support and comply with the requirements of that system.

It is unlikely that the creation of a new governance structure at APVMA would be sufficient to deliver the substantial improvements needed. The addition of a Board seems likely to merely add another layer of governance and decision-making to the registration process, resulting in increases to timelines and associated costs for applicants, but deliver minimal benefits or service improvements for applicants, or result in improvements in animal health and welfare.

Regardless of whether a board or executive management governance model is used, the priority for APVMA **must** be to provide its legislated services effectively and efficiently. This will afford industry greater certainty in their dealings with the regulator and encourage them to bring new and innovative veterinary products to the market for the benefit of all Australian animals.

Yours sincerely,

Ben Stapley

Executive Director