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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