Australian Government
Australian Pesticides and
Veterinary Medicines Authority

21 February 2018

Susan Cardell
Committee Secretary
Joint Committee of Public Accounts and Audit
PO BOX 6021
Parliament House, CANBERRA ACT 2600
jcpaa@aph.gov.au

Dear Ms Cardell

ANAO Report No. 56 (2016-17) *Pesticide and Veterinary Medicine Regulatory Reform*

Thank you for your letter dated 11 December 2017 regarding the Auditor-General's report, ANAO Report No. 56 (2016–17) *Pesticide and Veterinary Medicine Regulatory Reform*, into the effectiveness of our agency's implementation of reforms to agvet regulation.

In response to your request I am providing updated information (refer Attachment A), since our initial response to the ANAO report (refer Attachment B), on the activities undertaken to:

- address the 'areas for improvement' identified; and
- progress and fully implement the report's recommendations.

Our timeframe performance increased one percentage point in 2016–17, with 69 per cent of applications finalised within the statutory timeframes as opposed to the 68 per cent achieved in 2015–16. In the December 2017 quarter, timeframe performance for product, active and permit applications increased to 74 per cent, up from 58 per cent in the previous quarter. There is volatility throughout the APVMA's quarterly performance reports, the APVMA has never reached 100 per cent on time performance.

In August 2017 I commissioned an independent review into operational performance with the report publically released in January 2018. I have accepted all recommendations in this report and will immediately commence the implementation of the four priority findings, which will be overseen by the APVMA Major Projects Board.

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The loss of expertise and agency knowledge is still a risk for the APVMA, but we are managing this risk more effectively now. In 2016–17 we had 68 people leave the APVMA, and we've on boarded 92, so our recruitment is more than keeping pace with our rate of attrition. At 30 November 2017 the APVMA's headcount was 216. This is close to a full complement, and reflective of the increased responsibilities and funding to deliver both our relocation and projects funded by the Agricultural Competitiveness White Paper.

In October 2017 I tabled the APVMA Annual Report for 2016–17 outlining a financial deficit of $1.161 million. This result is not new and existed well before any plans to relocate the APVMA to Armidale in regional New South Wales. The APVMA has operated at a loss for the last three consecutive years. Expenses have exceeded actual revenue by $3.5 million on average each year. Our financial reserves have fallen well below our preferred position of $7 million and future deficits will impede efforts to replenish these reserves.

To address the declining financial position I have put in place a financial sustainability plan with the oversight of the APVMA Audit Committee. This plan outlines a number of short and long term actions to align our expenses with forecasted revenue now and into the future.

I have also sought to strengthen the governance and oversight arrangements within the APVMA and provide certainty to staff to about the pending relocation. This has included the appointment of a Deputy Chief Executive Officer to oversight operations and reform, the issuance of a number of staff related policies, and new risk management approaches. I am currently completing a review of the organisational risk framework and assessment. In November an update of the relocation risk register was finalised taking into account the significant work that has been completed towards the relocation of the APVMA, thereby reducing many of the earlier identified risks to more acceptably lower levels. The APVMA Relocation Advisory Committee (ARAC) was consulted as part of this process

We continue to work with the Department of Agriculture and Water Resources on legislative reform, and across 2017 and 2018 have been undertaking extensive consultation with stakeholders and industry on what more can be done. I have ensured that there is reliance placed upon international assessments to the fullest extent possible and put in place a practice statement and training for staff on the management of Commercial Confidential Information.

A high-level business operating model was publically released in December 2017 and we have been working with our staff and potential partners about how this may be implemented. This included an organisational structure for Armidale incorporating revised arrangements over quality control and standard setting in a Chief Regulatory Science function.

We are working through the Government budget process to implement our Digital Strategy which will focus firstly on stabilising our network and digitising our information. This will prepare the APVMA well for the future and for e-working.

Procurement for our permanent premises is on track. We shortlisted providers from an expression of interest process in 2017 and the official Request for Proposal was published to AusTender late last year with notification provided to four respondents. We are due to finalise lease negotiations later this month and received approval from the Parliamentary Standing Committee on Public works for the expenditure of public monies associated with the fit out on 8 February 2018. I expect to be able to announce the successful entering of a contract with the preferred supplier in March of this year.

Overall the APVMA now has much stronger project governance and risk management arrangements in place. In mid-2017 we undertook a full review of business risk and this is being revised and updated again now. Our risk assessment for the relocation project is also being regularly maintained and given oversight by the Executive Leadership Team, the Armidale Relocation Advisory Committee and internal program boards. I have confidence in the currency and appropriateness of our risk management practices.

These achievements are not insignificant.

I've outlined in the Corporate Plan a number of priorities that must be addressed to put the APVMA on a sustainable footing. There is a lot of reform for an agency of our size and high expectations to deliver. Our people are committed and willing to support these reforms because they understand the importance of what the APVMA does and want to see this work continue.

If you require further information, please contact Ms Amy Fox, Deputy Chief Executive Officer on

Yours sincerely

Dr Chris Parker
Chief Executive Officer

Attachment A

Implementation of the Reform Program – APVMA progress

Areas for improvement

Guidance Material for High Volume Applications

The APVMA is making registration easier with tailored guidance material that provides the information needed to lodge the right application, with the right data and supporting evidence to meet APVMA criteria. Through the current process, applications can be incorrectly aligned to legislative item numbers and require re-categorisation, leading to longer processing times and fee adjustments.

The APVMA have engaged with industry through a series of face to face workshops and follow up email coordination of feedback in 2017. The workshops have resulted in the establishment and prioritisation of a list of the most common applications for which tailored guidance material would be developed. Content has been drafted for six application types with the first two finalised and published through our website in August 2017. As at 25 January 2018, 34 applications have been submitted through this pathway successfully.

The APVMA has received positive feedback on the engagement model and continue to offer support to develop further guidance material. Work continues to develop the remaining 14 application types following the same engagement model and this is on track to be finalised by 30 June 2018.

Intelligence and Collection Arrangements

A business case has been drafted for acquiring a case management system and potential software providers have been identified. The APVMA is working through the Government budget process to implement our Digital Strategy which focuses firstly on stabilising our network and digitising our information followed by modernisation of business systems.

The Compliance and Enforcement Strategy 2015-17 is currently under review.

The Compliance Plan 2017-18 was developed with a strong emphasis on undertaking intelligence-led compliance activities. Many of the Plan activities were developed from existing intelligence about high risk areas of non-compliance. To date, the completed Plan activities have resulted in the identification and resolution of approximately 15 cases of non-compliance

Progress against Recommendation No. 1

Internal Quality Framework

The current processes for assessment of agvet chemicals are robust, with appropriate documentation and based on sound evidence, as acknowledged in the ANAO report. This provides for high quality scientific decision making for registration of agvet chemicals in line with the legislative framework.

These processes and activities include:

Provision of Pre-application assistance
The APVMA clarifies the nature and levels of assessment required prior to submitting an application at pre-application assistance.

Evaluation Planning at commencement of evaluation including request for advice from expert areas
The APVMA undertakes a planning stage when applications are accepted where the required nature and level assessments are identified based on the risks posed by the proposed registration/variation.

Project Planning for provision of external scientific assessments
When the APVMA determines that technical assessments are required for an application the scope of the required assessment is determined by APMVA staff. If the assessment is to be undertaken by contracted external reviewers this includes provision of appropriate guidance to reviewers on previous related decisions.

Peer review of science based recommendations
All reports providing recommendations against the safety, efficacy and trade criteria are peer reviewed by experts prior to these recommendations being accepted by the APVMA. This occurs equally for those reports generated by external and internal experts. These peer reviews are generally undertaken by senior APVMA staff and in some instances are supported by external experts. Applicants are also given the opportunity to review these reports through the early release process prior to a regulatory decision being made.

Our regulatory scientists participate in many international fora, such as experts on the FAO and WHO panel for the Joint Meeting on Pesticide Residues which consider toxicological and food safety aspects of agricultural chemicals, and on the WHO panel for the Joint Expert Committee for Food Additives which considers toxicological aspects of veterinary medicines. APVMA regulatory scientists also participate in a number of committees of the OECD Pesticides Program and of the VICH program (a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration), both of which develop guidelines and guidance documents for the assessment of hazards and risks associated with the use of agricultural and veterinary chemicals. This involvement ensures that our assessment staff are familiar with, and implementing global best practice in the Australian context.

Public consultation
Public consultation is undertaken as required by legislation for major applications (i.e. prior to the decision to register a product with a new active constituent or where the application is an extension of use to a new major food group)

Peer review of science based decisions
Recommendations against the safety, efficacy and trade criteria are subjected to further administrative and science based review when they are synthesised into a decision recommendation on the application by a risk manager. This decision is then further reviewed by the delegate for the decision before the decision is made. The allocation of delegations is based on the complexity of the application (e.g. decision to register a product with a new active constituent sits with Executive Director or above). The delegate for the decision has the ability to refer individual decisions to the Registration or Science Quality Committee for further review.

A business model for the APVMA in Armidale has been finalised in December 2017 which puts in place the structure to support the embedding of a Chief Regulatory Scientist within Scientific Assessment and Review. One of the key roles of this function will be to further support quality decision making across our regulatory functions and planning has commenced for an internal quality framework that will be implemented post the organisations move to Armidale.

The Office of the Chief Regulatory Scientist functions will continue to provide assurance across the agency through:

- specialist advice on complex and emerging regulatory science issues
- advice on science quality and regulatory science practice
- regulatory science partnerships (capacity building)
- regulatory science training and development (capability building)
- stakeholder communication and engagement

Identify, monitor and respond to emerging regulatory issues
New technologies deployed in crop production and animal husbandry may require the development of different regulatory frameworks and the assessment of special risk analysis approaches. In this regard, the agency has been particularly active preparing for the regulation of products of nanotechnology and biotechnology. The APVMA collaborated with international and national experts from industry, academia, research institutes and other regulatory agencies to prepare for these technologies. The output of this work included product registration data guidelines, peer-reviewed scientific publications, keynote conference presentations, symposiums and workshops

Science quality and regulatory science practices
The quality and efficiency of the agency's assessments are highly dependent on the quality of product registration submissions. The agency has a program of major projects aimed at improving the efficiency of finalising product registration applications. One project aims to elicit higher quality submissions from product registration applicants. The APVMA also participates in international workshare arrangements with overseas regulatory agencies.

Workshare offers a highly efficient program for product registrants to register their products in several countries concurrently and has been well received by industry stakeholders.

The Science Quality Committee regularly considers and addresses issues related to the quality of scientific processes and regulatory outputs, and offers guidance to scientific evaluators. An important component of work for monitoring and enhancing the APVMA's regulatory performance in future involves establishing an external audit function. The APVMA Executive will commission general or targeted science-decision quality audits, which will be conducted by international experts.

Advancements in science not only lead to better products but also to better ways of testing and evaluating them. An area of focus for the APVMA is improving the ability of tests, models and assessment methods to better predict product safety issues. In this respect, the agency has completed several projects that directly improved product assessment methodology including:

- methodology to assess risks posed by imported live microorganisms intended for use in veterinary vaccines
- a framework to evaluate software models used to calculate components of risk associated with agvet chemical products
- a system to analyse risk posed by pesticide use on insect pollinators.

These projects underwent public consultation and have been welcomed by APVMA stakeholders.

Regulatory science partnerships, training and development
During 2017, APVMA scientists developed links and networks with other Australian government regulatory agencies responsible for regulating chemicals and biological agents through the Regulatory Science Network (RSN). A key objective of the RSN is to help improve the performance of Australian Government regulatory agencies by bringing together senior scientists from the stakeholder group where regulatory and technical issues can be discussed and interagency cooperation can be strengthened.

The APVMA has strong links with overseas regulatory agencies in the USA, Europe, the United Kingdom, Canada and New Zealand and with international bodies such as the FAO, WHO, OECD, and VICH. Efficient and effective internationally-harmonised best-practice regulation helps deliver increased public confidence in government regulatory agencies and greater certainty for the regulated industry through reduced costs and reduced time-to-market. This approach is consistent with the Australian Government's Industry Innovation and Competitiveness Agenda and the National Innovation and Science Agenda. The APVMA's performance is improved as a result of these activities. For example, the agency participates in meetings of the VICH Steering Committee, which provides an opportunity to influence international standards regarding registration requirements of veterinary medicines. In 2013-14, the APVMA adopted 14 guidelines from the VICH. The APVMA also participates in the risk management committees for pesticide residues (CCPR) and veterinary medicine residues (CCRVDF) of the Codex Alimentarius Commission which establishes risk assessment policies and maximum residue limits that are used as trade an safety standards by many countries.

The APVMA launched the Accelerated Regulatory Science Training Program in July 2017 to maintain and build regulatory science capability that is essential for the agency. The training program will develop highly specialised skills and knowledge required by APVMA regulatory scientists. Further specialised regulatory science training will be offered at the University of New England, Armidale based on consultation with the APVMA Chief Scientist.

The APVMA Science Seminar series is another initiative that builds regulatory science capacity and capability in the agency. The series commenced in early February 2018 when Emeritus Professor Mary Barton AO delivered a presentation on antimicrobial resistance in animals. The seminar was attended by scientists from other agencies and Departments. A program of seminars is also be on offer for APVMA technical staff, which consists of lectures by eminent regulatory scientists on regulatory science topics.

Stakeholder communication and engagement
The APVMA engages with the public in order to raise the general level of awareness and understanding about the assessment process for agricultural and veterinary chemicals, especially its focus on human health and the environment. The agency uses a range of communication methods to ensure all stakeholders have appropriate access to information on regulatory science issues and have the opportunity to provide comment on proposed assessment methods and risk management options. The APVMA's external website is the crucial communication tool for the APVMA. In 2017, the content and format of the 'Our Science' web page was refreshed and expanded. Subsequently, the 'page views' have doubled and informed engagement has increased.

Progress against Recommendation No. 2

The APVMA continues to prioritise improving our performance.

From July 2014 to September 2017, 887 applicants submitted over 11,000 applications to the APVMA. During this time, there were 9677 assessments undertaken by APVMA, with 179 applicants submitting 80% of all assessments, 38 of which represent over 50% of the assessments.

In the December 2017 quarter, timeframe performance for product, active and permit applications increased to 74 per cent, up from 58 per cent in the previous quarter. Pesticide product applications at 72 per cent completed on time, up from 36 per cent in the previous quarter. Veterinary Medicine product applications at 71 percent completed on time, down from 76 per cent in the previous quarter.

The overall annual performance for 2016-17 in terms of timeliness of decisions held firm. Sixty nine per cent of applications were finalised within statutory timeframes up one percentage point on the previous year when 68 per cent were finalised on time.

Review of performance measures

An Independent Review of Assessment Performance, undertaken by Reason Group, was commissioned in August 2017 to identify the root causes for delays in the APVMA's assessment and registration of agricultural and veterinary chemicals. The review was concluded on 22 December 2017 and published on the APVMA website 18 January 2018.

All recommendations have been accepted by the APVMA and work is underway to put in place appropriate governance mechanisms and implement immediate priorities, working towards improved performance.

The report outlines recommendations against three broad themes: improve the use of regulatory instruments; build more efficient assessment processes; and modify legislation, cost recovery and reporting methods to better position the agency to deliver.

Overseen by the Major Project Board immediate action is being taken to address the four priority recommendations in the review including

- making better use of legislative instruments through the training and guidance provided to staff
- the exploration of earlier rejections of poor quality applications
- the improvement in the management of backlogs through resource management and scheduling
- the assessment of opportunities to delegate sign off of decisions to assessments teams.

The findings of the review confirm that the fluctuations and volatility in the assessment workload, and that the range in quality and complexity of applications received makes it difficult to meet the legislated performance measure of 100 per cent on-time assessments. It also confirms there are multiple factors contributing to delays in assessment and outlines a comprehensive plan for reform to be delivered over the forward years into 2020.

The report made a number of observations that:

- The APVMA receives a large number of poor quality applications which are time consuming to process.
- Compared to international regulators, the APVMA do not stop the assessment clock while awaiting information from the applicant.
- Assessment complexity has increased over the past five years, requiring more time and expertise from assessors. For example, the mean Residue Complexity Index (ROCI) almost doubled between 2009 and 2016.
- Internationally, similar agencies are also challenged in meeting their performance targets in an environment of increasing assessment complexity.

Progress against Governance arrangements

Future change programs

The APVMA acknowledges that the governance arrangements for the implementation of the legislative reform in 2014 were inadequate. A number of improved arrangements have been

put in place for current and future change programs to strengthen the governance and project management processes in line with best practice. Program and project boards have been established to provide program and project oversight along with dedicated project teams to manage the delivery and implementation of the Agricultural Competitiveness White Paper reforms and the relocation to Armidale.

Implementation of major reforms

The Major Projects Board membership has been revised and it now oversees a number of projects identified by the APVMA's executive leadership team that are critical to the future success of the agency. The projects include those funded under the *Agricultural Competitiveness White Paper* and other projects that relate to the APVMA's reform agenda (such as the response to the Review of Assessment Performance). The board includes representation from all critical areas of the APVMA and oversees the timely progress of the projects, ensures sufficient resources are allocated, resolves project issues and manages risks and dependencies.

The *Agricultural Competitiveness White Paper* has a comprehensive overarching program plan that outlines the objectives and the approach for the delivery of the reform program. Each of the white paper reform projects have detailed project plans and report to the board monthly on progress against each of the deliverables and to raise issues and risks.

The relocation activities are overseen by the APVMA's Relocation Program Board and the program of work is being managed by the APVMA's relocation operations team, across three streams, People, Place and Digital. The Relocation Program Board reports directly to the Chief Executive Officer and the APVMA's executive leadership team.

Progress against Recommendation No. 3

Since the ANAO audit on operations was published in June 2017, there have been a number of changes made to strengthen the governance arrangements of the APVMA.

- The CEO has established a Deputy CEO position and appointed Amy Fox in this role, to provide oversight of the business operations and reform. The Deputy CEO chairs the Major Projects Board that is in place to monitor the progress of projects, initiatives and changes, resolve issues and mange risks and dependencies.
- Stronger governance arrangements have been implemented for all white paper and relocation projects which address this recommendation. The Major Projects and Relocation Program Boards (refer Attachments C and D respectively) are in place to monitor the progress of projects, initiatives and changes, resolve issues and mange risks and dependencies.

The Audit Committee continues to closely monitor the progress of work and activities to implement the actions as a result of the audit recommendations. The committee is chaired by an independent member and has representation by the ANAO as part of the terms of reference.

The Department of Agriculture and Water Resources are currently considering policy options for the current governance arrangements of the APVMA.

Progress against Recommendation No. 4

Business Risks

The APVMA has undertaken a review of its approach to managing business risk, resulting in a revised risk management framework and an updated strategic enterprise risk profile. A supporting operational risk register has been formally endorsed by the APVMA executive leadership team with a rolling reporting cycle for all operational risks. The Audit Committee has also considered the risk register at its May and December 2017 meetings.

The APVMA Relocation Advisory Committee has a standing agenda item relating to risk and the Relocation Program Board has direct oversight of risk management, reporting monthly to the APVMA executive leadership team. Risk management relating to the relocation of the APVMA has been identified as a high priority with specific resources being engaged to identify, monitor and mitigate relocation-related risks.

In December 2017 the APVMA engaged O'Connor Marsden to undertake assurance mapping for the agency. The work will include analysis of the extent to which assurance activities are in place to address significant risks impacting the key operations of the APVMA. The work is expected to be completed in January 2018 and will deliver a gap analysis and key findings which will enable further improvements to the agencies current assurance/risk management arrangements.

Australian Government
Australian Pesticides and
Veterinary Medicines Authority

May 2017

Ms Michelle Kelly
Group Executive Director
Performance Audit
Australian National Audit Office
GPO Box 707
CANBERRA ACT 2601

Dear Ms Kelly

Thank you for your email dated 6 April 2017 regarding the proposed report on the performance audit of *Pesticide and veterinary medicine regulatory reform.*

The APVMA welcomes the audit by the ANAO of the effectiveness of implementation of reforms to agvet regulation which came into effect in July 2014.

The APVMA is widely respected for its scientific expertise and has been implementing a long term program of business and regulatory improvement to become a more contemporary world class regulator. The APVMA will use the recommendations in the report to further improve its regulatory operations and service delivery.

The legislative changes implemented from July 2014 were extensive and covered nearly all aspects of APVMA's operations and all sectors of industry.

The application process was moved completely online, new processes were introduced for pre-application assistance and preliminary assessment, and changes were made to a range of notice provisions and application types. New arrangements for development of workplans to manage reconsideration of chemicals were introduced. The amendments also provided for a graduated range of compliance and enforcement powers, introduced a power to apply statutory conditions to registrations and approvals and amended data protection provisions. At the same time, a significant change was made to the methodology for calculating timeframes to remove the ability to 'stop the clock' and to implement 100 per cent targets for timeframe performance.

While the proposed reforms had been under discussion since 2010, the legislation giving effect to the reforms was not passed until June 2013 with the commencement date being 1 July 2014. There was a further transition period through until 30 June 2015, at which point all pre-July 2014 applications and chemical reconsiderations were moved to the new arrangements, meaning the legislation has been fully operational for less than two years.

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The APVMA acknowledges that all aspects of the reform package were not finalised by the commencement date of 1 July 2014. However the basic process and system changes were in place with no significant disruption to industry being able to make applications under the new legislation. Since then, the APVMA has been implementing a continuous improvement program to enhance its efficiency and service delivery.

The APVMA believes that a full assessment of the overall effectiveness of the reforms requires a longer period of time to have elapsed given the scale of reform implemented over a relatively short timeframe.

Nevertheless, there were promising signs emerging in 2016, with timeframe performance for assessing pesticide and veterinary medicine applications reaching 83 per cent in the September quarter, with three out of four applications in the pipeline being within timeframe.

An independent analysis concluded that if the same methodology as used today was applied to applications prior to 2014, the proportion of applications finalised on time would drop from 91 per cent to 33 per cent. The analysis also found that the actual (or 'elapsed') time the APVMA took to finalise applications decreased by 70 per cent since compared to pre-July 2014.

The agency accepts all four recommendations with action already taken or underway to implement improvements consistent with the recommendations. This includes improvements in quality assurance processes for application assessment; better documentation of business processes to support consistency; and strengthening risk management, governance and performance monitoring frameworks. The agency is also implementing a major program of business process reform to improve the efficiency of its service delivery.

While the relocation of the APVMA poses some challenges for sustaining performance during the transition period, the agency is committed to ensuring the objectives of the legislation are met and that agricultural and veterinary chemicals available in Australia are safe to use.

A summary of the agency's overall response to the Proposed Report is provided at Attachment A and a detailed response to each of the recommendations is at Attachment B.

Yours sincerely

KAREENA ARTHY
Chief Executive Officer

Summary Response

The agency welcomes the audit by the ANAO of the effectiveness of implementation of reforms to agricultural and veterinary (agvet) chemical regulation which came into effect in July 2014. The agency acknowledges the findings and areas for improvement identified in the ANAO Report. The agency notes, however, that for the scale of reform undertaken the implementation timeframes were challenging and resourcing required to fully deliver within these timeframes was limited.

The agency notes the transition from pre-July 2014 to post-July 2014 reform arrangements was achieved without significant disruption to service delivery and involved an ongoing program of business improvement. Having moved through the transition period, the reforms were moving into a more mature phase of implementation in mid-to-late 2016, with 78 per cent of product applications processed within timeframe in the June quarter 2016 and 83 per cent in the September quarter 2016.

The agency accepts all four recommendations with action already taken or underway to implement improvements consistent with the recommendations. This includes improvements in quality assurance processes for application assessment; better documentation of business processes to support consistency; and strengthening risk management, governance and performance monitoring frameworks. The agency is also implementing a major program of business process reform to improve the efficiency of its service delivery.

APVMA response to recommendations

Recommendation No. 1
2.48 The Australian Pesticides and Veterinary Medicines Authority should implement an internal quality framework to provide an appropriate level of assurance that its assessments are undertaken in a consistent manner and made in accordance with agvet chemical legislation.

Australian Pesticides and Veterinary Medicines Authority's response:
2.49 Agreed.

The APVMA agrees the quality assurance framework for agvet chemical assessments can be improved. The APVMA believes the current processes for assessment of agvet chemicals are robust, with appropriate documentation and based on sound evidence, as acknowledged in the ANAO report. This provides for high quality scientific decision making for registration of agvet chemicals in line with the legislative framework.

Internal governance committees for registration management and science quality are operational within the agency to provide assurance that regulatory decision making is in line with legislative requirements, fit-for-purpose and consistent. The terms of reference for these committees will be reviewed to ensure they reflect action to implement the recommendation.

The APVMA will support the work of the committees through a program of better documentation of assessment frameworks, targeted training for assessment staff, and business process and IT improvements to standardise application processes as much as possible and improve consistency.

The APVMA notes the ANAO's suggestion regarding analysis of pre-application assistance outcomes with a view to developing appropriate industry guidance. The agency agrees improved guidance for industry continues to be an area for improvement and has commenced a process in consultation with industry to develop better guidance material for high volume applications.

The APVMA notes the ANAO's suggestion to develop intelligence collection and analysis arrangements to strengthen its compliance and enforcement strategy and will include this suggestion in future strategies.

Recommendation No. 2
3.27 The Australian Pesticides and Veterinary Medicines Authority should establish and monitor an appropriate set of measures and targets to assess the extent to which it is improving the effectiveness and efficiency of its regulatory activities through its ongoing reform agenda.

Australian Pesticides and Veterinary Medicines Authority's response:
3.28 Agreed.

The APVMA has a range of performance measures in its corporate and regulator performance plans and has reported against these indicators in the 2015-16 Annual Report. The APVMA also publishes quarterly a detailed report of timeframe performance and regulatory activity.

The APVMA agrees that a review of the performance measures is required to ensure they best reflect the regulatory framework within which it operates and to account for expectations under the government's *Agricultural Competitiveness White Paper* initiatives and the relocation of the APVMA to Armidale.

The APVMA notes that the Department of Agriculture and Water Resources has responsibility for the legislative framework for agvet chemicals and for designing regulatory reform measures and will work with the department on future reforms to ensure performance measures are clearly defined.

The APVMA notes the methods for calculating timeframe performance changed with the implementation of the legislation, making direct comparison of efficiency before and after the legislation difficult. Nevertheless, the APVMA showed significantly improved performance over 2016 with over 80 per cent of product applications being completed within legislated timeframes in the September quarter, despite a challenging operating environment relating to the announcement of the relocation of the APVMA to Armidale.

Recommendation No. 3

4.14 The Australian Pesticides and Veterinary Medicines Authority should improve its governance of the implementation of major reforms, including the maintenance of an oversight body with clearly defined responsibilities and robust project monitoring arrangements.

Australian Pesticides and Veterinary Medicines Authority's response:

4.15 Agreed.

The APVMA notes the governance arrangements for the implementation of the legislation in 2014 were inadequate and recognises that ongoing effort is required to ensure appropriate governance arrangements are in place for major initiatives.

Following the experiences in 2014, the APMVA established a Project Board, along with a dedicated team, to provide oversight of the key reform projects being progressed under the *Agricultural Competitiveness White Paper*. This provides for a coordinated approach to implementation planning, preparation of project documentation, identification and management of risks, anticipated benefits and budget management. The Project Board reports to the executive leadership team on a monthly basis.

Governance arrangements for the relocation of the APVMA to Armidale are in place with a dedicated executive leadership team and a steering committee established. There is also the APVMA Relocation Advisory Committee which meets monthly to provide advice on various aspects of the relocation with members drawn from industry, the Armidale Council, the University of New England and also the Department of Agriculture and Water Resources.

Recommendation No. 4

4.36 The Australian Pesticides and Veterinary Medicines Authority should implement a structured and systematic approach to identifying and responding to emerging business risks.

Australian Pesticides and Veterinary Medicines Authority's response:

4.37 Agreed.

The APVMA has undertaken a review of its approach to managing business risk, resulting in a revised risk management framework and an updated strategic enterprise risk profile, which is reviewed at monthly executive leadership meetings.

Risks relating to reform activities being progressed under the *Agricultural Competitiveness White Paper* risks are addressed in each project plan and monitored by the Project Board.

Risk management relating to the relocation of the APVMA has been identified as a high priority with specific resources being engaged to identify, monitor and mitigate relocation-related risks. The APVMA Relocation Advisory Committee has a standing agenda item relating to risk and the Relocation Steering Committee has direct oversight of risk management, reporting monthly to the APVMA executive leadership team.

Australian Government

Australian Pesticides and Veterinary Medicines Authority

SEPTEMBER 2017

APVMA Relocation Program Board Terms of Reference

Contents

1 BACKGROUND

In the 2016-17 MYEFO Budget, the government announced it will provide $25.6 million over six years to relocate the Australian Pesticide and Veterinary Medicines Authority (APVMA) to Armidale, New South Wales. This measure will support the establishment of a Centre of Agricultural Excellence at the University of New England (UNE), with the APVMA partnering with UNE and other specialist agriculture research centres to become an agriculture research hub.

The relocation of the APVMA to Armidale is being managed as a Program led by the Deputy CEO Legal, Corporate and Relocation, along with the Executive Director Digital Strategy and Executive Director Relocation Operations.

2 PURPOSE OF THE RELOCATION PROGRAM BOARD

The APVMA Relocation Program Board (RPB) will oversee the Relocation Program ensuring the Program meets its intended business outcomes through providing strategic guidance, support, and oversight of the Program's progress.

The RPB will also advise the CEO on key aspects of the relocation and provide input into the APVMA Relocation Advisory Committee (ARAC).

3 ROLE OF THE RELOCATION PROGRAM BOARD

The role of the Relocation Program Board includes:

- understanding the strategic implications and outcomes of initiatives being pursued through project outputs and providing strategic guidance
- ensuring the project scope aligns with the requirements of key stakeholder groups and considering impacts to scope changes from a finance, resource and schedule perspective
- reviewing project schedules and resourcing requirements
- reviewing associated project risks and issues and removing project road blocks
- approving new projects and closure of projects upon completion
- understand project plans and monitor progress against plan
- set tolerance levels within which the project manager must operate
- understand and act on those factors that affect the successful delivery of the project
- have the authority to release necessary funding and resources from their respective user and supplier communities
- broker and maintain relationships with stakeholders within and outside the project
- provide delegated authority, as required, to ensure the project meets its objectives

4 GENERAL

Membership

The membership of the Relocation Program includes:

- Senior Responsible Officer (SRO) - Chair
- Executive Director Relocation Operations – Deputy Chair
- Executive Director Digital
- Program/Project Managers
    - People
    - Place
    - Digital

Specialist Advisors to the RPB:

- Chief Financial Officer (as needed)
- DCEO, Business Operations and Reform
- Director, Public Affairs and Communication

Meeting Chair

The Chair of the Program Board will be the Deputy CEO Legal, Corporate and Relocation of APVMA. The Deputy Chair of the Program Board will be the Executive Director Relocation Operations. If the designated Chair is not available, the Deputy Chair will be responsible for convening and conducting that meeting. The Acting Chair is responsible for informing the Chair as to the salient points/decisions raised or agreed to at that meeting. If both the Chair and Deputy Chair are unavailable, the meeting will be cancelled or rescheduled.

Agenda Items

The Secretariat will call for agenda items a minimum of six working days prior to the next scheduled meeting. All Relocation Program Board agenda items and papers will be provided to Secretariat a minimum of four working days prior to the next scheduled meeting. The agenda and papers will then be distributed to Program Board members a minimum of two working days prior to the next scheduled meeting.

The Chair has the right to refuse to list an item on the formal agenda, but members may raise an item under ‘Other Business’ if necessary and as time permits.

Minutes & Meeting Papers

The minutes of each Relocation Program Board meeting will be prepared by the Program Management Office (PMO).

Full copies of the Minutes, including attachments, shall be provided to all RPB members no later than five working days following each meeting.

By agreement of the Board out-of-session decisions shall be recorded in the minutes of the next scheduled RPB meeting.

Relocation Program Steering Committee

Frequency of Meetings

The RPB shall meet monthly, as per the Relocation Program governance calendar.

Proxies to Meetings

Members of the RPB shall not nominate a proxy to attend a meeting if the member is unable to attend. A substitution will only be allowable in the event of acting arrangements. The Chair will be informed of the substitution at least three working days prior to the scheduled nominated meeting.

The nominated proxy shall have voting rights at the attended meeting. The nominated shall provide relevant comments/feedback, of the RPB member they are representing, to the attended meeting.

Quorum Requirements

A minimum of three (3) RPB members is required for the meeting to be recognised as an authorised meeting for the recommendations or resolutions to be valid.

Terms of Reference

Purpose

The Major Projects Board oversees a number of projects identified by the APVMA Executive Leadership Team (ELT) that are critical to the future success of the agency. The projects include those funded under the Agricultural Competitiveness White Paper and other projects that relate to APVMA's reform agenda.

The Major Projects Board oversees the timely progress of the projects, ensures sufficient resources are allocated, resolves project issues and manages risks and dependencies.

The Major Projects Board reports to the ELT and to the Chief Executive Officer.

Objectives

The Major Projects Board will:

- review and endorse project plans for consideration by ELT or the CEO
- approve the initiation and closure of approved projects
- review and monitor progress of approved projects, including the impact of change to staff and clients
- provide advice and input to the development of strategies, blueprints, action and implementation plans
- ensure alignment of projects with broader organisational initiatives such as the Corporate Plan
- monitor and manage risks and issues including oversighting implementation of mitigation strategies
- review business impact and business readiness assessments for projects
- approve implementation of changes based on assessments of impact and business readiness
- ensure planning and reporting requirements are addressed.

Membership

The Committee is chaired by the Deputy Chief Executive Officer, Business Operations and Reform and has the following membership comprised of Senior Leadership Team representatives that are responsible for delivering or enabling a major project:

- Chief Information Officer
- Chief Finance Officer
- Director, Office of the Chief Executive Officer
- Director, Efficacy Assessment Coordinator
- Director, Scientific Standards and Data Guidelines
- Director, Quality Oversight and Reporting
- Director, Public Affairs and Communications
- Director, Portfolio Director – Veterinary Medicines
- Director, Compliance and Monitoring

Note: all Executive Directors and Department of Agriculture and Water Resources representatives are invited to attend as observers. Project managers will be required to attend and present a status report and associated project deliverables as required.

Meetings

The committee will meet:

- Monthly—meetings will be formal and minuted.
- Weekly—meetings with the project managers will be informal and not minuted.

Planning

The Innovation and Implementation team will develop a forward meeting schedule that includes the dates and proposed agenda items for each meeting.

Quorum

A quorum will consist of a majority of committee members and must be present for any decision making.

Secretariat

Secretariat services will be provided by the Innovation and Implementation team.

The secretariat will:

- ensure the agenda for each monthly meeting is approved by the Chair
- the agenda and supporting papers are circulated, at least five working days before the meeting
- ensure the minutes of the meetings are prepared and circulated within five working days after the meeting.

Review of charter

At least once a year the committee will review this charter. Any substantive changes to the charter will be recommended by the committee and formally approved by the Chief Executive Officer.