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# CHAPTER 4

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Corporate governance and management



## Corporate and operational plans

As an independent statutory authority, the APVMA is required to conduct rigorous corporate planning and reporting. Our planning and reporting requirements are set out in the Administration Act.

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

In addition, each year we develop an operational plan that sets out the actions required to implement our corporate strategies and objectives. We measure our operational effectiveness annually through the performance indicators in the corporate and operational plans and the PBS.

## Governance

The APVMA is a corporate Commonwealth entity and is subject to the PGPA Act. The APVMA is a body corporate with a separate legal identity from the Commonwealth of Australia. The CEO of the APVMA is responsible for the governance and management of the APVMA, with the support of the executive team (see Chapter 2) and the Audit Committee (see below).

To ensure decision-making is best practice when delivering scientific assessment and operational effectiveness, the APVMA governance structure makes responsibilities clear. The APVMA CEO is the accountable authority for purposes of the PGPA Act and is appointed as a statutory officer by the minister. The CEO, who has responsibility for the management and governance of the authority, together with the APVMA's executive team, is responsible for delivering against the performance measures within the Australian Government Regulator Performance Framework.

## Internal committees

The APVMA governance committees (Table 3) adhere to the principles of public sector governance to provide accountability, transparency, integrity, stewardship, efficiency and leadership.

**Table 3:** APVMA governance committees

Group	Description
<b>Executive Leadership Team</b>	The team, chaired by the CEO, provides strategic, whole-of-organisation advice and direction relevant to decision-making, management and oversight of the APVMA's operations and performance.
<b>Senior Leadership Team</b>	The team provides a forum for APVMA senior operational managers to identify opportunities for cross-agency collaboration, innovation and performance improvement, and to develop leadership.
<b>Audit Committee</b>	This subcommittee reports to the CEO. It helps the authority to discharge its legislative responsibilities regarding financial reporting, performance reporting, risk oversight and management, internal control, and compliance with relevant laws and policies.
<b>Science Quality Committee</b>	This subcommittee reports to the executive team. It advises and provides recommendations on matters of science and science quality relevant to the functions of the APVMA.
<b>Registration Quality Committee</b>	This subcommittee reports to the executive team. 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.
<b>Enforcement Committee</b>	This subcommittee reports to the executive team. It oversees the potential use and actual use of coercive powers.
<b>Armidale Relocation Advisory Committee</b>	This committee, established by the APVMA CEO, provides strategic advice to the executive on major aspects of the relocation and the transition of our operations from Canberra to Armidale, including the business model, digital strategy, strategic risk and mitigation, stakeholder issues and engagement.
<b>Relocation Program Board</b>	The board oversees the relocation program of work and ensures that the program meets its intended business outcomes by providing strategic guidance and support. The board advises the CEO on key aspects of the programs on relocation and enabling technology, and provides input into the Armidale Relocation Advisory Committee.
<b>Major Projects Board</b>	The board oversees the progress of projects that are significant to the operational direction of the authority. 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.
<b>Staff Consultative Committee</b>	The committee was established under the <i>APVMA Enterprise Agreement 2017-20</i> , and provides a forum to ensure that staff are appropriately consulted about significant decisions that may affect the workplace.
<b>Work Health and Safety Committee</b>	The committee provides a framework to allow workers to be consulted on significant work health and safety decisions that affect their working lives.

The governance structure, senior management and guidance material support APVMA staff in delivering high-quality scientific assessment and operational effectiveness, and in adhering to the public sector values to be impartial, committed to service, respectful, accountable and ethical.

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 Audit Committee*

The APVMA 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 its performance reporting and external accountability responsibilities.

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

The Audit Committee met four times in 2017–18: in September and November 2017, and in February and June 2018. Attendance at Audit Committee meetings is shown in Table 4.

**Table 4:** Attendance at Audit Committee meetings

Representative	Member's organisation	Meetings eligible to attend	Meetings attended
Peter Hoefer	External independent chair	4	4
Claude Gauchat	External organisation representative	4	4
Lisa Croft	APVMA	1	1
Amy Fox	APVMA	2	2
Stefanie Janiec	APVMA	2	2

In 2017–18, the Audit Committee considered:

- the 2016–17 financial statements
- annual assessment of the Protective Security Policy Framework
- annual assessment of the Regulator Performance Framework
- business risk management and continuity plans
- the Financial Sustainability Plan
- the agency's relocation to Armidale.

No conflicts of interest that would conflict with the proper performance of the Audit Committee's functions were declared at any meeting in 2017–18.

## 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 twice in 2017–18, in November 2017 and March 2018. Figures for membership and attendance at MLSILC meetings are shown in Table 5.

**Table 5:** Attendance at Manufacturers' Licensing Scheme Industry Liaison Committee meetings

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Susan Hanns (Chair)	APVMA	1	1
Michelle Wooster (Chair)	APVMA	1	1
Garry Hartridge (Secretary)	APVMA	2	2
Ian Saunders	Veterinary Manufacturers and Distributors Association	2	1
Martin Snowball	Animal Medicines Australia Ltd	2	2
Noelene Davis	Feed Ingredients and Additives Association of Australia	2	2
Ian Wheatley	Auditors' representative	2	2

## Issues considered

Issues considered in 2017–18 included:

- review and status of the Code of Good Manufacturing Practice
- certificates of export
- frequency and timing of overseas audits
- differing requirements for approval of an overseas site and an Australian site of manufacture
- the role of the MLSILC and its interaction with the Industry Steering Group, which was established for a finite time and purpose to support consultation during the 2016 review of Good Manufacturing Practice
- frequency of committee meetings and timelines for committee meeting documents.

## 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.

## APVMA Relocation Advisory Committee

The APVMA Relocation Advisory Committee (ARAC) was established by the APVMA CEO in 2016 to provide strategic advice on major aspects of the relocation and transition of the APVMA to Armidale.

The committee is not a decision making body and does not have direct say on the day-to-day management of the relocation project or the allocation of resources. ARAC members include industry representatives, APVMA staff, university delegates, and representatives of local and federal government departments. The committee provides input and advice into a range of relocation related projects, such as risk management, development of the business operating model and stakeholder impacts where appropriate. The terms of reference for ARAC are available at [apvma.gov.au](http://apvma.gov.au)

### Meetings and attendance

The committee met four times throughout the year, once in Armidale during September and three times in Canberra during December, March and June. Meetings hosted in Canberra were supported via teleconference, with members electing to attend face-to-face or remotely through teleconference.

Attendance was recorded in the minutes for each meeting as outlined in Table 6.

**Table 6:** Attendance at APVMA Relocation Advisory Committee meetings

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Chris Parker	APVMA	4	3
Stephanie Janiec	APVMA	2	2
Amy Fox	APVMA	2	2
Paul Kruspe	APVMA	2	2
Mitch Levy	APVMA	2	2
Paul Grutt	APVMA	2	2
Lisa Croft	APVMA	2	2
Bob Smith	APVMA	2	2
Ala Mosleh	APVMA	2	1
Alex Bagnara	APVMA	1	1
Roxanne Ruscoe	APVMA	1	1

**Table 6:** (Continued)

Representative	Member organisation	Meetings eligible to attend	Meetings attended
Cindy Briscoe	Department of Agriculture and Water Resources	2	2
Ian Thompson	Department of Agriculture and Water Resources	1	1
David Williamson	Department of Agriculture and Water Resources	2	0
Andrew McDonald	Department of Agriculture and Water Resources	1	1
Ben Stapley	Animal Medicines Australia	4	3
Tirza Anglin	Animal Medicines Australia	1	1
Matthew Cossey	CropLife	4	0
Alastair James	CropLife	4	3
Reg Kidd	National Farmers Federation	4	3
Prof. Peter Creamer	University of New England	4	2
Greg Lawrence	Armidale Regional Council	1	1
Tony Broomfield	Armidale Regional Council	4	2
Jim Adams	Veterinary Manufacturers and Distributors Association	4	4

### *Issues considered*

Issues considered in 2017–18 include:

- relocation risk management
- the business operating model for the APVMA in Armidale
- timeframe performance – for approvals, permits and product registrations
- improvements to IT systems to facilitate a move to cloud-based systems to streamline the registration process
- development and delivery of the Accelerated Regulatory Science Training Program
- construction of the new leased premises in Armidale
- inputs from white paper reform projects and deliverables
- consultation on the Independent review of assessment performance.

## Related entity transactions

The APVMA contracted the Australian Government Department of the Environment and Energy to provide environmental scientific assessment advice; during 2017–18 there were four individual transactions totalling \$73 706. We did not contract the Department of Health for environmental scientific assessment services in 2017–18.

## Consultation and collaboration

Our stakeholders are at the core of our business, so consulting and working with them, and with other regulatory agencies, to ensure that we meet their needs is a priority. Stakeholders from industry, chemical users, government and the community provide input and are involved in our decision-making and the development of guidelines and operational policy.

We work closely with the Australian Government Department of Agriculture and Water Resources to ensure that policy and legislation development and change is effective and best placed to help our clients and stakeholders.

In 2017–18, the APVMA conducted 46 public consultations on various topics, including chemical registrations, trade advice notices, public release summaries, chemical reviews and revisions to the Australia New Zealand Food Standards Code. Key client and stakeholder engagements included two-day industry information sessions in Canberra (September 2017), which provided first-hand feedback on regulatory impediments and a view of new science and industry challenges.

We also continued our program of international engagement in 2017–18, including participating in key international scientific and regulatory forums (Table 7).

**Table 7:** APVMA participation in international forums

Meeting	Date	Participant
OECD Expert Group on Electronic Exchange of Pesticide Data	30 August 2017 (teleconference)	Mitch Levy, Director ICT
Society for Environmental Toxicology and Chemistry, North America Focused Topic Meeting: Risk assessment of chemical mixtures: from scientific evidence to environmental regulation (Denver, United States)	6–8 September 2017	Janine Knight, Director, Environmental Assessment
FAO/WHO Joint Meeting on Pesticide Residues (Geneva, Switzerland)	7–21 September 2017	Sam Margerison, Director, Chemistry and Manufacture
Global Summit on Regulatory Science (Brasilia, Brazil)	18–20 September 2017	Phil Reeves, Chief Regulatory Scientist
EU Good Manufacturing Practice Inspectors Working Group	September 2017 (teleconference)	Susan Hanns, Director, Manufacturing Quality and Licensing
3rd Global Minor Use Summit (Montreal, Canada)	1–5 October 2017	Alan Norden, Executive Director, Registration Management and Evaluation
Joint FAO/WHO Expert Committee on Food Additives—veterinary drug residues in food (Geneva, Switzerland)	16–27 October 2017	Chris Schyvens, Director, Health Assessment Utz Mueller, Principal Scientist
OECD Residues Chemistry Expert Group	Ongoing (teleconference)	Jason Lutze, A/g Executive Director, Scientific Assessment
35th International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (Tokyo, Japan)	13–16 November 2017	Chris Parker, Chief Executive Officer
VICH Anthelmintic Export Working Group	Ongoing (teleconference)	Michelle Wooster, Director, Manufacturing Quality and Licensing
6th OECD Network on Illegal Trade in Pesticides	26–27 February 2018 (teleconference)	Elizabeth Butt, A/g Director Compliance and Monitoring

**Table 7:** (Continued)

Codex Committee on Pesticide Residues eWorking Group	(Ongoing teleconference)	Jason Lutze, A/g Executive Director, Scientific Assessment and Chemical Review Sam Margerison, Director Chemistry and Manufacture
Codex Committee on Residues of Veterinary Drugs in Foods (Chicago, United States)	22–27 April 2018	James Deller, A/g Director Residues and Trade
Joint FAO/WHO Expert Committee on Food Additives (Geneva, Switzerland)	12–21 June 2018	Utz Mueller, Principal Scientist
OECD Expert Group on Bio Pesticides, Expert Group on Minor Use and Working Group on Pesticides (Paris, France)	18–22 June 2018	Alan Norden, Executive Director, Registration Management and Evaluation
36th International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (Bruges, Belgium)	25–28 June 2018	Alan Norden, Executive Director, Registration Management and Evaluation

A/g = acting; EU = European Union; FAO = Food and Agriculture Organization of the United Nations; OECD = Organisation for Economic Co-operation and Development; VICH = International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; WHO = World Health Organization

## Advertising and market research

With the exception of recruitment advertising, the APVMA did not undertake any advertising in 2017–18. In early 2018, we engaged a market research company to support the development and delivery of the APVMA client and stakeholder survey.

## Obtaining information from subsidiaries

The APVMA has no subsidiaries.

## Accountability

The APVMA has internal and external structures and processes to ensure that we meet our legislative responsibilities and relevant standards.

### Corporate risk management

In 2017-18, we reviewed and updated the APVMA Risk Management Framework. The framework consists of a suite of documents that guides strategies for how the APVMA deals with risk on an ongoing basis. The framework describes the:

- APVMA's policy for the management of risk
- methodology used in the assessment of risk across the APVMA
- operation of APVMA's risk registers and the integration of risk management through the APVMA
- way APVMA works to develop a risk-aware organisational culture in which proactive risk management is at the forefront of the decision-making process
- means for employees to understand their roles in active risk management.

The Strategic Risk Register specifies the most significant and material business risks managed by the APVMA. The Operational Risk Register identifies and categorises key business risks that need structured management within the APVMA.

### Fraud control

The APVMA fraud risk assessment and control plan complies with the *Commonwealth fraud control guidelines*. The plan includes fraud prevention, detection, investigation, reporting and data collection procedures.

No cases of fraud were reported or identified in 2017-18.

### 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 was published fortnightly and is available from our website.

The APVMA prepares reports of its performance in meeting regulatory obligations, including:

- registration of chemical products
- approval of active ingredients
- issuance of permits
- licensing and audit of veterinary manufacturers
- 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.

## Adverse Experience Reporting Program

Under the Administration Act, the APVMA is required to publish information about the AERP. This annual report contains the required details of the number of AERP reports received by the APVMA during the year. We also provide a summary of any action taken by the APVMA during the year in relation to adverse experience reports (see *Key activity: Maintain and energise the Adverse Experience Reporting Program (AERP) to better inform current and future decisions*).

## APVMA service charter

We aim to provide the highest quality service to all our stakeholders. The APVMA Client Service Charter outlines the standards of service that external parties can expect in their dealings with us. The charter applies to all stakeholders, including the chemicals industry that we regulate, other government agencies, chemical users and the community.

We started a review of the client service charter in 2018 and will undertake further consultation with industry clients and stakeholders in 2018–19.

## Privacy

The APVMA adheres to the *Privacy Act 1988* and our privacy policy is on our website. Our operations were not subject to any report or determinations by the Privacy Commissioner in 2017–18.

## 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 24 October 2017 (supplementary), 1 March 2018 (additional) and 23 May 2018 (budget).

In March 2018, the APVMA appeared before the House of Representatives Committee public hearing of the ANAO report on Pesticide and Veterinary Medicine Regulatory Reform.

## Auditor-General's reports

The ANAO performed the following audits for the APVMA in 2017–18:

- APVMA 2016–17 Financial Statements
- Pesticide and Veterinary Medicine Regulatory Reform.

## Ombudsman

During 2017–18, the Commonwealth Ombudsman conducted three investigations that concerned the APVMA.

## Courts and tribunals

During 2017–18, the APVMA was notified of two matters before the Administrative Appeals Tribunal.

## Office of the Australian Information Commissioner reviews

During 2017–18, there were no notices of review or complaint received by the APVMA from the Office of the Australian Information Commissioner.

## Work health and safety

As part of our work health and safety arrangements, the APVMA:

- promoted and developed arrangements to ensure employees' health, safety and wellbeing at work, in accordance with the *Work Health and Safety Act 2011*
- provided operational guidelines for the operation of the Health and Safety Committee
- maintained mechanisms for reviewing, varying and informing employees about work health and safety arrangements, and for dealing with disputes during consultation.

The APVMA Health and Safety Committee monitored and informed APVMA-wide work health and safety activities. Two new health and safety representatives, based in our Armidale office, were elected to the committee in 2018 and undertook the required training.

## Health and wellbeing initiatives

In 2017–18, we implemented various initiatives to help staff manage their health and wellbeing at work and at home. We provided free influenza vaccinations for staff, and invited staff to undertake onsite fitness and general health assessments with qualified health practitioners.

Our focus on ensuring a positive employee experience included the promotion of physical and mental health and wellbeing initiatives. The APVMA facilitated active workstation assessments for staff in Armidale and Canberra to address the hazards of working in an increasingly digital environment, and actively promoted the benefits and facilities available through our employee assistance program.

## Disability reporting

Since 1994, non-corporate Commonwealth entities have reported on their performance as policy adviser, purchaser, employer, regulator and provider under the Commonwealth Disability Strategy. In 2007–08, reporting on the employer role was transferred to the APS Commission's *State of the service* reports and the *APS Statistical Bulletin*. These reports are available on the Commission's website. Since 2010–11, entities have not been required to report on these functions.

The Commonwealth Disability Strategy has been overtaken by the National Disability Strategy 2010–20, which 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 will track progress against each of the six outcome areas of the strategy and present a picture of how people with disability are faring. The first of these progress reports was published in 2014.

## Ecologically sustainable development and environmental performance

The APVMA adopted an environmental management system that meets the requirements of s. 516A of the *Environment Protection and Biodiversity Conservation Act 1999*, the Agvet Code and the Greening of Government program. The environmental management system uses ISO 14001:2004 as its framework.

The APVMA strives to be a 'paperless' office, implementing an electronic document and records management system to significantly reduce the amount of paper and printer consumables used within the office. With implementation of the digitisation project under the Enabling technology program, the APVMA will progressively expand its digital (i.e. paperless) operations over coming years.

We also worked to reduce our environmental impact by:

- recycling paper, plastic and kitchen waste to reduce landfill
- maintaining water tanks for watering gardens at the APVMA's premises in Canberra
- meeting the whole-of-government Energy Efficiency in Government Operations target for energy use of 7500 megajoules per person per year
- purchasing 100 per cent recycled paper
- using environmental criteria guidelines for all purchases
- using VMware computer hardware to reduce electricity consumption
- using high-efficiency T5 lighting and movement-activated lighting
- improving our communication and collaboration capabilities (e.g. meeting room and desktop videoconferencing) to minimise travel
- using multifunction-device printers that reduce paper waste by authentication and secure release of all print, copy, scan and fax jobs
- maintaining onsite worm farms at the Canberra office to process waste food collected from APVMA kitchens to reduce waste going to landfill.

The APVMA created 'ECONet', which is a voluntary network of staff who encourage and promote environmentally friendly office practices. It was modelled on ECONets already established in the Australian Government Department of Environment and Energy and the Department of Agriculture and Water Resources. The APVMA ECONet identifies opportunities and implements initiatives that reduce our environmental footprint in both the Canberra and Armidale offices.

With construction of the new building in Armidale, ECONet will help the APVMA to ensure that environmentally responsible processes and functionality are considered in the fit-out planning and in the establishment of support contracts.

