

# Operational Plan

2004 - 2005



*Protecting the Health & Safety of People, Animals and the Environment.*



**Australian Pesticides &  
Veterinary Medicines Authority**

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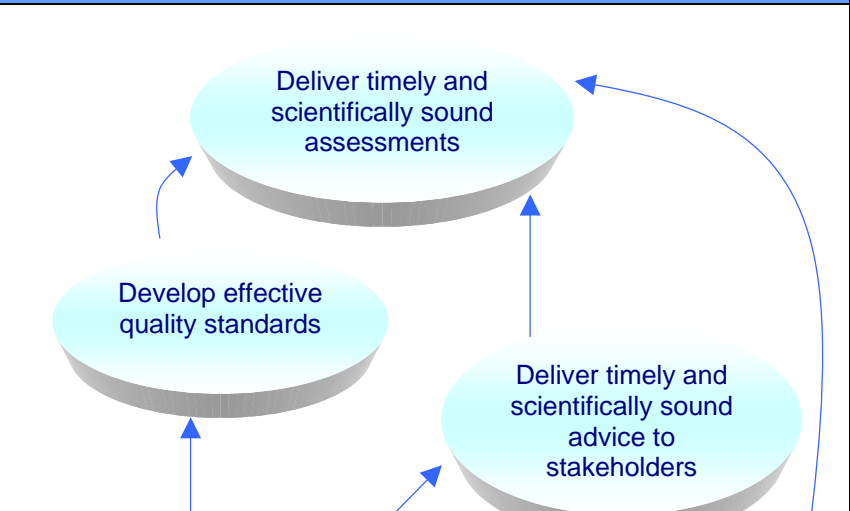
Key Strategy Map	KEY OUTPUT: A world-class national registration scheme for pesticides and veterinary medicine products	Objective Statement	Key Performance Indicators		
Stakeholders – Community, Government, Users, Chemical industry		Build stakeholder confidence that independent risk assessment protects public health, environment and trade.	Stakeholder confidence.		
		Inform public debate and support development of relevant government policy.	Information provided and policy development assisted.		
		Achieve product quality and safety through operational excellence, aligned with international best practice and supported by enhanced intelligence, quality assurance, and compliance and enforcement programs.	Registered products meet legislative requirements for performance, safety and trade . Quality of products in the market place meets acceptable standards.		
Internal Business Processes (including financial management)		Review chemical safety, quality and performance against contemporary standards.	Chemicals of concern assessed and decisions made in a timely manner.		
		Undertake risk-based quality assurance and compliance strategies to ensure product quality.	GMP licences issued. Valid non-compliance reports resolved within timeframes.		
		Conduct independent risk-based assessments, that are effective and efficient, of pesticides and veterinary medicines.	Decisions within statutory timeframes.		
		Enhance intelligence, feedback loops, monitoring and reporting to achieve system excellence.	Improvements to the regulatory system made as a result of new information, feedback and process enhancements.		
		Provide targeted information and develop key links with stakeholders to enhance system outcomes and build stakeholder confidence.	Key links developed. Positive media coverage.		
		Ensure sound financial management and optimal use of resources.	ANAO audit report. Budget vs actual.		
		Act within governing legislation.	Quality system processes and decisions reflect legislation.		
		People, Learning & Development		Facilitate valued and highly trained people to deliver quality services and promote leadership, teamwork, structure and organisation culture.	Staff satisfaction. Trained Staff.
				Enhance information capital through development of information systems and databases.	IT system uptime. ISO audits.

Strategy:  
Conduct Independent Risk Based Assessments, that are Both Efficient and Effective, of Pesticides and Veterinary Medicines

Objective Statement

Initiatives

Stakeholders  
(Community, Users, Industry and Government)



Deliver scientifically sound assessment decisions that underpin regulatory authorisations within legislative timeframes thereby promoting fairness and consistency of decisions.

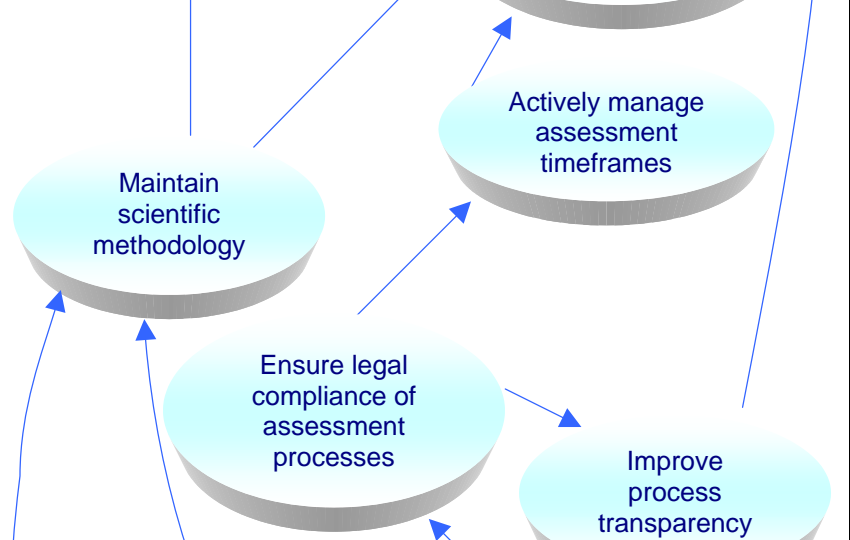
Conduct survey of stakeholders.

Develop effective quality standards for products, active constituents and agvet chemical residues.

Deliver timely, scientifically sound technical advice to internal and external stakeholders.

Conduct survey of stakeholders.

Internal Business Processes (including financial management)



Actively manage assessment timeframes for products, approvals and permits using databases and reporting systems.

Productivity Improvement Program.  
Minor Use program.

Develop effective quality standards.

Maintain scientific rigour through peer review.

Agency science quality program.

Improve process transparency and enhance visibility of assessments.

Data Protection.  
Early public disclosure.

People, Learning & Development



Increase understanding of legislative provisions relating to assessment and decision making under the Agvet Codes.

Broaden technical skills base and increase intellectual capital.

Undertake existing skills and gaps analysis.  
Implement a job rotation program.

Improve training in scientific risk assessment methodologies and quality system procedures.

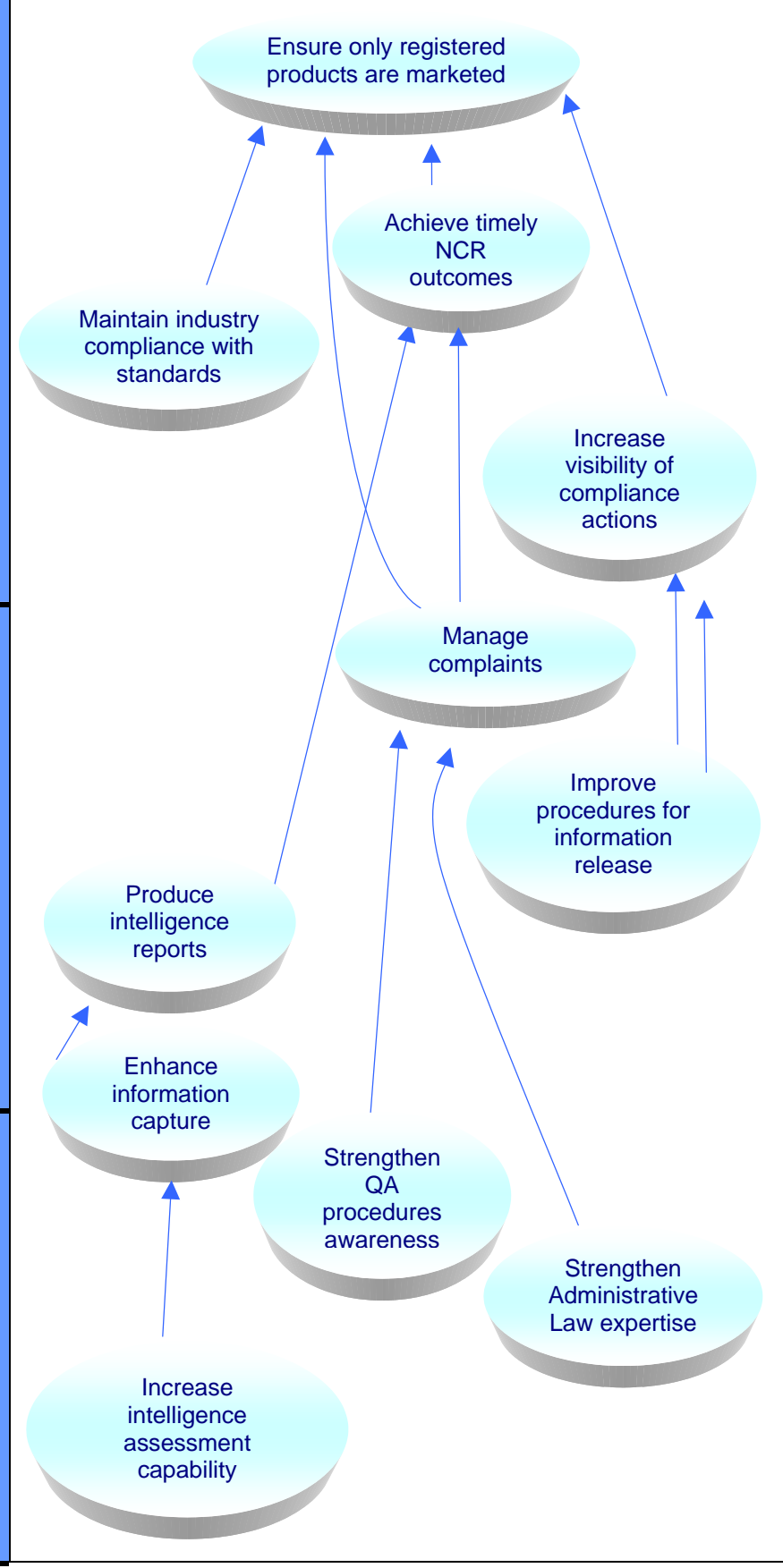
Provide effective targeted training.

<b>Strategy:</b> Ensure Product Quality Through Risk Based Quality Assurance and Compliance Strategies	<b>Objective Statement</b>	<b>Initiatives</b>
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**Stakeholders**  
 (Community, Users, Industry and Government)

**Internal Business Processes**  
 (including financial management)

**People, Learning & Development**



Ensure only registered products are marketed.	Repeat non-compliance strategy.
Achieve NCR outcomes within 90 days and ensure recalls and investigations meet expected industry timeframes.	Advertising Complaints Policy. Repeat non-compliance strategy.
Maintain industry compliance of products and active constituents with quality and regulatory standards set at registration and approval.	Ag QA Initiative. Commence monitoring of cancelled veterinary manufacturer licenses.
Increase visibility of compliance actions.	APVMA Communication Strategy. Revised QA System. Procedures for communication of actions.
Manage complaints within timeframes.	
Improve procedures for public information release.	APVMA Communication Strategy. Revised QA System procedures for communication of actions.
Produce intelligence reports to drive effective risk assessment and compliance actions.	Intelligence database development.
Enhance information capture to complement the intelligence analysis capabilities.	Intelligence database development. IBase extended to include Intel Notes.
Strengthen staff awareness through training as quality system procedures are updated.	Monthly updates to procedures. OH&S compliance for sampling and storage of chemicals and actives.
Strengthen expertise in Administrative Law as part of testing and recalls.	Administrative law training.
Increase capability of systems and personnel for collection and analysis of intelligence information.	Identify and attend a course in criminal intelligence. Undertake training in Analyst Notebook.



	Strategy: Ensure Product Quality Through Risk Based Quality Assurance and Compliance Strategies	Objective Statement	Initiatives
<b>Stakeholders</b> (Community, Users, Industry and Government)		Ensure quality of veterinary medicines through local and overseas manufacturers meeting GMP standards.	Develop efficient program for compliance of overseas manufacturers.  Participation in international harmonisation/MRA.
<b>Internal Business Processes</b> (including financial management)			Ag QA initiative.
Maintain compliance with manufacturing standards (GMP).		Explore options for better measuring the effectiveness of audits.  Develop and conduct un-announced audits.  Assign APVMA staff as authorised inspectors.  Issue suspend and cancel licences, impose conditions etc.	
Assess & review ag actives and related products under new initiative.		Ag QA initiative.	
		Ag QA initiatives.	
Implement risk based monitoring activities of agricultural actives.		Ag QA initiative.	
Maintain quality of GMP audits.		Develop and implement routine manufacturer feedback.  Revise the Auditor Deed of Authorisation.  Revise the code of GMP.  Re-introduction of product audits.	
Maintain and develop knowledge of QA and manufacturing.		Undertake targeted training.  Encourage industry education awareness – GMP seminars, APVMA News, site visits.	
Strengthen staff awareness through training as quality system procedures are updated.			
<b>People, Learning &amp; Development</b>			

	Strategy: Review Chemical Safety, Quality and Performance Against Contemporary Standards	Objective Statement	Initiatives
Stakeholders (Community, Users, Industry and Government)		Make effective regulatory decisions to ensure registered chemicals comply with contemporary standards thereby protecting people, environment and trade.	Outcomes project.
Internal Business Processes (including financial management)		Conduct scientifically sound reviews against contemporary standards within appropriate timeframes.	
		Enhance feedback loops and monitoring of domestic and international developments and initiate reviews when warranted.	Increase International engagement.
		Prioritise reviews based on sound risk analysis principles.	
		Improve stakeholder participation throughout the review process to increase transparency.	Update website information. Develop methods of providing information. Develop review stakeholder lists. Review included in next round of registration seminars. Regular review column in APVMA News.
		Strengthen staff awareness through training as quality system procedures are updated.	
People, Learning & Development		Enhance knowledge of administrative law.	Appropriate training identified and conducted through IPAD.
		Increase expertise and awareness of contemporary science and risk analysis through targeted training.	Appropriate training identified and conducted through IPAD.

	<b>Strategy:</b> Enhance Intelligence, Feedback Loops, Monitoring and Reporting	Objective Statement	Initiatives
<b>Stakeholders</b> (Community, Users, Industry and Government)		Support ongoing product quality in the marketplace by recommending changes to labels, registrations and approvals.	
<b>Internal Business Processes</b> (including financial management)		Enhance stakeholder feedback loops to the APVMA to facilitate reporting of incidents.	E-lodgement facility developed. AERP Communications Plan. CEO contacts with key stakeholders.
<b>People, Learning &amp; Development</b>		Improve the transparency and visibility of processes to stakeholders. Provide recommendations to other sections of the APVMA.	AERP Communication Plan.
See also Review Chemical Safety Pg 8 Ensure Product Quality Pg 6		Assess adverse experience reports in a timely manner to ensure feedback loops are effective.	Further development of Ag AERP.
		Improve industry compliance with legislative requirements through appropriate guidelines, and auditing against requirements.	Implement auditing.
		Train staff in AERP reporting and analysis.	Implement training in pharmacovigilance.
		Operate effective data management systems to facilitate submission of reports, to capture adverse experience information and to facilitate reporting.	Develop e-lodgement. Develop new data base.
		Train staff in audit procedures.	Implement training in auditing and provide feedback to APVMA on effectiveness of courses undertaken.

	<b>Strategy:</b> Provide Targeted Information and Develop Key Links with Stakeholders	<b>Objective Statement</b>	<b>Initiatives</b>
<b>Stakeholders</b> (Community, Users, Industry and Government)		Develop stakeholders' awareness of the APVMA role and responsibilities, understanding of the rationale for decisions and appreciation of the Authority's regulatory processes and requirements.	APVMA Communication Plan.  Account Manager Program.  Targeted information.  CEO relationships.
<b>Internal Business Processes</b> (including financial management)		Provide targeted information that is relevant to the needs of respective stakeholders.	Development of information products in concert with some stakeholder groups and based on research findings.
<b>People, Learning &amp; Development</b>		Manage media relations to promote the organisation, key information and decisions to stakeholders.	Media release; targeted; briefings; maintenance of media networks; focused liaison with networks.
		Develop key links with stakeholders through a network of channels to provide for effective two-way communication.	Account Manager Program.  Maintenance of formal and informal networks. List server.
		Enhance stakeholder access to information through a variety of relevant communication tools including Gazette, APVMA News, website, print materials, displays and events.	Production of high standard information materials.  Promotion of information channels - website, list server, APVMA news, participation in field days etc.
		Monitor external environment to ensure organisation is aware of relevant current and emerging issues with key stakeholder groups through programs of market research and management of network of stakeholder consultative and advisory groups.	Program of market research. ILC, RLC, CCC.  Account manager network.
		Provide selected staff with media coaching and support.	Management of media contact.
		Enhance staff skills to communicate effectively in ongoing operations through provisions of communication training, guidelines, advice and editorial services.	Style guide.  Editing services.  Templates.



	Strategy: Ensure Sound Financial Management	Objective Statement	Initiatives
<b>Stakeholders</b> (Community, Users, Industry and Government)		Provide accurate and timely financial reports to Government, the Board and management, including annual budget, monthly management accounts and annual financial statements.	Distribution of monthly accounts electronically.
<b>Internal Business Processes</b> (including financial management)		Ensure professional management of Accounts Payable and Accounts Receivable.	
<b>People, Learning &amp; Development</b>		Maintain compliance with accounting standards, CAC Act, tax legislation and other relevant guidelines.	Fees Review
		Undertake efficient and timely collection of revenue and calculation of legislated fees, including annual levy audits.	Publicise due dates and late payment penalties. Promote e-commerce facility. Enhanced levy audit program.
		Ensure accurate and timely payments to creditors.	
		Manage budget in accordance with Board approval.	
		Maintain knowledge of accounting standards and relevant legislation by ensuring financial staff are aware of changes.	
		Enhance staff knowledge on the correct processes for purchasing goods and services.	

	Strategy: Act within Governing Legislation	Objective Statement	Initiatives
Stakeholders (Community, Users, Industry and Government)		Provide effective legal advice and guidance to enable APVMA delegates to correctly apply governing legislation.	Intranet database of key legal advices.
		Manage litigation and administrative actions (e.g. Subpoenas, FOI)	Litigation Outcomes Plan to be settled at commencement of each matter.
		Provide targeted training including legal awareness.	Annual formal legal training program.
Internal Business Processes (including financial management)		Establish effective APVMA corporate governance	
		Monitor compliance with APVMA corporate governance standards.	
		Monitor adequacy of governing legislative framework.	
People, Learning & Development	Maintain awareness of current legal developments.		

	<b>Strategy:</b> Facilitate Valued and Highly Trained People to Deliver Quality Services and Enable Organisation Capital	<b>Objective Statement</b>	<b>Initiatives</b>
<b>Stakeholders</b> (Community, Users, Industry and Government)		Promote organisational capital through promotion of leadership, structure, teamwork and organisation culture.	Operational needs analysis implemented. Band 2/3 Development Program.
<b>Internal Business Processes</b> (including financial management)		Facilitate valued and highly trained people to deliver quality services.	Strategic L&D.
		Improve workforce planning into HR policies and practices including enhanced succession planning.	Succession Plan.
		Encourage staff to introduce and embrace innovative people practices.	Promotion and encouragement of new initiatives and ideas.
		Recruit and retain high quality employees.	STAY Program. Best practice recruitment.
		Improve performance management through advice support and the provision of relevant tools.	Improved IPAD system.
		Enhance statutory OH&S and Workplace Diversity Plan requirements and develop and enhance efficient programs.	Enhance WD Plan. Review OH&S policies and practices.
		Develop sound employee relations through staff consultative committee and other forums.	
		Provide timely HR client services and accurate advice.	
		Identify current capability and provide appropriate development where necessary.	Complete skills audit.
			Strategic L&D Plan, Band 2/3 Program.
		Increase knowledge of best practice HR through research and analysis of appropriate international and domestic best practice HR.	STAY program, quality coaching, Innovative recruitment practices.
<b>People, Learning &amp; Development</b>		Cross train to increase HR service delivery.	Improved communication and sharing of information.

	Strategy: Enhance Information Capital	Objective Statement	Initiatives
<b>Stakeholders</b> (Community, Users, Industry and Government)		Develop knowledge management.	Skills audit. Re-engineering DAISY. KNOWS Project.
		Maintain ISO Accreditation.	
		Provide helpdesk services to APVMA staff.	
		Enhance, maintain and protect IT systems.	Secure remote access (VPN) provided. External audit of security.
<b>Internal Business Processes</b> (including financial management)		Build appropriate business applications.	Survey of user satisfaction. New online services. EARS.
		Manage quality system, its control documentation and audit process.	Reconciliation of all versions of documents. Removal of redundant documents. Plain English naming.
		Increase computer literacy.	Introduce 30 min briefs on technical and applications topics.
<b>People, Learning &amp; Development</b>		Develop information retrieval/search discovery expertise.	30 min briefs/one-on-one training in info search and retrieval
		Maintain and develop web services.	
		Improve user awareness of quality systems requirements.	

	Enhance intelligence, feedback loops, monitoring and reporting	Provide targeted information and develop key links	Review chemical safety, quality and performance	Ensure product quality through risk based quality assurance and compliance strategies	Conduct independent risk-based assessments	Conduct Effective Business Management	Ensure sound financial management	Act within governing legislation	Enable valued and highly trained people and promote organisational capital	Enhance information capital
Veterinary Medicines Program	●	●	●	⊖	●	⊖	⊖	●	⊖	⊖
Pesticides Program	●	●	●	⊖	●	⊖	⊖	●	⊖	⊖
Chemistry & Residues Program	⊖	●	●	⊖	●	⊖	⊖	●	⊖	⊖
Quality Assurance & Compliance Program	●	●	⊖	●	⊖	⊖	⊖	●	⊖	⊖
Legal & Governance Program	⊖	⊖	⊖	⊖	⊖	●	⊖	●	●	⊖
Corporate Services Program	⊖	●	⊖	⊖	⊖	●	●	●	●	●

Legend:

- Primary
- Contributor
- ⊖ Support



## Glossary of Terms

AERP	Adverse Experience Reporting Program
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
BAS	Business Activity Statement
CAC	Commonwealth Authorities and Companies Act
CARS	Corrective Action Reporting System
CCC	Community Consultative Committee
DAISY	The APVMA Intranet Facility
DoFA	Department of Finance and Administration
EARS	Electronic Application Registration System
FBT	Fringe Benefits Tax
FOI	Freedom of Information
GMP	Good Manufacturing Practice
ILC	Industry Liaison Committee
IPAD	Individual Performance and Development
ISO	International Standards Organisation
KNOWS	Knowledge Management System
L&D	Learning and Development
MRA	Mutual Recognition Agreement
NET	The APVMA Executive Team
NCR	Non-compliance Report
PSIC	Product Safety and Integrity Committee
QA	Quality Assurance
RLC	Registration Liaison Committee
STAY	Strategy to Avoid Yearning
WD	Workplace Diversity
VPN	Virtual Private Network