

Operational Plan 2007-2008

Corporate Statement

Our Vision

What we want to achieve...

To be recognised nationally and internationally as a best-practice regulator of pesticides and veterinary medicines that has the respect and confidence of governments, the community, the rural sector, chemical users and the chemicals industry.

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Our Mission

Why we are here...

 ${f T}$ o protect the health and safety of people, animals and crops, the environment, and trade, and support Australian primary industries, through evidence-based, effective and efficient regulation of pesticides and veterinary medicines.

Operational Plan 2007–2008

This Operational Plan underpins the Australian Pesticides and Veterinary Medicines Authority's (APVMA) Corporate Plan, which defines the organisation's desired outcomes and principal goals over the period 2006-2009. The 2007-2008 Operational Plan outlines the actions necessary to achieve the desired outcomes. In turn, comprehensive action plans setting out specific performance indicators are developed within the APVMA that identify responsible areas and individuals and allow progress to be routinely monitored.

An overview of the APVMA's Corporate Plan is shown on page 2. For each of the strategies and organisational support goals a strategy map has been developed to illustrate how the strategy will be undertaken.

The Balanced Scorecard Methodology

This Operational Plan has again been developed utilising the Kaplan and Norton Balanced Scorecard (BSC) Methodology.

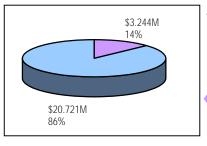
The use of the BSC methodology enhances the planning process, facilitates translation of strategy into action, and allows better communication of strategy, objectives and initiatives with stakeholders and staff. The use of strategy maps allows "visualisation" of strategy.

Organisational performance management is strengthened through a shared vision and common understanding of strategy. The BSC improves the alignment of key performance measures across all areas of the organisation and enhances performance monitoring by the APVMA Board and Senior Management.

Kaplan and Norton's traditional four perspectives have been modified slightly to the APVMA's particular circumstances. Three perspectives have been used:

- 1. A Stakeholder Perspective including the community, chemical users, the chemicals industry and government;
- 2. An Internal Business Processes Perspective including financial management; and
- 3. A People Learning and Development Perspective.

Distribution of the APVMA's budget towards meeting outputs

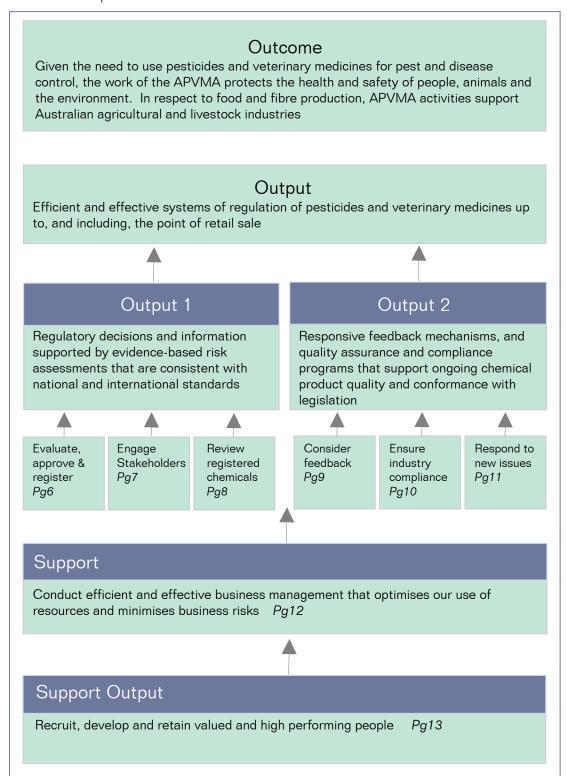


Total \$23.965M

- Regulatory decisions and information supported by evidence-based risk assessments that are consistent with national and international standards.
- Responsive feedback mechanisms, and quality assurance and compliance programs that support ongoing chemical product quality and conformance with legislation.

Strategic Framework

The APVMA's Corporate Plan identifies six key strategies and two support strategies. The following diagram shows the relationship between these strategies and the APVMA's Outputs and Outcome.



Role of the APVMA

The APVMA is responsible for regulating pesticides and veterinary medicines in Australia up to and including the point of retail sale. We administer the National Registration Scheme for Agricultural and Veterinary Chemicals in partnership with the States and Territories and with the active involvement of other Australian Government agencies. We evaluate and register pesticides and veterinary medicines and manage quality assurance programs that aim to ensure the ongoing safety and quality of registered products.

The work of the APVMA protects the health and safety of people, animals, the environment and trade. It supports primary industries – agriculture, forestry, horticulture and aquaculture – by allowing the supply of safe, effective animal health and crop protection products. It also supports consumers by allowing the supply of safe, effective home garden and household pesticides and pet products.

Our role is important in maintaining confidence in the safety of Australia's food supply, the wellbeing of the environment, and the integrity of our export markets.

In undertaking its role, the APVMA consults with industry clients and other stakeholders, including primary producers, the broader community and other government agencies.

This year's Operational Plan will be delivered in the context of the transition to new governance arrangements for the APVMA following the Uhrig¹ review.

The APVMA devotes considerable attention to continuous improvement across all areas of its activities, with a view to ensuring quality outcomes consistent with legislative requirements and sound scientific principles, encouraging productive communication with clients and stakeholders and staff development.

The APVMA is guided by the policy direction of the Australian, State and Territory Governments for the regulation of agricultural and veterinary chemicals as determined by the Primary Industries Ministerial Council.

In fulfilling its legislated obligations to protect public health, the environment and trade, the APVMA seeks to reduce the regulatory burden on business wherever practical.

We welcome the views of chemical users, consumers and the chemicals industry, recognising the diversity of views that exist about the regulation of pesticides and veterinary medicines.

Strategy Map

This Plan contains a series of individual Strategy Maps, all directed to achieving the APVMA's Outputs and Outcomes. Building stakeholder confidence, achieving operational excellence and informing policy development remain central themes within these strategies. Individual Program responsibilities are outlined on page 14.

¹ Review of the Corporate Governance of Statutory Authorities and Office Holders

Key Priorities

Within the framework of this Operational Plan, a number of key priorities are identified. We will focus on:

Stakeholder Engagement

- By strengthening our interaction with stakeholders, particularly the rural sector, through implementing the review of existing stakeholder forums and through better relationship management;
- By progressing initiatives to improve consultation associated with chemical reviews, enhance staff issue management skills and improve communication tools; and
- By continued development of the website to enhance information architecture, assist more intuitive searching, and provide more relevant content to stakeholders.

Organisational Reform

- By implementing the ANAO audit recommendations; and
- By implementing the transition to the new governance framework.

Registration Reform

- By improving both efficiency and effectiveness of registration processes through implementing the ANAO audit recommendations;
- By enhancing the framework for listed registration and reservation;
- By advancing key projects such as labelling reform;
- By expanding the functionality of the EARS system by increasing the types of applications that can be submitted electronically and further developing applications to process the submitted data; and
- By further enhancing the Manual of Requirements and Guidelines (MORAG).

International Cooperation

- By delivering tangible outcomes from work sharing and cooperation with regulators in other countries; and
- By enhancing the communication of trade advice, contributing to the Japanese Positive List project and progressing the development of the software for determining export intervals.

Minor Use Reform

• By consolidating current initiatives to improve the cost-effective and timely availability of safe, effective chemicals for minor uses.

Compliance Reform

- By progressing legislative reform of the Compliance toolkit; and
- By more effectively using our existing powers.

Key Priorities (Cont'd)

Quality of Agricultural and Veterinary Products

- By reviewing the Ag QA scheme; and
- By enhancing the veterinary medicines Manufacturers Licensing Scheme, including full implementation of the revised Code of GMP and the overseas manufacturers scheme, and implementing the ANAO audit recommendations.

MRL Setting

 By consolidating implementation of the JECFA approach for setting MRLs for Veterinary Medicines and aligning processes with FSANZ to enter MRLs in the Food Standards Code in a timely manner.

Informing Policy

By providing input to important government initiatives such as the COAG Review of
Hazardous Materials, Productivity Commission Review of Chemicals and Plastics Regulation
in Australia, the Environment Protection and Heritage Council NCHEM initiative and the
regulation of low risk products.

Regulatory Science Quality

- By delivering on our science quality standards;
- By progressing initiatives (particularly through training by Science Fellows and the Science Fellows Forum) to enhance regulatory science quality within the APVMA;
- By further improving external service provider quality and cost effectiveness and greater international cooperation; and
- By continuing initiatives to improve the quality of chemistry data in applications.

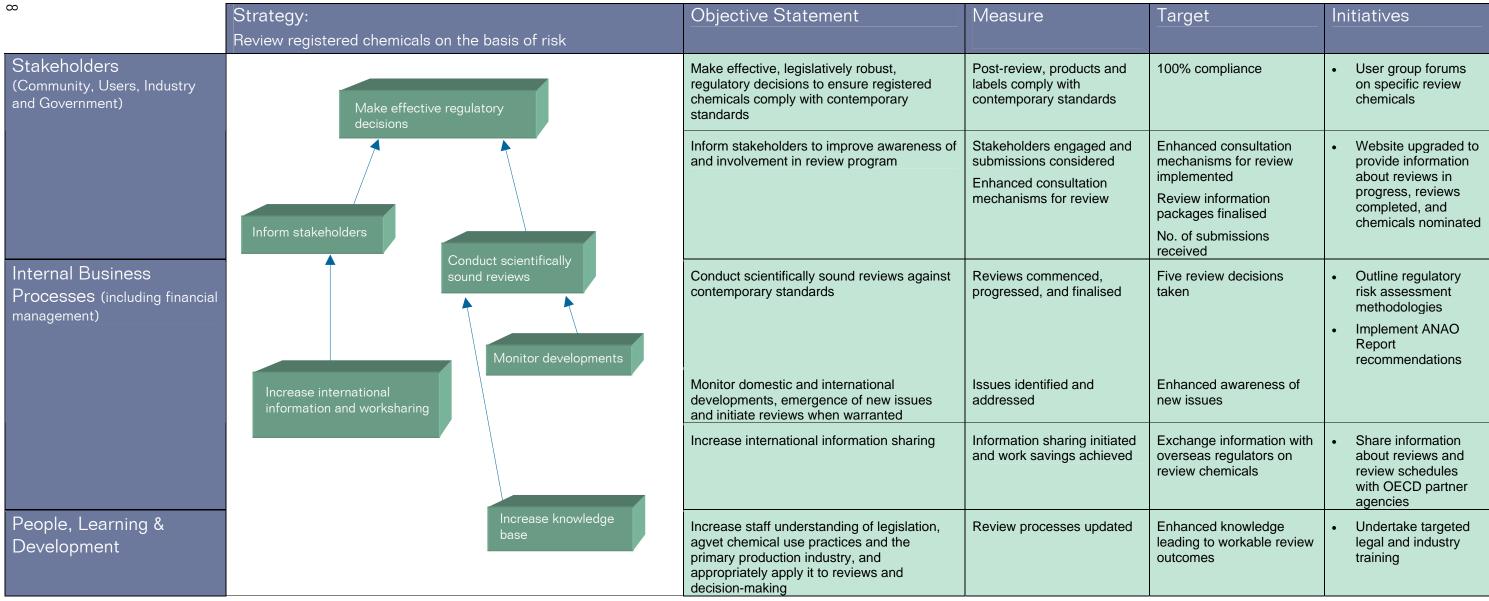
Maintaining Capabilities

- By recruiting, retaining and developing quality, valued people; and
- By optimising organisational structures and resource allocations.

methodologies

enhanced

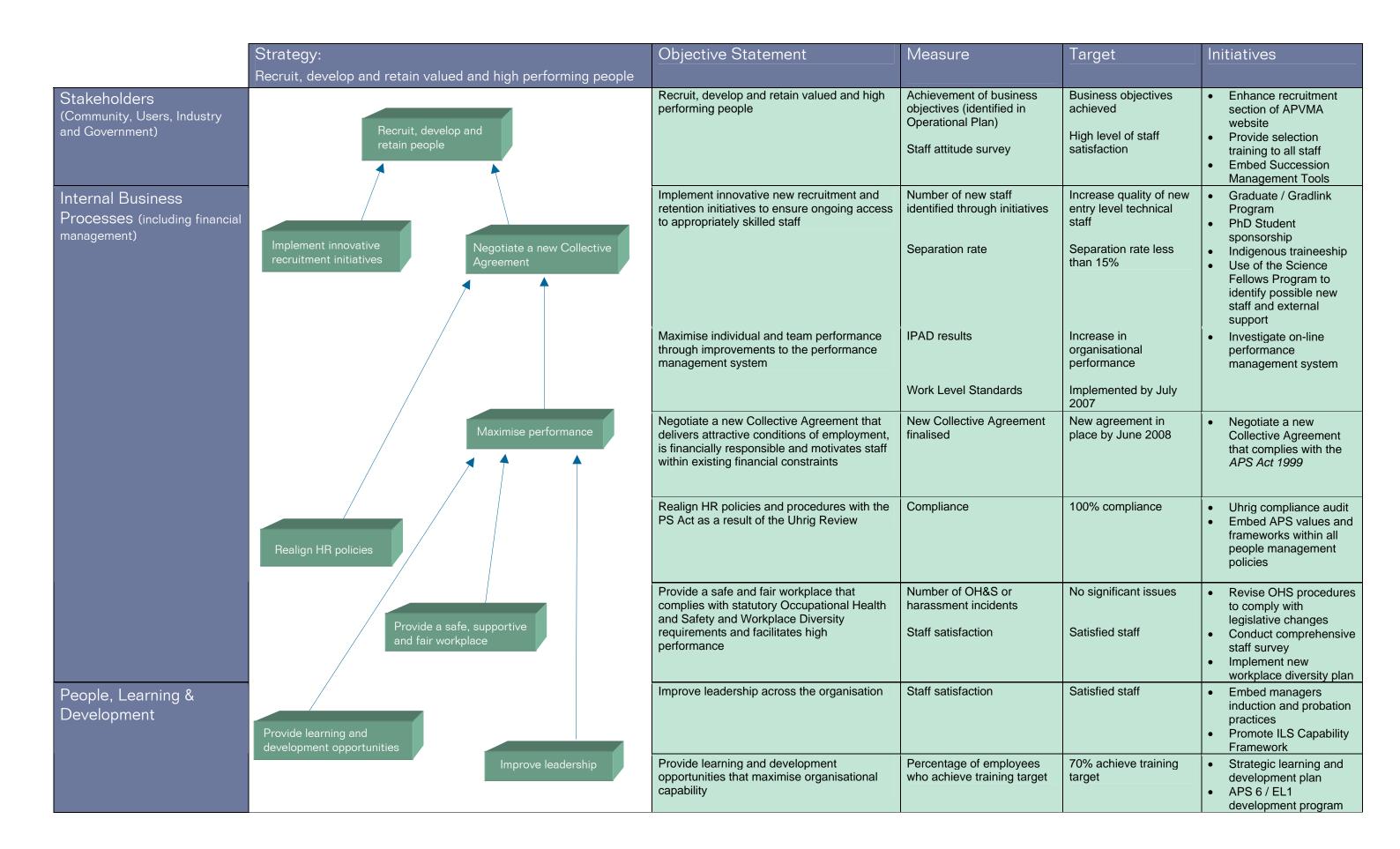
| | Strategy: | Objective Statement | Measure | Target | Initiatives | |
|--|---|--|---|---|---|--|
| | Engage stakeholders to improve awareness and inform policy development and to optimise the regulatory framework within which APVMA operates | | | | | |
| Stakeholders (Community, Users, Industry and Government) | Enhance stakeholder relations Promote a more harmonised and integrated approach to agvet chemical regulation | Enhance stakeholder relations and increase involvement in planning | Improved stakeholder awareness and engagement Policy development informed by stakeholder views | Positive feedback User Forum established Increased APVMA awareness of new issues | Improved stakeholder consultation tools Stakeholder information seminars and workshops New Advisory Board New User Forum | |
| | | Promote a more harmonised and integrated approach to agvet chemical regulation and risk management throughout Australia | Policies implemented that have APVMA input APVMA input to PSIC, NRS national performance report | APVMA input made to policy reform through the Product Safety & Integrity Committee with NRS partners and elsewhere APVMA data provided annually | Involvement at PSIC With DAFF input to policy initiatives such as Productivity Commission reviews, COAG Chemicals Security etc Minor Use policy reforms | |
| Internal Business Processes (including financial management) | Provide targeted and accessible information Enhance partnerships within the National Registration Scheme | Provide targeted and accessible information for key stakeholders through a range of communication tools | No. of website visits Number of presentations at external forums Provision of information that meets stakeholder needs No. of contacts obtained through consultation tools | Increased no. of visits Increased awareness and engagement Increase in satisfaction 50% increase in no. of contacts | Enhancement of information channels and development of stakeholder materials Provision of targeted information to key national audiences Development of style guide | |
| | Manage public affairs | Enhance partnerships within the National Registration Scheme including Australian States and Territories Governments | Formal agreements with government agencies undertaken | MOUs in place or updated with DoHA, DEW and State and Territory partners | Revision of Memoranda of Understanding with government departments Interaction increased with other State and Territory agencies (Health, Environment) | |
| | | Manage public affairs (including media relations) to address issues and raise awareness of key information and decisions with stakeholders | Media coverage received | Accurate, timely and effective media engagement | Media releasesMedia briefingsMaintenance of media networks | |
| People, Learning & Development | | Build internal capability to better inform and provide appropriate input to policy reform activities external to the APVMA | Capability to inform policy enhanced | Timely, well considered input provided to major policy reforms | Executive engagement with policy processes | |
| | Build capability to better inform and coordinate policy input Provide staff training | Provide staff with training including stakeholder awareness and media assistance | Trained staff | Capable and effective media skills Heightened state of preparedness of critical incident management protocols and processes | Media training Enhancement of critical incident management processes | |



| | Strategy: | Objective Statement | Measure | Target | Initiatives | |
|--|--|---|---|--|--|--|
| | Consider stakeholder feedback including adverse experience reporting | | | | | |
| Stakeholders (Community, Users, Industry and Government) | Ensure feedback identified, considered and acted on | Ensure feedback is identified, considered and acted on appropriately | Re-occurrence of adverse experience reports relating to issues that have been identified and addressed Feedback mechanisms | Nil re-occurrence | Optimise whole of APVMA feedback linkages | |
| | Improve transparency and visibility | Improve transparency and visibility to all stakeholders | Extent to which ongoing promotional activities have been undertaken | Increased stakeholder awareness | Awareness raising of AERP scheme Implement improved communication strategies for stakeholders | |
| Internal Business Processes (including financial management) | Assess and categorise adverse experience reports Develop better processes to deal with feedback Review AERP Ag scheme Train staff in AERP | Develop better APVMA-wide processes to deal with feedback | Better developed processes | Whole of APVMA approach achieved | Integrated feedback project | |
| | | Assess and categorise adverse experience reports in a timely manner to ensure that feedback loops are effective | Number of adverse experience reports processed | AERP Ag - 75% finalised within 3 months AERP Vet - >90% finalised within 3 months | Rationalise AERP quality system procedures Identify and develop the collection of feedback from new sources and/or using new technologies | |
| | | Review AERP Ag scheme | Review completed | Review recommendations considered | | |
| People, Learning & Development | reporting, analysis and auditing | Train staff in AERP reporting, analysis and audit processes | Trained staff | Staff appropriately trained | | |

10 Strategy: Objective Statement Measure Target Initiatives Ensure industry compliance with the legislation, including maintenance of quality assurance programs Stakeholders Ensure only registered products are supplied Stakeholder awareness of, and Increased visibility of confidence in, APVMA compliance toolkit (Community, Users, Industry compliance actions and Government) Ensure quality of pesticides and veterinary Industry compliance with Greater than 95% of ag Ag QA Scheme Ensure quality of chemical Ensure only registered conditions of registration under products meet regulatory Awareness seminars and the Ag QA scheme standards for quality and website information Ensure registered veterinary medicines are assessed sources Implementation of ANAO GMP compliance and response manufactured in GMP compliant facilities. All audits satisfactorily closed recommendations to MLS audit findings regarding the MLS Influence compliant industry behaviour with Repeat non-compliance Decreased reporting of same Continued Non-Compliance Strategy respect to import, supply and advertising non-compliance Implement ANAO audit Identified changes in industry Improved % of compliance at recommendations nfluence compliant industry behaviour first contact behaviour No. of MLS GMP audits 70 per annum Assess compliance of veterinary medicines Un-announced MLS Internal Business manufacturers Processes (including financial - audit and license local manufacturers of No. of MLS licences issued. Subject to operational demand veterinary medicines under the Manufacturing suspended, cancelled and management) GMP export certificates issued Licensing Scheme (MLS) Facilitate industry Assess compliance of - assess compliance of overseas manufacturers under Overseas GMP scheme No. of post-registration 150 products per annum with compliance audits conducted 90% compliant at first audit on products manufactured at overseas sites Seminars, information sheets Current information sheets and Facilitate industry actions to comply with the Contribute to website regulatory requirements of the Agvet legislation and website information website information reviewed redevelopment as a tool provided to disseminate Industry seminars presented on compliance information compliance improvement APVMA seminars Ensure effectiveness of GMP assessment Quality assurance and control Issues identified and Annual auditors systems and strategies of MLS auditors addressed workshop Apply compliance Inter-agency co-Manufacturer feedback on 95% positive feedback operation, eg MoU with audits received TGA. NZFSĂ Apply compliance tools including the Hormonal Non-compliance reports 90% finalised in timeframe Strategic Intelligence Growth Promotants Control Scheme and Import (NCRs) finalised Analysis Consents Participation in National Compliance with HGP Control 65% compliance on first audit HGP Control Scheme Scheme 100% of audit timeframes met Internal reviews of HGP and import consent Administrative resource Reduced resource input whilst processes Ensure effectiveness Utilise intelligence required for HGP Control maintaining effectiveness of GMP assessment analysis and risk Scheme supply component and import consent Undertake risk based monitoring of agricultural Number of assessments 40 product data call-ins and 30 Ag QA Scheme chemicals against conditions of registration and completed and reported on for on-site visits Formal review of Ag QA APVMA Standards under Ag QA Scheme selected products scheme 80 products ranging across at Selected products tested least 4 actives Utilise intelligence analysis and risk assessment Compliance actions arising 20% of actions result from Strategic Intelligence to support compliance toolkit and to prioritise Ag from strategic intelligence strategic intelligence Analysis QA scheme selections Strengthen liaison with Ag QA scheme visits, data call-80% of selections are overseas authorities to ins and testing based on risk intelligence driven risk verify chemical sources APVMA-State cooperation in compliance intelligence Strengthen understanding of processes and Procedures reviewed annually 100% of procedures are Annual review of quality People, Learning & procedures. and staff trained in changes. reviewed annually system procedures Development Strengthen understanding of manufacture and Training completed within 1 month of procedure changes Improve Compliance GMP and ISO auditor training within 2 years of recruitment Number of new effective Implemented and toolkit Improve Compliance toolkit via legislative reform Industry consultation compliance tools improved PSIC policy paper

| | Strategy: | Objective Statement | Measure | Target | Initiatives |
|--|---|--|--|--|---|
| | Respond to and manage emerging regulatory issues | | | | |
| Stakeholders (Community, Users, Industry and Government) | Implement effective issues management strategies Respond to government initiatives | Implement effective issues management strategies | Number of issues managed Stakeholder feedback on effectiveness | As per demand Stakeholder satisfaction with issue management | Development of issue management strategies Stakeholder consultation through direct communication channels and consultative committees |
| | Ensure effective regulation of new technologies | Ensure effective regulation of new technologies | New technologies | Developed and adopted as needed | Refer 'Evaluate and consider applications' |
| | | Respond to government initiatives and external reviews | Responded to initiatives | Recommendations implemented | Implement ANAO Performance Audit recommendations New governance framework implemented |
| Internal Business Processes (including financial management) | Enhance the APVMA's | Enhance the APVMA's capacity to identify emerging issues | Readiness for new issues, prevention of problems | Early identification of emerging issues | Media monitoring Enhanced feedback and consultation mechanisms |
| | capacity to identify emerging issues Enhance issue management capacity | Enhance issue and relationship management capacity | Awareness of issue management processes Relationship management | Effective issue management capacity across organisation Implemented by Dec 2007 | Development of issue management strategies Training and implementation of |
| | | | program fully implemented | implemented by Dec 2007 | management principles |
| People, Learning & Development | Provide staff with media training, support and assistance | Provide executive and other staff (as necessary) with media training, support and assistance | Maintenance of trained media spokespeople in each program area | Capable and effective media performers Heightened state of preparedness of critical incident management protocols and processes | Periodic media training Enhancement of critical incident management processes Relationship management skill training |



Responsibilities of APVMA Programs

| PrimarySupport | Evaluate & consider applications | Engage stakeholders to improve public awareness & policy developments | Review registered chemicals on the basis of risk | Consider stakeholder feedback including AERP | Ensure industry compliance with legislation | Respond to new issues | Conduct efficient & effective business management | Recruit, develop & retain valued & high performing people |
|---|----------------------------------|---|--|--|---|-----------------------|---|--|
| Veterinary Medicines Program | • | • | • | • | • | • | • | • |
| Pesticides Program | • | • | • | • | • | • | • | • |
| Chemistry & Residues Program | • | • | • | • | • | • | • | • |
| Quality Assurance & Compliance Program | • | • | • | • | • | • | • | • |
| Legal & Governance Program | • | • | • | • | • | • | • | • |
| Corporate Services Program | • | • | • | • | • | • | • | • |

Glossary of Terms

Ag QA Agricultural Quality Assurance Scheme
AERP Adverse Experience Reporting Program

ANAO Australian National Audit Office
APS Australian Public Service

APVMA Australian Pesticides and Veterinary Medicines Authority

BAS Business Activity Statement
BCP Business Continuity Plan
CA Collective Agreement

CAC Commonwealth Authorities and Companies Act

CAR Corrective Action Reports

CCC Community Consultative Committee

CIPAC Collaborative International Pesticides Analytical Council

CODEX Codex Alimentarius Commission
COAG Council of Australian Governments

DAFF Department of Agriculture, Forestry and Fisheries

DAISY The APVMA Intranet Facility

DoFA Department of Finance and Administration

DoHA Department of Health and Ageing

DEW Department of the Environment and Water Resources

EARS Electronic Application Registration System

El Export Interval EL Executive Level

ESI Export Slaughter Interval

EPHC Environment Protection and Heritage Council

FBT Fringe Benefits Tax
FOI Freedom of Information

FSANZ Food Standards Australia New Zealand

GHS Globally Harmonised System for the Classification and Labelling of Chemicals

GMP Good Manufacturing Practice
HGP Hormonal Growth Promotant
ILC Industry Liaison Committee
ILS Integrated Leadership System
ISO International Standards Organisation

JECFA FAO/WHO Joint Expert Committee on Food Additives

L&D Learning and Development

MLS Manufacturers Licensing Scheme

MORAG Manual of Requirements and Guidelines for Registering Agricultural and Veterinary Products

MOU Memorandum of Understanding NET The APVMA Executive Team

NCHEM National Chemicals Environmental Management

NCR Non-compliance Report
NRS National Registration System
NZFSA New Zealand Food Safety Authority

OECD Organisation for Economic Cooperation and Development

OH&S Occupational Health & Safety
PRS Public Release Summary

PSIC Product Safety and Integrity Committee

QA Quality Assurance

RLC Registration Liaison Committee
TGA Therapeutic Goods Administration

UHRIG REVIEW Review of the Corporate Governance of Statutory Authorities and Office Holders

VICH International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary

Medicinal Products



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