ANNUAL REPORT
2015–16
Letter of transmittal

Australian Government
Australian Pesticides and Veterinary Medicines Authority

12 September 2016

The Hon Barnaby Joyce MP
Deputy Prime Minister
Minister for Agriculture and Water Resources
Parliament House
Canberra ACT 2600

Dear Minister

I am pleased to submit the Australian Pesticides and Veterinary Medicines Authority (APVMA) annual report for the year ending 30 June 2016 for your agreement to table.

The APVMA is required by the Agricultural and Veterinary Chemicals (Administration) Act 1992 to provide an annual report on its operations for the preceding financial year. Among other things, the report must contain the financial statements required by s. 42 of the Public Governance, Performance and Accountability Act 2013 (PGPA Act) and an audit report on those statements under s. 43 of the PGPA Act. I confirm that this annual report complies with these requirements.

In accordance with the Commonwealth fraud control guidelines, I certify that the APVMA has prepared a fraud risk assessment and a fraud control plan, and has in place appropriate fraud prevention, detection, investigation, reporting and data collection procedures.

Yours sincerely,

[Signature]

KAREENA ARTHY
Chief Executive Officer
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Vision and mission

Vision
Australians have confidence that agricultural and veterinary chemicals are safe to use.

Mission
To protect the health and safety of Australia—its people, animals and environment—and support Australian agriculture, by taking a scientific and risk-based approach to regulating agricultural and veterinary chemicals.
Chief Executive Officer’s report and outlook

In 2015–16, the Australian Pesticides and Veterinary Medicines Authority (APVMA) focused heavily on ways to lower the regulatory burden for industry when it comes to making an application, as well as improving the overall experience of applicants in interacting and transacting with the APVMA.

We looked across the agency and to industry and asked what we had done well and what could be improved. We focused on user-centred improvements to our systems and processes, while continuing to build a capable and high-performing organisation with scientific excellence at its heart.

Our governance, risk-management and decision-making approaches were reviewed and revamped and we built organisational capability in project design and delivery.

We effectively implemented a range of legislative reforms and provided greater transparency for industry by publishing our performance against statutory timeframes on our website.

Importantly, our efforts were informed by collaboration and consultation, by designing systems with the user in mind, and by taking action to stop things that were not working. This approach has been well received by industry, and we are starting to see early signs it will translate into productivity gains for both the regulated community and the APVMA.

Reducing the regulatory burden for industry

Building on our work with the University of Melbourne’s Centre of Excellence for Biosecurity Risk Analysis, we finalised a risk-assessment model and have started a pilot to test innovative and fast-tracked registration pathways for products. Through this work our intention is to better align regulatory effort with risk—further reducing the regulatory burden for industry. This is ground-breaking work that has not been done by any other regulator. The APVMA received $7.3 million in funding from the Agriculture White Paper to advance this work.

Improving timeframe performance

Since the introduction of reforms in 2014, we have continued to make steady progress in improving application assessment times. An audit undertaken this year shows that the average time taken to register a product is now shorter than under the previous legislation.

Final quarter 2015–16 results showed an overall improvement in timeframe performance and the numbers of applications being finalised. We invested effort in clearing overdue applications, particularly those transitioned from the previous legislation, to ensure that our performance against timeframes for finalising applications can improve over time.

Recruitment of new specialist staff and improvements to systems and workflow processes implemented in the second half of 2015–16 is continuing, and final quarter results show promising signs for longer-term improvement.
A new approach to pre-application assistance

We also took action in 2015–16 to address issues with the initial implementation of the pre-application assistance initiative—part of the package of 2014 reforms. Working with industry, we co-designed a new process for managing all types of requests for assistance from applicants.

At the same time, we simplified the previously complex fee-for-service arrangements for pre-application and technical assistance and replaced them with a simpler more flexible three-tiered approach. We also streamlined our internal processes for advice and assistance to improve the user experience, including moving to a designated account manager model for managing all enquiries.

It’s all about the science

This year, the APVMA continued its positive contribution to international forums.

Our scientists provided independent expert advice to United Nations and World Health Organization committees, including the Joint Meeting on Pesticides Residues, and represented Australia on the international standard-setting committees of the Codex Alimentarius Commission for pesticides and veterinary medicines.

We continued to contribute to global harmonisation in agricultural and veterinary (agvet) chemical regulation, including chairing three OECD committees. The APVMA CEO became chair of the OECD Working Group on Pesticides—the main international gathering of pesticide regulators across the world. We also co-chaired two expert groups—one developing guidance for conducting rotational crop field trials, and the other in the emerging field of RNA interference (RNAi).

Our annual science day, held in Canberra in October 2015, attracted more than 200 industry and government attendees to hear from world-renowned scientists on advances in risk assessment, including aquatic risk modelling, dietary exposure, and veterinary drug residues.

Through participation in the Australian Regulatory Science Network, we contributed to a whole-of-government approach to the regulation of chemicals and biological agents, and through our APVMA-initiated workshops and seminars we shared regulatory science expertise with staff, industry, government and the scientific community on a range of topics, including risk-profiling, emerging technologies and exposure modelling.

We complemented and built in-house expertise by tapping into academic and industry scientific excellence through our science fellows program, and we initiated work to support future regulatory science capability by working with universities to develop course content that is directly relevant to regulatory science.

Compliance and good manufacturing practice

This year we reviewed and strengthened our strategic risk-based approach to compliance and good manufacturing practice, and engaged a specialist consultant to review our overall approach to licensing and auditing of veterinary manufacturers for completion in 2016–17.

We investigated every allegation of non-compliance and risk-assessed each one before any action was taken, to ensure our efforts on behalf of industry and the community were proportional to the risk and maintained the integrity of the Australian regulatory system.
Consultation

In 2015–16, the APVMA initiated over 60 separate consultations. While the majority of matters were related to our statutory requirements for registration and approval of chemicals, we also sought industry and stakeholder views on standard setting policies, including the adoption and use of international standards, assessments and data guidelines.

During 2015, we also conducted public consultations around Australia, with industry, growers, government agencies and the community, to prioritise chemicals as part of our formal chemical review program.

Improving access to chemicals

Our work with the Department of Agriculture and Water Resources to develop an Australian crop group list will mean improved access to chemicals for Australian growers, as well as a reduction in the costs involved in registering agvet chemicals for a broader range of uses in Australia.

We considered more than 500 permits to identify whether their use could be moved to permanent label registration. This work will be progressed in 2016–17, and when fully operational, has the potential to eliminate the need for industry and growers to renew permits each year, saving considerable time and effort for all parties.

Inquiries, reviews and court decisions

The APVMA appeared before both the Senate Estimates Rural and Regional Affairs and Transport Legislation Committee and the House of Representatives Standing Committee on Agriculture, for their inquiry into agricultural innovation.

We also provided submissions to the Productivity Commission’s public inquiry into regulation of agriculture and to the Queensland Parliament’s inquiry into veterinary surgeons’ use of the Hendra virus vaccine.

A Federal Court decision in June 2016 has meant a change in how we assess applications for generic products involving reference products—we now have to assess each application on a case by case basis to determine whether any confidential commercial information may be disclosed.

We will work with industry to streamline these processes as much as possible, while ensuring the interests of both product innovators and the generics industry are considered.

Looking forward

We will continue to build on the expertise and scientific capability of our people to regulate safe chemicals for the Australian community.

We will use our involvement and contribution to scientific and regulatory thinking—through forums in Australia and around the world—to bring the latest scientific expertise to the table in the regulatory decisions we make every day.

This commitment to scientific excellence, combined with our ongoing drive for business process improvement and efficiency, will continue to support our long-term goals of reducing the regulatory burden for industry, improving access to chemicals and increasing productivity.

I am pleased to present this annual report of our work in 2015–16.

Kareena Arthy
Chief Executive Officer
September 2016