





CHAPTER 2

Corporate governance
and management

Planning

Corporate and operational plans

Our central planning document is the corporate plan, which defines the principal objectives of the APVMA and gives a broad outline of the strategies devised to achieve these objectives. The corporate plan aligns with the APVMA Regulator Performance Framework (RPF), which outlines our key performance measures.

In addition, each year we develop an operational plan that sets out the actions needed to achieve the objectives in the corporate plan. We measure our operational effectiveness annually through the performance indicators in the operational plan and the Portfolio Budget Statement (PBS).

Consultation and collaboration

We work closely with industry stakeholders, national and international regulatory agencies and standard-setting bodies to ensure we are meeting the needs of the regulated community and continuing to operate as a world-class regulator. Stakeholders from industry, chemical users, government and the community are regularly invited to provide input to our decision making, through consultations on chemicals proposed for registration or active approvals and in the development of standards, guidelines and operational policy.

Governance structure

The APVMA governance structure aligns accountabilities relating to decision making, scientific assessment and operational delivery to support the agency in delivering outcomes. The committee governance structure aligns with principles of public sector governance to provide accountability, transparency, integrity, stewardship, efficiency and leadership. It supports APVMA staff in adhering to public sector values to be impartial, committed to service, respectful, accountable and ethical.

Table 2: APVMA governance committees

Executive Leadership Team	The Executive Leadership Team (ELT) comprises the senior executive and is chaired by the CEO. The ELT provides strategic, whole-of-organisation advice and direction relevant to decision making, management and oversight of the APVMA's operations and performance.
Audit Committee	This subcommittee reports to the CEO. It assists the agency to discharge its responsibilities under the <i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i> and the <i>Public Governance, Performance and Accountability Act 2013</i> regarding financial reporting, performance reporting, risk oversight and management, internal control and compliance with relevant laws and policies. The committee is not responsible for the executive management of these functions.
Registration Quality Committee	The Registration Quality Committee is a subcommittee reporting to the ELT. It oversees the quality of decision making in the registration activities of the APVMA, and ensures that systems, processes and capability support high-quality decision making that is consistent and legally defensible.
Science Quality Committee	The Science Quality Committee (SQC) is a subcommittee reporting to the ELT. It advises and decides on matters of science and science quality relevant to the functions of the APVMA.
Enforcement Committee	The Enforcement Committee is a subcommittee reporting to the ELT. It oversees the potential use and actual use of coercive powers.
Major Projects Board	The Major Projects Board oversees the progress of projects that are significant to the operational direction of the agency. The board oversees project deliverables, resourcing requirements, timeframes and management of risks. It also ensures that cross-project opportunities and issues are identified and addressed.

The Senior Leadership Team provides a forum for the senior operational managers in the agency to identify opportunities for internal collaboration, innovation and performance improvement, and to develop leadership.

The APVMA operates a Work Health and Safety Committee and a Staff Consultative Committee to consider and progress employee matters.

The Administration Act provides for an advisory board to advise and make recommendations to the APVMA CEO regarding the performance, function or exercise of particular powers of the APVMA. There are currently no members appointed to the board. Previous appointments expired in November 2015.

The APVMA CEO is the accountable authority for purposes of the PGPA Act and is a statutory officer. APVMA guidance material for employees includes policies relating to security, appropriate management of confidential information, financial and procurement practices, use of social media, conflicts of interest, travel, performance management and workplace safety. These policies operate in line with and in addition to requirements under the APS Code of Conduct and legislative framework governing the conduct of APS employees. The APVMA undertakes corporate risk management with regular review by executive staff.

APVMA Advisory Board

The advisory board was established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act) to provide advice and make recommendations to the CEO regarding APVMA activities.

Advisory board members did not represent particular interests, and were appointed by the minister based on experience in the regulation of chemical products, the agricultural chemical industry, primary production, environmental toxicology, consumer interests, public health, and work health and safety.

There are no members currently appointed to the advisory board, and previous memberships expired in November 2015.

Meetings and attendance

The advisory board met twice in 2015-16: on 27 August, 2015 and 5 November 2015. Attendance at advisory board meetings is shown in Table 3.

Table 3: Attendance at advisory board meetings 2015

MEMBER	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Lyn Fragar (Chair)	2	2
Sandra Baxendell	2	2
Bronwyn Capanna	2	1
John Hassell	2	2
David Lawson	2	2
Gordon Reidy	2	2
Selwyn Snell	2	1
Roger Toffolon	2	2
Lisa Wade	2	2
Australian Department of Agriculture and Water Resources representative	2	2

Issues considered

Key matters discussed included the development of strategies regarding regulatory science and compliance, industry engagement, regulatory reform projects, consideration of reform activities and updating the environmental scan for the APVMA operating environment. The board also provided advice and recommendations concerning APVMA activities to the APVMA CEO.

Declarations of interest

Members of the advisory board are required under the Administration Act to disclose any direct or indirect financial interests that could conflict with the proper performance of the advisory board's function. No conflicts of interest were reported during 2015–16.

APVMA Audit Committee

The audit committee is part of the APVMA governance and risk framework. Its terms of reference are to provide independent assurance and advice to the CEO concerning the risk control and compliance framework, the APVMA's financial and management responsibilities, and performance reporting and external accountability responsibilities.

The committee members include an external independent chair, a representative from an external organisation, and a member of APVMA executive management. Committee observers and advisers can include representatives from the Australian National Audit Office, the internal auditor, the APVMA CEO, the APVMA Chief Financial Officer, the APVMA Chief Information Officer and other management representatives.

Meetings and attendance

The audit committee met four times in 2015–16: in September and November 2015, and February and May 2016. Attendance at audit committee meetings is shown in Table 4.

Table 4: Attendance at audit committee meetings 2015–16

REPRESENTATIVE	MEMBER'S ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Peter Hoefer	External independent chair	4	4
Cate Saunders	APVMA	4	4
Claude Gauchat	External organisation representative	4	4
Appointment pending	External organisation representative	4	0

Issues considered

In 2015-16, the audit committee:

- reviewed the previous year's financial statements and Certificate of Compliance
- monitored the schedule for preparation of annual financial statements for 2015-16
- monitored the financial planning and performance of the APVMA
- monitored and advised on the continued implementation of legislative reforms, the associated business reforms and IT enhancements from 1 July 2014
- reviewed and monitored the Risk Management Plan and Risk Register
- reviewed the APVMA Fraud Control Plan 2015-16
- monitored key performance indicators of the committee
- monitored and advised on the internal audit program, including audits of records management, the enforcement of the Agvet Code and the agency's regulatory framework performance metrics.

Presentations

In 2015-16, the audit committee received a presentation by Deloitte Australia on the agency's Strategic Risk Profile and Risk Appetite, and by KPMG on the Protective Security Policy Framework (PSPF).

Declarations of interest

No conflicts of interest that would interfere with the proper performance of the audit committee's functions were declared at any meeting in 2015-16.

Manufacturers' Licensing Scheme Industry Liaison Committee

The APVMA established the Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC) as a forum to discuss strategic and operational issues relating to the Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice Scheme with industry representatives and auditors.

Terms of reference

The terms of reference of the MLSILC are to:

- obtain the views of industry members and auditors on issues of an operational, technical or strategic nature
- advance the development and review of operating procedures, manufacturing standards and guidelines relevant to the Australian Manufacturers' Licensing Scheme and the Overseas Good Manufacturing Practice Scheme
- provide industry input into APVMA operational planning processes relating to manufacturing issues
- identify opportunities for regulatory reform within the existing framework
- consider the effect of proposed policy changes on APVMA operations, and implications for industry
- facilitate communication with industry and other stakeholders.

Meetings and attendance

The committee met three times in 2015–16: in August and December 2015, and April 2016. Figures for membership and attendance at MLSILC meetings are shown in Table 5.

Table 5: Manufacturers' Licensing Scheme Industry Liaison Committee meetings 2015–16

REPRESENTATIVE	MEMBER ORGANISATION	MEETINGS ELIGIBLE TO ATTEND	MEETINGS ATTENDED
Bruce Johnson (Chair: August 2015, retired 31 March 2016)	APVMA	2	1
Kathryn Winterton (Chair: December 2015, April 2016)	APVMA	3	3
Garry Hartridge (Secretary: August 2015, December 2015)	APVMA	3	2
Sean Jacovelli (Secretary: April 2016)	APVMA	1	1
Bill Blackhall (retired after August 2015)	Veterinary Manufacturers and Distributors Association	1	1
Ian Saunders	Veterinary Manufacturers and Distributors Association	3	3
Matthew Sherriff	Animal Medicines Australia Ltd	3	2
John Aird	Feed Ingredients and Additives Association of Australia	3	2
Ian Wheatley	Auditors' representative	3	3
Jim Adams (attended part of one meeting)	Veterinary Manufacturers and Distributors Association	1	1

Issues considered

Issues considered in 2015–16 included:

- feedback from 2015 auditors' workshop on topics raised by industry
- updates on the progress of revised risk-based audit scheduling and management methodology
- updates on guidance for 'release for supply' by toll manufacturers
- progress with auditing and licensing of veterinary medicine product manufacturers
- international recognition issues
- status of the external review of APVMA's good manufacturing practice (GMP) programs
- APVMA's compliance and enforcement strategy
- the future operation of the committee.

Declarations of interest

There were no matters declared by any member of the MLSILC that would give rise to any personal material conflict of interest. The APVMA maintains records of declarations.

Accountability

Corporate risk management

The methodology used to assess risk at the APVMA is consistent with the international risk management standard and best practice. The APVMA reviewed its approach to strategic risk in 2016–17 and developed a new risk management framework.

The APVMA's Senior Leadership Team conducts regular reviews to ensure that all risks to the organisation are identified. Risk analysis of major projects is also undertaken and regularly reviewed. Risks are assessed and scored, with consensus sought on the likelihood of the risk occurring and the possible consequences. Treatments are developed and controls are documented for high and unacceptable risks. The treatments are monitored to ensure that they are implemented. A regularly updated risk register documents these risks.

The APVMA Audit Committee regularly reviews this framework and the risk register.

Fraud control

The APVMA has a fraud risk assessment and a fraud control plan that comply with the *Commonwealth fraud control guidelines*. The plan includes fraud prevention, detection, investigation, reporting and data collection procedures. This year we developed a new fraud control plan for 2014–16.

There were no cases of fraud during the reporting period.

Reporting

The APVMA Gazette lists all APVMA notices and decisions as required under the Agvet Code, including registrations, reviews and changes to registration status. The gazette is published fortnightly and is available from our website.

The APVMA prepares reports of its performance in meeting regulatory obligations, and presents a range of statistics, including:

- chemical product registration
- active ingredient approvals
- permits issued
- veterinary manufacturers licensing and auditing
- preliminary assessment and pre-application assistance.

The reporting includes:

- the number of applications started and finalised
- the proportion of applications finalised within legislative timeframes
- work in progress at the end of the period.

APVMA service charter

The APVMA has a service charter that outlines the standards of service people can expect when engaging and transacting with us, and what we expect from them. We take action to improve our processes regularly with the aim of both reducing the regulatory burden for industry and increasing productivity at the APVMA.

Privacy

The APVMA adheres to the *Privacy Act 1988*. You can find our privacy policy on our website. Our operations were not subject to any report or determinations by the Privacy Commissioner during the period covered by this report.

Related entity transactions

During 2015–16, the APVMA contracted the Department of Health to provide scientific assessment advice related to toxicology and work health and safety. This was the continuation of a relationship that began in 2000. Initially, the Department of Health was the sole provider of these services; however, since 2015, several other external entities have provided these services. In 2015–16 there were 63 individual transactions with the Department of Health totalling \$1 958 000 (on an accrual basis).

Similarly, the APVMA contracted the Department of Environment and Energy to provide environmental scientific assessment advice during 2015–16. The Department of Environment and Energy is now one of several entities that provide this service. During 2015–16 there were 31 individual transactions totalling \$563 000 (on an accrual basis).

Judicial decisions and reviews by outside bodies

Parliamentary committees and other reviews

The APVMA appeared before the Senate Estimates Rural and Regional Affairs and Transport Legislation Committee hearings on 20 November 2015 (supplementary), 9 February 2016 (additional) and 5 May 2016 (budget).

The APVMA appeared before the House of Representatives Standing Committee on Agriculture and Industry's *Inquiry into agricultural innovation* on 17 March 2016. The APVMA provided submissions to the Productivity Commission's *Public inquiry into regulation of agriculture* on 12 February 2016 and the Queensland Parliament's Agriculture and Environment Committee's *Inquiry into the Hendra virus (HeV) Equivacc vaccine and its use by veterinary surgeons in Queensland* in April 2016.

Auditor-General's reports

The Australian National Audit Office did not audit the APVMA in 2015–16, other than to audit the APVMA 2014–15 financial statements.

Ombudsman

During 2015–16, the Commonwealth Ombudsman conducted one investigation that concerned the APVMA. A complaint had been made about our decision to treat a registration application as withdrawn. After receiving submissions from the APVMA, the Commonwealth Ombudsman decided that no further investigation was required.

Courts and tribunals

During 2015–16, the APVMA was notified of four matters before the Administrative Appeals Tribunal (AAT), and one matter before the Federal Court of Australia. The AAT matters were adjourned pending the outcome of the Federal Court matter.

A Federal Court matter carried over from 2014–15 was completed in August 2015.

Office of the Australian Information Commissioner reviews

During 2015–16, the APVMA received notification of one review or complaint from the Office of the Australian Information Commissioner (OAIC).

The OAIC review of a freedom of information internal review decision was withdrawn.

Obtaining information from subsidiaries

The APVMA has no subsidiaries.

Indemnities and insurance premiums

The APVMA's insurance with Comcover includes liability cover up to \$150 million for professional indemnity, and directors' and officers' liability. The insurance premium paid to cover the 2015–16 financial year was \$50 655 (including GST).

Disability reporting

The new National Disability Strategy 2010–20, which supersedes the Commonwealth Disability Strategy, sets out a 10-year national policy framework to improve the lives of people with disability, promote participation and create a more inclusive society. A high-level two-yearly report tracks progress against each of the six outcome areas of the strategy, and presents a picture of how people with disability are faring.

The APVMA partnered with Black Mountain School, an ACT public school specialising in the field of special education, on the placement of a student within the APVMA. This initiative assists students to develop their skills to improve employability after leaving school. It has been a truly rewarding experience for the student and APVMA staff.