





# CHAPTER 5

Appendixes

# Appendix A: Progress against APVMA *operational plan 2015-16* initiatives

The following tables summarise progress against each of the initiatives articulated in the APVMA *operational plan 2015-16*. The following key applies to each response:

INITIATIVES	PROGRESS	COMMENT
<b>STRATEGY 1: DELIVER REGULATORY DECISIONS THAT ARE TIMELY, SCIENCE-BASED AND PROPORTIONATE TO THE RISKS BEING MANAGED.</b>		
Key result area: regulatory decisions are completed within timeframes		
Assess applications for (PAA), registration of products and permits and approval of active ingredients	Completed	Refer to performance statistics in Table 7
Implement new legislative requirements for chemical review	Completed	Legislation and new process in place. See 'Chemical review' ( <a href="http://apvma.gov.au/node10916">apvma.gov.au/node10916</a> )
Key result area: actions undertaken are proportionate to the regulatory risk being managed		
New risk assessment framework finalised by June 2016	Ongoing	A conceptual framework for the risk assessment was completed in December 2015  Work is now progressing to run a pilot in 2016-17
<i>Compliance and enforcement strategy 2015-17</i> finalised and published	Completed	Strategy available on the APVMA website, see 'Corporate documents' ( <a href="http://apvma.gov.au/node/11026">apvma.gov.au/node/11026</a> )
Framework for regulating spray drift finalised by December 2015	Ongoing	Targeted consultation with stakeholders on the APVMA's operating principles in relation to spray drift risk was undertaken in 2015-16  The review of this framework is continuing

<p>Framework in place to provide assurance about the quality of APVMA decision making</p>	<p>Ongoing</p>	<p>A range of activities have begun and are in various stages of development:</p> <ul style="list-style-type: none"> <li>■ creation of an internal guide to safety, efficacy, trade and labelling legislative criteria for agricultural and veterinary chemical products</li> <li>■ publication systems for decision summaries</li> <li>■ creation of a new decision document</li> </ul>
<p>Design and implement a contestable efficacy pilot</p>	<p>Completed</p>	<p>A contestability pilot for efficacy assessments is on track. Activities completed include:</p> <ul style="list-style-type: none"> <li>■ public and industry consultation</li> <li>■ list of pilot reviewers compiled</li> <li>■ pilot guidance documents are available at 'Contestability of the efficacy assessment' (<a href="http://apvma.gov.au/node/18691">apvma.gov.au/node/18691</a>)</li> </ul>
<p>Streamline approach to veterinary residues by publishing and implementing the Joint FAO/WHO Expert Committee on Food Additives (JECFA) review findings by February 2016</p>	<p>Completed</p>	<p>The recommendations from the JECFA report were reviewed and implemented</p>
<p>Revise criteria for when efficacy is a relevant consideration in assessing an application; for implementation from 1 July 2016</p>	<p>Partially completed</p>	<p>Consultation process was completed to ascertain possible amendments to the efficacy legislative instrument</p> <p>Results are currently being assessed by the APVMA</p>
<p>Complete a review of the approach to licensing and auditing of veterinary manufacturers with implementation from 1 July 2016 (if applicable)</p>	<p>Ongoing</p>	<p>A consultant was engaged to undertake the review</p>

Complete crop grouping project to group similar crop types for minor use consideration	Ongoing	A consultation process was completed on a draft Australian crop list  Publication of the list and identification of representative crops is continuing
Review all permits to identify candidates that can be moved to registered product labels	Ongoing	Of the 563 permits examined, 400 are suitable for further review  Industry will be consulted in 2016-17 to ascertain if their permit approvals should move to permanent label registration
Publish 2015-17 compliance and enforcement strategy by December 2015	Completed	Strategy available on the APVMA website, see 'Corporate documents' ( <a href="http://apvma.gov.au/node/11026">apvma.gov.au/node/11026</a> )
Review GMP audit schedule and implement from 1 January 2016	Completed	Review completed  Findings were presented at the APVMA industry seminar in May 2016
Refined compliance and enforcement risk model applied to new allegations from 1 July 2015. Responses employ graduated tools and are proportionate to risk	Completed	A risk management framework included in the APVMA compliance and enforcement strategy, which can be found under 'Corporate documents' ( <a href="http://apvma.gov.au/node/11026">apvma.gov.au/node/11026</a> ), focuses on a risk-based approach that responds to risks in a proportionate manner based on the assessment of risks

#### Key result area: regulatory science underpins quality regulatory decision making

Develop APVMA regulatory science strategy	Completed	The regulatory science strategy is available at <a href="http://apvma.gov.au/node/11026">apvma.gov.au/node/11026</a>
Identify opportunities to align the APVMA's regulation of veterinary medicines with those of overseas jurisdictions	Completed	Report completed and findings presented at the APVMA industry seminar in May 2016 in Melbourne
Expand the content of 'Our science' web page	Completed	Science web pages published. See 'Our science' ( <a href="http://apvma.gov.au/node/15486">apvma.gov.au/node/15486</a> )

Develop staff capability by providing training in regulatory science and new chemical/biological technologies	Completed	Training provided to staff on mastitis therapy, 'gene drive' technology, neonicotinoids and pollinators and bioequivalence
Progress chief scientist projects:		
■ pharmaceutical equivalence	Completed	Report provided to SQC with generics guidelines to be completed in 2016–17
■ a model framework for the regulation of products of emerging technologies	Partially completed	Report provided to SQC with additional information made available on 'Our science' at <a href="http://apvma.gov.au/node/15631">apvma.gov.au/node/15631</a>
■ risk profiling of imported live micro-organisms for use in veterinary vaccines	Completed	Received final draft of the risk profiling decision tree incorporating industry feedback
■ suitability of new United States of America and European Union worker exposure methods for adoption in Australia	Partially completed	Draft report received. Comparison work on European Food Safety Authority and United States Environmental Protection Agency worker exposure continues  Bystander and resident comparison exposure calculations have been received from expert consultant
■ tier-3 aquatic exposure modelling (dryland cropping component)	Partially completed	Report completed and reviewed by SQC
■ develop a regulatory framework to support a revised spray drift policy	Ongoing	Targeted consultation with stakeholders on the APVMA's operating principles in relation to spray drift risk  The review of this framework is continuing
■ scoping the development of an approach to assessing fumigants	N/A	This project has stopped
Develop and implement a framework for obtaining external expert scientific advice	Ongoing	Ongoing

## STRATEGY 2: REDUCE THE BURDEN ON INDUSTRY IN COMPLYING WITH REGULATORY REQUIREMENTS

Key result area: unnecessary impediments to the efficient operation of regulated entities are removed

Hold two CEO-only forums with key industry stakeholder groups to discuss APVMA performance and key issues	Completed	The CEO held and attended regular meetings and forums with key industry stakeholder groups to discuss performance and other issues
Conduct a series of industry information sessions	Completed	Industry information sessions were held in August and October 2015 and May 2016
Hold quarterly briefings for APVMA staff about industry-specific issues/trends/practices	Completed	The APVMA conducted industry awareness sessions and workshops throughout the year, including a tailored workshop on the lifecycle of product development and looking at the registration process from the applicant's perspective
Undertake an environmental scan with stakeholders each year for publishing in the operational plan	Completed	Environmental scan completed and provided to the Minister in June 2016  Key aspects incorporated into the 2016-17 operational plan
Develop and implement a plan for review and adoption of international guidelines and standards, including a website to communicate decisions to stakeholders	Partially completed	Two public consultations were undertaken in 2015-16 on the APVMA's framework for the use of international assessments
Identify opportunities to improve data sharing and access to assessment with international regulators		Detailed information has been published on the website and the framework will be implemented in 2016-17
Develop and implement an international engagement strategy	Partially completed	The APVMA continued its program of international engagement in 2015-16, including participating in key international scientific and regulatory forums, such as OECD, VICH and WHO

Partner in at least three GJRs	Completed	The first joint review of a veterinary medicine (meloxicam) completed with Canada and New Zealand  Completed GJR: oxathiapiprolin  Ongoing GJR: bicyclopyrone, flupyradifurone and cyclaniliprole
As part of the OECD network and with GJR partners, participate in a review of the conduct of GJRs to streamline processes and ensure it meets the needs of industry and regulators	N/A	The APVMA is continuing to engage with the OECD with a view to improving the GJR partnership process
Participate in relevant OECD and VICH activities designed to harmonise assessment, data requirements and/or registration systems across international regulators	Completed	APVMA participated in the 33rd meeting of the VICH in June 2016, and provided a report on survey of RNAi regulation for Regulatory Reference Groups RSGs and RRGs and contributed to the crop field test and rotational residues guidelines
Complete a usability review of the external portal, and implement enhancements	Partially completed	The useability review commenced in 2015–16 with the report and recommendations considered in early 2016–17
Enhance online automatic validation of applications to facilitate complete applications	Ongoing	A range of activities were completed within these initiatives, including:
Streamline application process through end-to-end project management		<ul style="list-style-type: none"> <li>■ a process map for Item 7 applications</li> <li>■ a release process for advice reports on applications from the Scientific Assessment and Chemical Review program</li> <li>■ updating of the preliminary assessment work instruction</li> <li>■ mapping of s. 14 criteria</li> <li>■ review of e-label portal</li> </ul>

Continuously improve access to external scientific reviewers	Completed	A larger number of external science reviewers are now available to conduct technical assessments on behalf of the APVMA in a range of fields, including efficacy, toxicology, health and safety, and environmental science
Identify opportunities for the further expansion of Objective Workflow	Completed	Twenty workflows were developed encompassing 112 active users of Objective Workflow
Collect annual returns on active information for the Department of Agriculture and Water	Completed	Developed and deployed an online system to collect annual returns
Review GMP business processes and implement administrative enhancements	Ongoing	GMP business processes were mapped and the associated IT requirements articulated  However, new administrative enhancements were not implemented this year because of competing requirements for IT resources
System developed to capture and report on data on assessment of non-compliance allegations and how compliance tools are used	Completed	The internal records management system was identified as the most appropriate system to collect and extract compliance statistics in the short to medium term
Undertake compliance assessments and relevant compliance activities	Completed	The compliance and enforcement program focuses on education, engagement and enforcement in alignment with the strategy
Review existing memorandum of understanding with Therapeutic Goods Administration (TGA) and identify opportunities to minimise duplication of audits for manufacturers of mutual interest	Completed	A new draft bilateral MOU with TGA was completed
Progress EU recognition of APVMA GMP audits to facilitate export to the EU	Completed	EMA and EU discussions held in May 2016  Discussions are underway with industry to ascertain the level of interest in progressing EU recognition of our audits

Explore options for conducting additional joint audits	Deferred	This activity was deferred pending the outcome of the GMP review
Develop MOUs with partner regulators for exchange of compliance and enforcement information	Ongoing	Work commenced with Australian Sports Anti-Doping Authority to develop an MOU for law enforcement and information sharing
Conduct an audit of refusals and section 159 notices to demonstrate 100% are within policy parameters	Completed	<p>A sample audit of files was conducted to ascertain whether refusals given under various provisions of the Agvet Code and the issuing of notices under s.159 of the Agvet Code met both policy parameters (for example relevant CEO directions and work instructions) and legislative requirements</p> <p>While the audit identified some administrative issues, it indicated that the decisions were technically sound</p>
Develop system to capture and report average number of requests for information	Completed	<p>Information is requested under s. 159</p> <p>These requests can be captured through the APVMA's business intelligence tools</p>
Identify options to improve adverse experience reporting (AER) through process automation and integration of AER intelligence	Ongoing	An options paper is in development

### STRATEGY 3: BUILD A CLIENT-FOCUSED APPROACH TO SERVICE DELIVERY, COMMITTED TO CONTINUOUS IMPROVEMENT

Key result area: the APVMA is open and transparent in its dealings with regulated entities

Design and implement a system to publish performance information and decisions	Completed	<p>A system was developed to prepare key APVMA performance information for publication</p> <p>Information was published on our website in February, May and August 2016 at 'Performance statistics' (<a href="http://apvma.gov.au/node/19741">apvma.gov.au/node/19741</a>)</p>
Implement a survey to benchmark and track client experience across a range of criteria for APVMA service delivery	Ongoing	The survey design brief was prepared and the survey is expected to be run in 2016-17
Communication of compliance and enforcement outcomes is consistent with the compliance and enforcement strategy	Completed	<p>Key compliance performance information has been published on the APVMA website through CEO blogs, regulatory updates and other media pieces</p> <p>We continue to add new information</p>
Publish new chemical review work plans	Completed	Work plans for chemical review were published and can be accessed via <a href="http://apvma.gov.au/chemicals-and-products/chemical-review/listing">apvma.gov.au/chemicals-and-products/chemical-review/listing</a>
Review existing online feedback system to inform the design and implementation of service delivery	Completed	A review was completed and implementation of the review findings will begin in 2016-17

Key result area: communication with regulated entities is clear, targeted and effective		
Design and implement a new model for PAA	Completed	A new PAA process was implemented from 3 November 2015
Design and implement a system to capture and report data relevant to customer service standards	Ongoing	The APVMA is currently exploring options to capture and report on service statistics via a CRM tool
Implement a stakeholder perceptions survey to establish baseline metrics on satisfaction	Ongoing	The survey design brief was prepared and the survey will be run in 2016–17
Refresh the design of the APVMA's regulatory updates, and seek quarterly user feedback on content relevance	Partially completed	A regulatory update subscriber survey was conducted in 2015–16 to seek feedback  Improvements will be implemented as part of the useability review of our online services and channels
Design and implement a system to regularly check stakeholder views and experiences with APVMA website	Completed	A website feedback mechanism is now available on every page of the APVMA website  The information collected is passed to individual page owners for appropriate action
Design and implement a program of content review for guidance material on the website	Completed	A web governance policy was developed that includes a content review process, and identifies owners for each page on the APVMA website

Key result area: the APVMA actively contributes to continuous improvement of regulatory frameworks		
Design and implement a new stakeholder consultation framework	Ongoing	A consolidated stakeholder list for key companies, industry associations and government agencies was prepared as part of the stakeholder consultation framework
Engage with states and territories on initiatives as required	Completed	The APVMA regularly engages with states and territories and held a face-to-face forum with states and territories in 2015-16
Offer hosting of twice-yearly forums for states and territories	Completed	A state forum was held to discuss minor use permits
Hold monthly meetings with the Department of Agriculture and Water Resources about legislative frameworks and implementation	Completed	Regular meetings held with the Department of Agriculture and Water Resources with the following items progressed: <ul style="list-style-type: none"> <li>■ implementation of legislative changes relating to overseas manufacture, name and web content on primary/secondary applications</li> <li>■ comments on GHS review consultation paper</li> <li>■ IT business system changes for excipient substitution</li> <li>■ IT changes for applications with item numbers of 13A and 29</li> </ul>
Provide input as requested to government documents, including ministerials, policy documents and legislative proposals	Completed	Requests completed as required. Key activities include: <ul style="list-style-type: none"> <li>■ work instruction for supply chain, and logistics</li> <li>■ submission for Regulation of Agriculture Productivity Commission</li> <li>■ information for agricultural innovation inquiry and Hendra virus vaccine inquiry</li> </ul>

## STRATEGY 4: OPERATE AS A CONTEMPORARY, HIGH-PERFORMING AND EFFICIENT ORGANISATION

### Key result area: organisational health and financial viability

Implement a new quality system by 30 June 2016, including the development of a business model and definition of key APVMA business process	Completed	<p>A new quality management system has been implemented, and instructional material is being added to it</p> <p>Key business processes for the APVMA registration process have been identified and defined</p>
Complete a new cost recovery impact statement based on current fee structure for implementation from 1 July 2016	Partially completed	<p>An activity-based costing exercise was completed and a possible new fee structure identified</p> <p>This will likely be implemented in October 2016 following ministerial approval</p>
Complete a refresh of desktop PCs by December 2020	Completed	New desktop PCs were rolled out in March 2016
Conduct a pilot of secure cloud infrastructure for public-facing IT systems	Ongoing	This work has been delayed, but this activity will resume following the development of an APVMA enterprise architecture and ICT strategic plan
Comply with the PSPF and review APVMA compliance against the ASD top 35 mitigation strategies for cyber security	Completed	<p>KPMG completed an external PSPF review</p> <p>The report provided a basis to develop a cyber security road map</p> <p>This task will be completed parallel to the development of an ICT strategic plan</p>
Undertake a project to cleanse the agvet database	Completed	Data cleansing was completed
Improvements to the APVMA's external and internal applications completed to agreed timeframes	Completed	Improvements were made within agreed timeframes and include the delivery of a new client module, security module, and tasks and milestones

Key result area: organisational health and financial viability		
Develop and implement a new enterprise agreement (EA)	Partially completed	Draft EA provided to APVMA staff in May 2016
Develop and implement a learning and development strategy flowing from the needs identified in the capability review by June 2016	Completed	A learning and development strategy was developed and delivered to APVMA staff in May 2016  Implementation has started and will continue in 2016-17
Implement a learning network to better tailor and target learning requirements	Completed	A learning network of 10 members is in place with terms of reference and governance documents  High-priority learning requirements were identified for several Microsoft software products  Audits were completed and training delivered
Implement a corporate training calendar focused on personal efficiency and management, by 30 June 2016	Completed	A training calendar was developed. Training has been delivered on a range of topics, including scientific analysis, use of spreadsheets, legal, administration and management principles

# Appendix B: Information on specific statutory provisions

## Work health and safety

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

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

The APVMA Health and Safety Committee continues to monitor and inform APVMA-wide WHS activities. Two new health and safety representatives were elected to the committee in 2016, and have undertaken the required training.

### Health and wellbeing initiatives

In 2015–16, we continued to support initiatives to help staff manage their health and wellbeing at work and at home. We provided free influenza vaccinations for staff, facilitated corporate gym memberships, and invited staff to undertake on-site fitness and general health assessments with qualified health practitioners.

The APVMA People Strategy, released in May 2016, focuses on ensuring a positive employee experience, including the promotion of physical and mental health and wellbeing initiatives. Partnering with the ACT Government, staff were invited to participate in an online health and wellbeing survey that provided tailored individual feedback, and a summary on the general wellbeing of the APVMA workforce. Additionally, a large number of APVMA staff participated in the Healthier Work Get Active Challenge, promoting ways to keep active while at work.

We focused on discussing mental health over 2015–16, actively promoting initiatives such as the 'Heads Up' campaign (a joint Safe Work Australia and Beyond Blue initiative) to staff, who were encouraged to participate. The APVMA has a number of staff who are accredited Mental Health First Aid practitioners. Mental wellbeing will remain a focus of activities throughout 2016–17.

# Advertising and market research

There was no advertising and market research undertaken during 2015–16.

## Ecologically sustainable development and environmental performance

The APVMA has adopted an environmental management system that meets the requirements of s. 516A of the *Environment Protection and Biodiversity Conservation Act 1999* and the Agvet Code. The system follows the principles of ecologically sustainable development and environmental management, enabling the APVMA to minimise its effect on the environment. The environmental management system uses ISO 14001:2004 as its framework.

As far as possible, the APVMA strives to be a 'paperless' office, implementing an electronic document and records management system (EDRMS) to significantly reduce the amount of paper and printer consumables used within the office. Additionally, the APVMA works to reduce its 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
- purchasing 100 per cent recycled paper
- using environmental criteria guidelines to ensure that environmental effects are considered for all purchases
- using VMware computer hardware to reduce electricity consumption
- using high-efficiency T5 lighting and movement-activated lighting
- using video and teleconferencing facilities to minimise travel
- using multifunction-device printers that reduce paper waste by secure release, and authenticate all print, copy, scan and fax jobs
- maintaining on-site worm farms to process waste food collected from APVMA kitchens to reduce waste going to landfill.