





Chapter 1
Summary
and outlook
2016–17

Summary and outlook 2016–17



As interim Chief Executive Officer (CEO) for the Australian Pesticides and Veterinary Medicines Authority (APVMA), I am pleased to present the *Annual report* for the year ending 30 June 2017.

The APVMA plays an important role in regulating the safety and effectiveness of agricultural and veterinary (agvet) chemicals in Australia that support productive agricultural industries, protect the health and wellbeing of companion animals, and safeguard our unique environment against pests and diseases.

With such an important role comes the responsibility to balance robust science-based decisions with efficient regulation that meets modern client service standards. The APVMA's dedicated and highly trained staff have delivered on a full and challenging work program that has positioned the agency to implement the government's broader agenda over the coming years.

Significant changes to the APVMA's operating context were announced in November 2016 when a Government Policy Order was issued that will see the agency relocate to regional Australia in Armidale, New South Wales (NSW), by 2019. Preparatory work was undertaken to develop strategies that capture and manage the agency's knowledge, define elements of the APVMA's Digital strategy, and consult on key staffing policies that support relocation and retention. A key deliverable in 2016–17 was the release of the *APVMA in Armidale: relocation strategy*, which outlines the forward activities that will enable the transition of the agency's regulatory operations to Armidale by 2019.

The APVMA has achieved significant milestones against our corporate strategies of reducing regulatory burden, robust decision making, continuous improvement and organisational efficiency. We have developed new approaches that reduce the burden on industry in meeting regulatory requirements. We have delivered on our statutory responsibilities for compliance and enforcement, and chemical reconsiderations, and come close to meeting our targets for audits and registrations.

A significant amount of work has gone into understanding our applicants and developing a view of what our clients need from us to navigate the regulatory system. We continued to develop and improve our information and communication technology systems (ICTs) to support business operations and are well positioned to use the opportunities that the APVMA Digital strategy provides to stabilise and modernise our service platforms into the future.

Decision making

Quarterly performance statistics demonstrated a level of volatility in the agency's ability to meet statutory timeframes for assessment and registration. The reports show a trend of increasing applications over time with work in progress increasing steadily by 50–80 applications each quarter over the first three quarters.

Despite fluctuations in our performance, the APVMA finalised 2453 applications for new actives, products and permits in 2016–17, providing Australian farmers and veterinarians with access to additional products that bring new chemicals and innovative crop protection and vet medicines to Australia. Of the 2453 applications finalised this year, 69 per cent were completed within the statutory timeframes, up one percentage point on 2015–16 when 68 per cent of applications were finalised on time.

Further improvement on our operational performance will be a focus for the APVMA as we implement business process reforms and invest in our ICT systems to enhance efficiency.

In March we finalised the reconsideration of dimethoate, closing out years of extensive industry engagement, scientific assessment and the evaluation of new data that enabled a number of uses to be maintained.

Proving that timeliness is just one indicator of quality regulation, the APVMA was honoured to receive international recognition from Health Canada for our contributions to the first ever trilateral joint review of a veterinary chemical product. The awards recognise the APVMA's world-class approach to regulating veterinary medicines and highlight the many benefits of international scientific collaboration that has led to the simultaneous assessment and registration of a veterinary medicine across jurisdictions.

Aligning regulatory burden with risk

This year we operationalised strategies that reduce the regulatory burden for industry and better align our regulatory effort with risk. Several applications seeking to repack an existing product were fast-tracked through the registration process under a pilot program that streamlines the current application requirements and internal process.

We published new guidance on the use of international assessments that will support the use of data and scientific assessments from comparable overseas regulators and further work in this area will streamline registration for applicants wanting to invest in the Australian market. We trialled a new approach to efficacy assessments that reflects a more commercial mindset and expanded the list of notifiable variations, allowing clients to make simple administrative changes to their registration particulars for active constituents, products and labels without the need for a formal application.

The groundwork has been laid for business process reform and systems improvements through a coordinated program led by our Innovation and Implementation Taskforce established in 2016 to deliver projects funded through the Agricultural Competitiveness White Paper. The application and risk profiling undertaken in 2016–17 has established platforms to deliver further improvements to the regulatory framework.

A proactive approach to compliance and monitoring has seen the agency work with industry to manage potential risk in the market, disrupting the flow of unregistered veterinary chemical products and responding to industry concerns through a sampling and testing regime for agricultural chemicals to verify that products supplied in Australia continue to meet the conditions of registration.

Client focus

Towards our vision of world-class regulation, the APVMA maintained a strong commitment to client service and communication, seeking input from clients and stakeholders through a range of channels and forums. In April we opened the Armidale interim office, taking those important first steps to establish a local presence and develop partnerships with the Armidale community and businesses.

We engaged our clients to better understand what applicants expect and need from the APVMA when they navigate the registration process. More than 180 clients and stakeholders attended the industry information forum in Canberra during November 2016 where we presented the initial findings of an online usability review. This investigative work has already delivered improvements to the search functionality applied to the APVMA website and new guidance material provided to support users submitting applications online.

Implementing a case manager model for enquiries has improved continuity of handling and we continue to monitor and respond to feedback provided in person, over the phone, through email and online.

High performance and organisational efficiency

Retaining and building capability has been a key focus for the agency in 2016–17. Our staff separation rate increased during the year, highlighting the need for more aggressive recruitment action, complemented by strategies to manage organisational knowledge and accelerate the development of regulatory science expertise.

We continued to improve our online services and information technology platforms and finalised the *ICT strategic plan 2016–19* that outlines the path to becoming a data centric agency. Legacy systems were decommissioned and new platforms launched for financial and records management to stabilise the IT environment and strengthen corporate governance and reporting.

Looking forward

The year ahead represents the start of significant transformation for the APVMA. A year when the agency delivers the business improvements funded through the Agricultural Competitiveness White Paper, works to implement legislative reform and establishes the plans, policies and partnerships that we will need to run our business in Armidale by 2019. We will refine our planning and bring forward elements of the *APVMA in Armidale: relocation strategy*, to support the movement of staff and recruit into our Armidale interim office.

We will continue to reflect on feedback provided to us from clients and stakeholders, and use the opportunities that the relocation affords to think critically about how we operate now and how we can operate in the future. Further consideration of lower regulatory approaches will be a focus of our scientific work, particularly in the areas of international assessments and provisional registration.

The APVMA last undertook a full review of cost recovery arrangements in 2012. The fees and charges received from industry no longer reflect the costs of delivering the APVMA's regulatory function. The agency has run an operating loss for the previous three years, with expenses exceeding actual revenue by \$3.5 million on average each year.

Financial management and sustainability will be a priority, with adjustments to our systems and processes to provide quality financial information for internal and external stakeholders. We can no longer afford to underinvest in our information technology and make plans for capital investment to improve our stakeholder experience. We will commence a review of cost recovery arrangements in line with the Australian Government Charging Framework, and consult with stakeholders to ensure the financial sustainability of the APVMA into the future. Putting in place short-, medium- and long-term plans to ensure the costs of regulation reflect the true costs of delivering the regulatory function to a standard acceptable to external scrutiny.

We must revise our internal budget and align our expenditure with our expected revenue. We will not shy away from the difficult decisions and are committed to realign our internal operations. We will improve our governance, apply our new enterprise risk framework to manage the business risks that are within our control, and use recommendations from the Australian National Audit Office to mature as a regulator. We will investigate the root causes of delays in the assessment and management of applications and work with our staff and clients to put strategies in place to address these.

As the interim CEO, my focus will be on providing the clarity our people need to understand the path forward and creating an agile and responsive business environment that enables the future leadership to come in and take up the reins.

Dr Chris Parker

Interim Chief Executive Officer
September 2017



*“The year ahead represents
the start of significant
transformation for the APVMA.”*

APVMA 2016–17 highlights

Significant activities and changes

- On 24 November 2016, a Government Policy Order (GPO) made under s. 22 of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) was issued to the APVMA CEO specifying that corporate Commonwealth entities with agricultural policy or regulatory responsibilities are to be located in a regional community that is near a main campus of a regional university recognised for research and teaching in the field of agricultural science. On the 25 November 2016, the Deputy Prime Minister and Minister for Agriculture and Water Resources, Hon. Barnaby Joyce MP, announced that the Government had approved \$25.6 million to fund relocation of the APVMA to Armidale in regional NSW.
- This led us to develop a relocation strategy that outlines the broad activities needed to efficiently transfer APVMA functions from Canberra to Armidale.
- We are in the planning phase of the relocation and have established an APVMA Relocation Advisory Committee with staff and representatives from peak bodies as members.

Performance against Strategy 1—Decision making

- We have achieved our statutory responsibilities in terms of compliance, enforcement and reviews, and achieved close to our target in terms of audits. We did not achieve our timeframe performance aims. However, the average time an application spends in the system has been reduced. We continue to review and identify opportunities for improvement.

Performance against Strategy 2—Regulatory burden

- We have developed a number of new approaches that aim to reduce the burden on industry in meeting regulatory requirements, including:
 - new data guidelines to better align with the international material and guidance for industry about the use of international data and standards in applications
 - a new semiautomated decision document template that has reduced the time required to record decisions
 - a new fast-track system for low-risk applications.

Performance against Strategy 3—Client focus

- We have worked on projects to obtain a clear understanding of what applicants want from the APVMA and to improve our communication and technical guidance material, including:
 - a review of our online channels and information, and of outgoing letters, notices and emails
 - initial changes to the APVMA website that have improved user searches and discoverability of guidance material; additional changes are planned
 - new guidance on online applications and the submission of international data and assessments
 - public consultation on 45 regulatory decisions and changes to operational policy and guidelines.

Performance against Strategy 4—High performance and efficiency

- We have recruited and inducted 85 staff members, and focused training on technical and scientific processes.
- We have upgraded the electronic document records management system (EDRMS) and implemented an internal instructional material library to manage APVMA management documentation.
- To ensure future information and communication technology (ICT) needs are met, we have developed the *ICT strategic plan 2016–19*. We have also started to develop an APVMA Digital strategy to enable the operation of the APVMA from Armidale.

Corporate governance and management

- In May 2017, Kareena Arthy resigned as APVMA CEO. Dr Chris Parker was appointed as interim CEO in June 2017.
- All governance committees performed as required in 2016–17.