Australian Government

Australian Pesticides and Veterinary Medicines Authority

OPERATIONAL PLAN

2011-2012

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This plan was produced by the Public Affairs section of the APVMA.

This plan is available on the APVMA's website at: http://www.apvma.gov.au/

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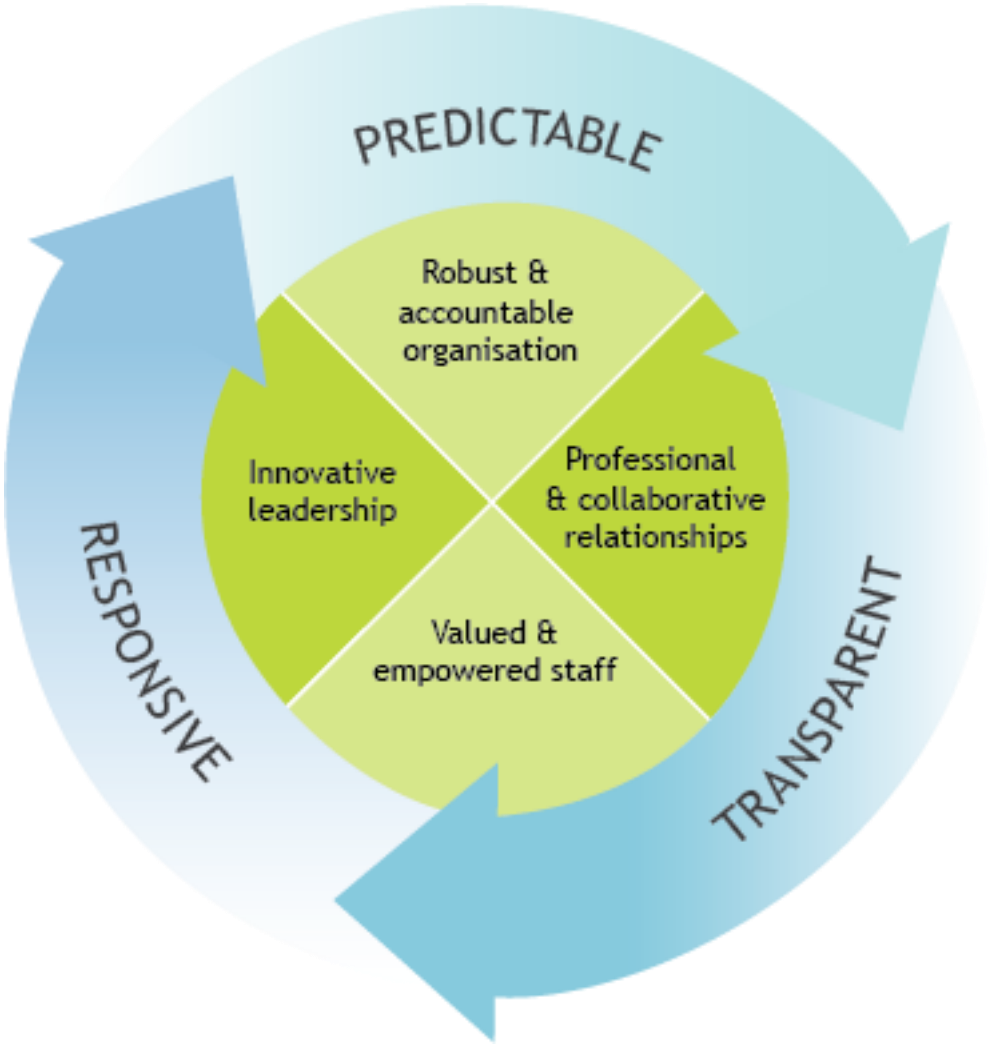
OUR VISION

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 chemical industry.

OUR MISSION

To 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.

OUR VALUES



OPERATIONAL PLAN 2011-12

This Operational Plan underpins the Australian Pesticides and Veterinary Medicines Authority's (APVMA) Corporate Plan, Risk Management Plan and Workforce Plan. The 2009–2012 Corporate Plan provides direction for the authority's activities, the Risk Management Plan outlines the findings of the risk assessment and proposes treatments for the residual risks while the Workforce Plan captures our strategic approach to recruit, develop and retain high performing people. Each of our five operational areas have developed comprehensive action plans while individual performance agreements set out key expected results. This allows progress to be monitored at the organisational and individual level.

An overview of the APVMA's Corporate Plan is shown on page 4. A map has been developed for each of the strategies to illustrate the key measures, targets and initiatives identified to deliver each strategy.

THE BALANCED SCORECARD METHODOLOGY

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

The use of the BSC methodology is designed to enhance the planning process, to facilitate translation of strategy into action, and to allow better communication of strategy, objectives and initiatives to stakeholders and staff. The use of strategy maps allows "visualisation" of the 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 Chief Executive Officer (CEO) and Executive Management (EM).

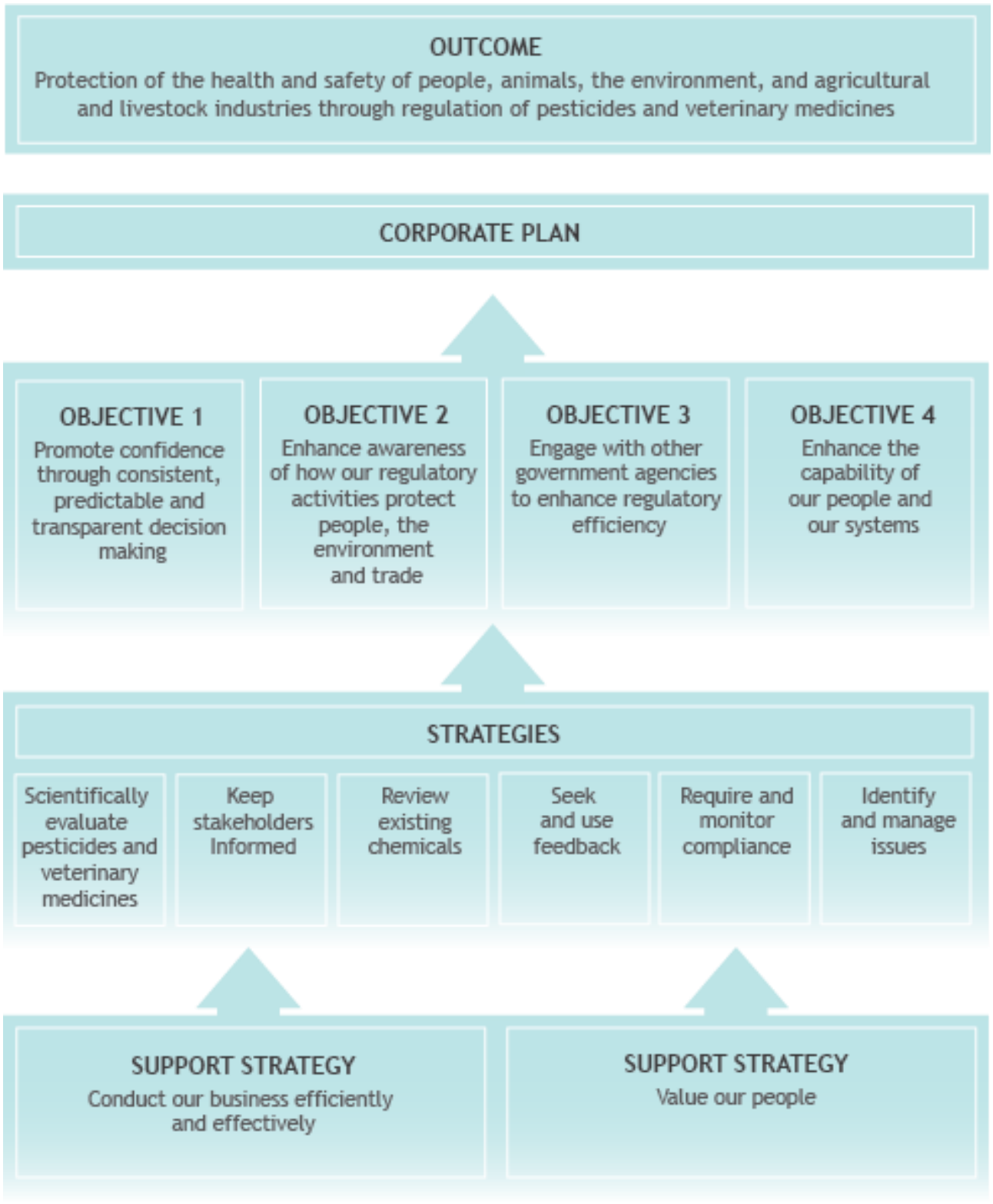
Kaplan and Norton's traditional four perspectives have been modified slightly to the APVMA's particular circumstances. Three perspectives have been used:

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.

STRATEGIC FRAMEWORK

The APVMA's Corporate Plan identifies four objectives. The following diagram shows the relationship between these objectives, the eight strategies to achieve the objectives and the APVMA's Outcome.

STRATEGIES



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 (NRS) 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 monitor 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 assessing the safety and effectiveness of animal health and crop protection products. It also supports consumers by assessing the safety and effectiveness of 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.

The APVMA is guided by the policy direction of the Australian, state and territory governments for the regulation of agricultural and veterinary (agvet) chemicals as determined by the Primary Industries Ministerial Council (PIMC).

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

The CEO is responsible for the governance and management of the authority, including the performance of its functions and exercise of its power. The Advisory Board and the Audit Committee support the CEO.

The role of the Advisory Board is to advise and make recommendations to the CEO by providing an expert consultative mechanism.

The Audit Committee is an essential part of the governance and risk framework. It provides assurance to the CEO in relation to internal controls, compliance, risk, financial management and reporting.

The APVMA looks to continuously improve across all areas of its activities, to optimise efficiency and strive for quality outcomes consistent with legislative requirements and sound scientific principles, to minimise regulatory burden on business, to encourage productive communication with clients and stakeholders and to support and develop staff.

GOVERNMENT REVIEWS

COAG Review of Chemicals and Plastics Regulation: The APVMA continues to participate in the Council of Australian Governments (COAG) review of chemicals and plastics regulation. As part of this review COAG has directed the PIMC to develop a proposal for a single national framework to improve the efficiency and effectiveness of the national regulation of agvet chemicals for its consideration in 2011.

In developing the proposal for a single national framework, all aspects of the NRS are being examined including regulation of products up to the point of retail sale as well as regulation controlling use once sold.

Better Regulation Ministerial Partnership: In November 2010 the Minister for Agriculture, Fisheries and Forestry released a policy discussion paper, *Better Regulation of Agricultural and Veterinary Chemicals* (the Reform Agenda) outlining eight areas for reform of the Australian Pesticides and Veterinary Medicines Authority (APVMA). The reforms seek to improve the efficiency and effectiveness of the Authority and complement the Better Regulation Ministerial Partnership commenced in 2009 with the Minister for Finance and Deregulation, with the intention to improve the efficiency and effectiveness of agvet chemical regulation. The key areas of reform are:

- Implementing complete risk frameworks for agvet chemicals assessment and review;
- Improve the quality and efficiency of agvet chemical assessment and registration processes;
- Enhancing the agvet chemical review arrangements;
- Using overseas assessments to their full extent;
- Establishing an independent science panel;
- Enhancing the provision of expert advice;
- Improving legal interaction with the APVMA; and
- Improving the APVMA's compliance enforcement capacity.

Implementation of these reforms is included in this plan and indicated by the following icon. 

KEY PRIORITIES

The key priority for the APVMA for 2011–2012 is to commence implementation of the Reform Agenda whilst maintaining core activities. This will pose a number of challenges to the authority, particularly meeting the expectations of our stakeholders. We will focus on:

STAKEHOLDER CONFIDENCE—RESPONDING TO WHAT IS IMPORTANT

- Supporting a robust and accountable organisation: effectively manage science and regulatory issues

OPERATIONAL EXCELLENCE—MAKING SURE WE DO THE BEST WE CAN

- Predictability, transparency and responsiveness: proactively publish information and enhance information access
- Valuing and empowering staff: integrate talent management processes and focus on workforce planning to maintain a high level of scientific expertise and support staff capability and leadership
- Professional and collaborative relationships: make more effective use of work conducted by comparable overseas agencies

INFORMING POLICY—WORKING WITH OUR GOVERNMENT PARTNERS

- Supporting a robust and accountable organisation: inform and respond to government policy and implement reforms

CORE BUSINESS

REGISTRATION AND APPROVALS

- Evaluation of applications to approve active constituents, register chemicals, approve labels and provide regulatory consents such as permits

CHEMICAL REVIEW AND ADVERSE EXPERIENCE REPORTING PROGRAM (AERP)

- Reviewing registered chemicals and Adverse Experience Reporting

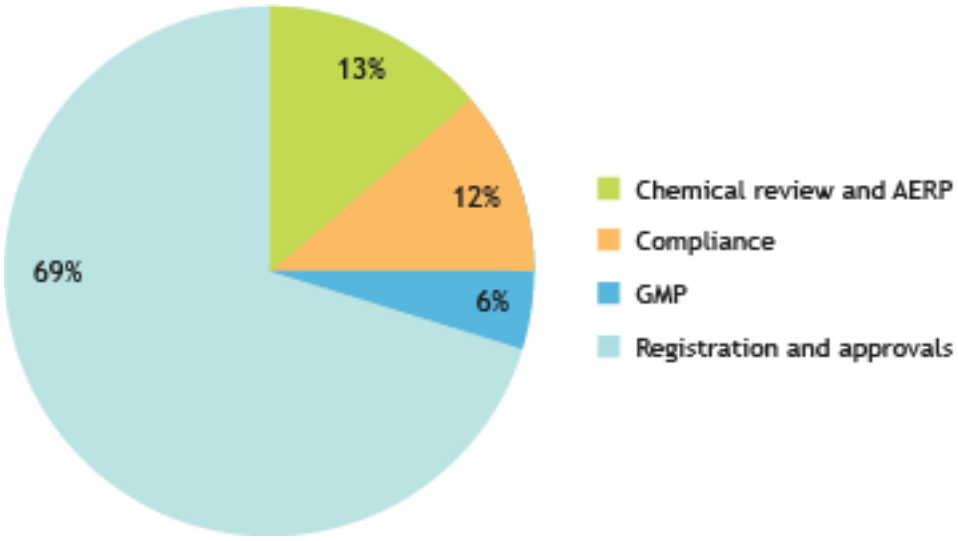
COMPLIANCE

- Ensuring industry compliance with the legislation, including maintenance of quality assurance programs

Good Manufacturing Practice (GMP)

- Ensuring industry compliance with the Australian Code of Good Manufacturing Practice for Veterinary Medicines

ANTICIPATED EXPENDITURE ACROSS CORE ACTIVITIES

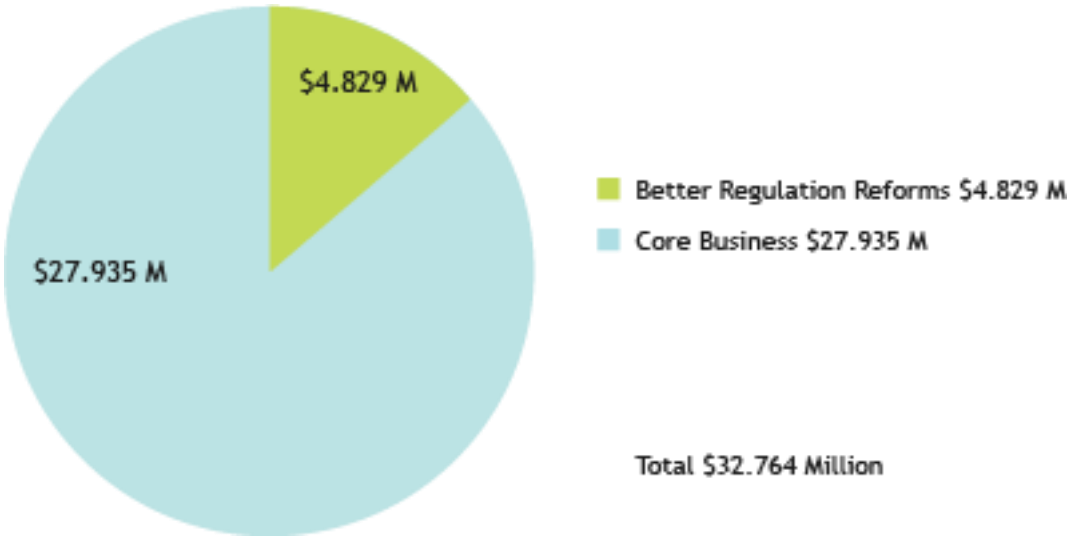


ALLOCATION OF FUNDING FOR THE BETTER REGULATION REFORM AGENDA

	FY2010-11 $	FY2011-12 $	FY2012-13 $	FY2013-14 $	TOTAL $
Better Regulation (incl. Chem Review)	1,800,000	3,873,000	0	0	
EDRMS/IT Upgrades	700,000	1,589,000	0	0	
Science Panel	0	248,000	257,000	237,000	
TOTAL					**8,704,000***

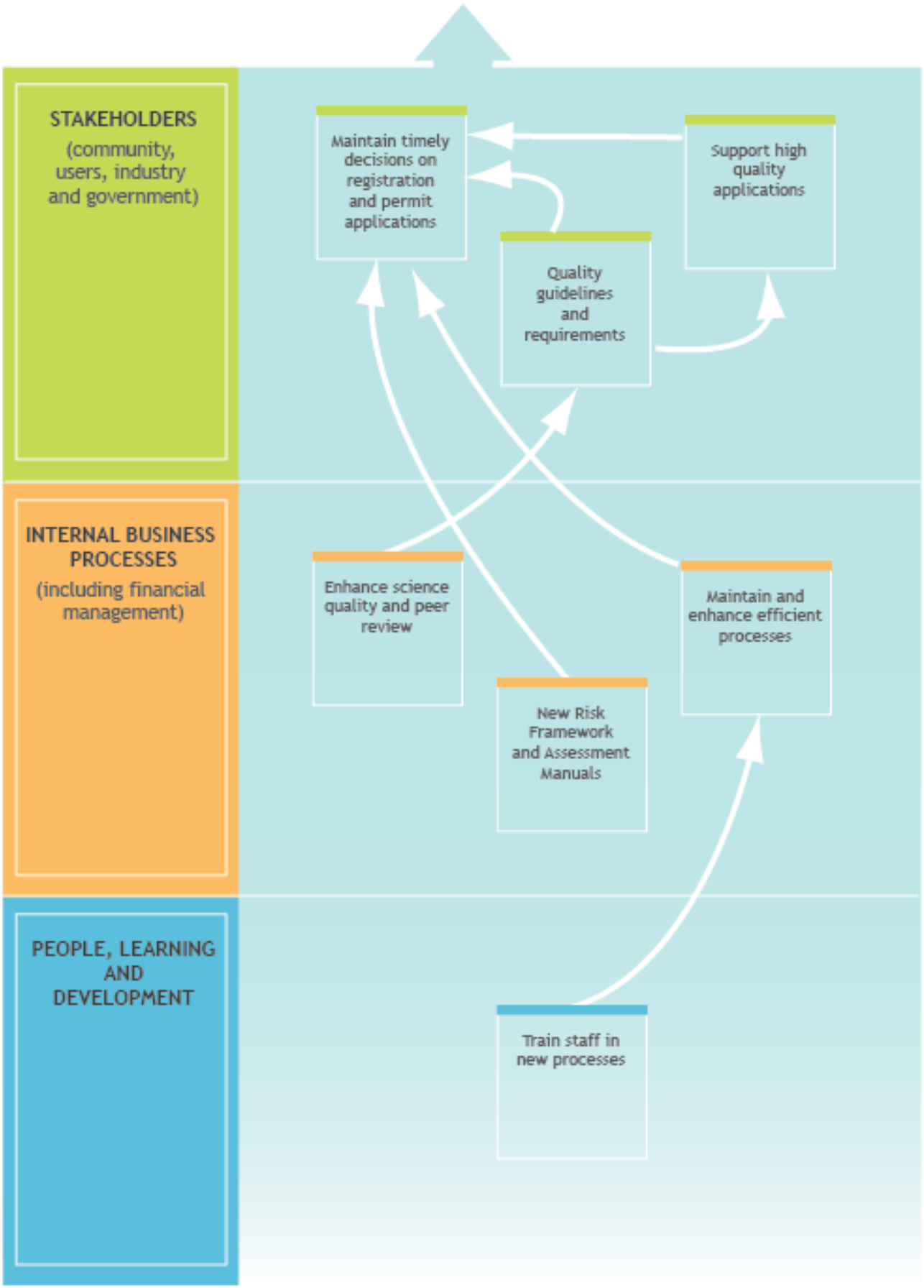
*$2Mil to be repaid/includes efficiency dividend

ANTICIPATED EXPENDITURE



STRATEGY 1

Use robust risk based methods to scientifically evaluate pesticides and veterinary medicines used in Australia



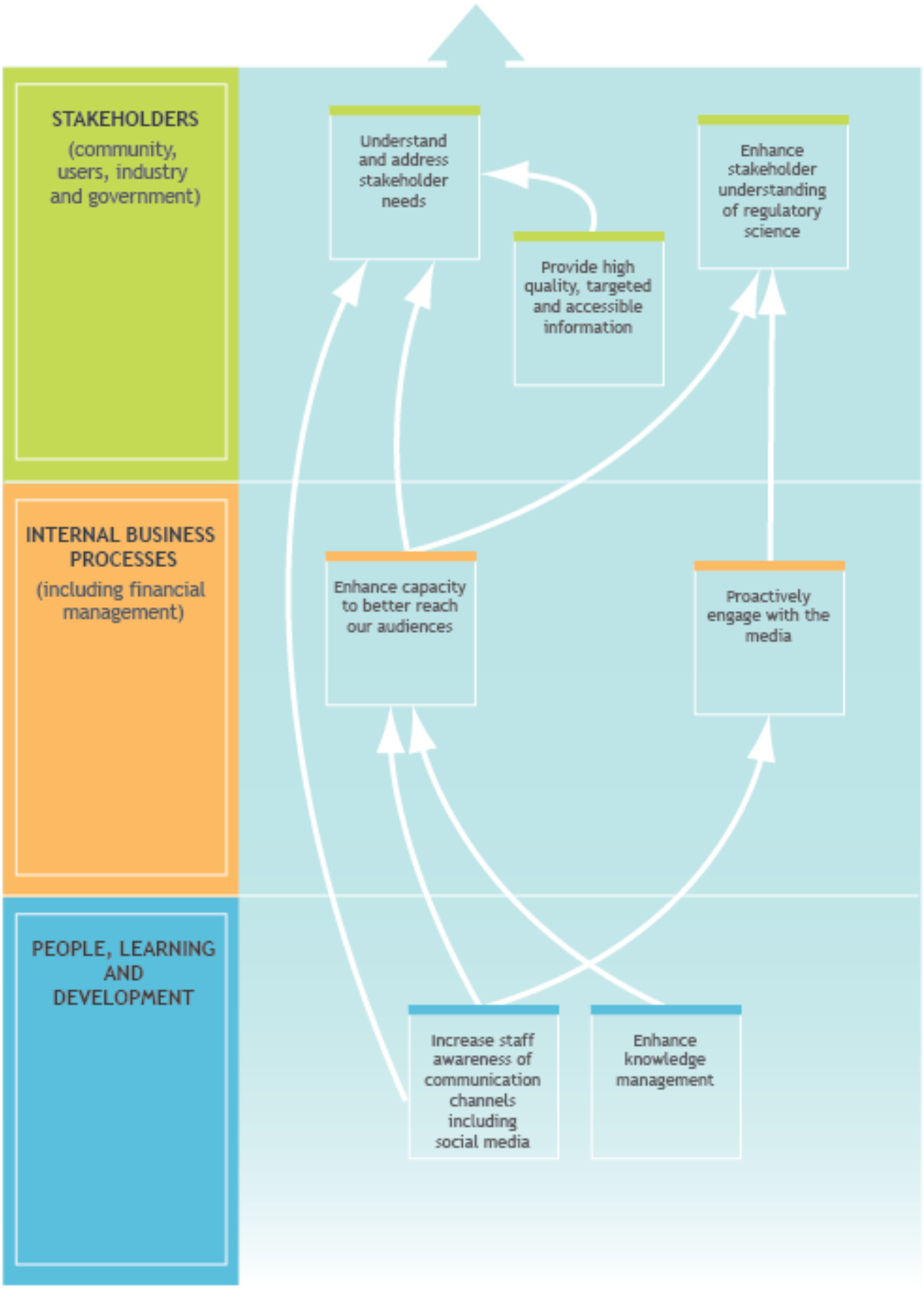
ACTIVITY	MEASURE	TARGET	INITIATIVES

Maintain timely decisions on registration and permit applications	• Evaluation timeframes	• Timeframe performance
		  • 88% products
		  • 55% active approvals
		  • 85% permits
			• Publish labeling standard and guides
			• Review non-essential functions

Support submission of high quality applications	• Quality of applications • Recording of deficiencies in applications	• Analyse results quarterly	• Implement completeness checks and Elapsed Time • Contribute to the development of VICH Bioequivalence Guideline • Pre-submission meetings
Maintain and develop quality guidelines and requirements	• New and revised guidelines meet international best practice	• Provide guidance for Industry on their development of Low Risk models • Guidelines accurate, complete and up-to-date	• Commence Chemistry and Product Integrity Project
Drafting of new Risk Framework and Assessment Manuals	• Progress towards finalisation of Framework and Manuals	• Volume 1 of Framework in place by 31 December 2011 • Commence three components of Volume 3 • Complete five components of Volume 2	• Risk Framework Volume 1, 2 and 3
Enhance science quality	• Use of Science Fellows and other external experts as required • Learning from and contributing to international worksharing	• Robust and defensible regulatory decisions • APVMA's input into the development of international guidelines and harmonisation activities is considered	• Identify suitable candidate product groups for Recognition of Overseas Assessments • Use Veterinary Medicines Expert Advisory Panel for complex regulatory advice • Establish Expert Advisory Panel for pesticide regulatory science advice • Develop and implement an enhanced science quality and process
Maintain and enhance efficient processes	• Implement measures to improve timeframes	• Measures in place by 30 June 2012	• New Agreements in place with external scientific service providers and international counterparts • Strengthen APVMA utilisation of electronic screening for GJRs and external scientific service providers.
Train staff in new processes	• Staff complete mandatory training to develop expertise	• 100% staff trained	• Training delivered on new processes from Reform Agenda • Implement on-line Data Protection training module • Develop on-line agvet chemical risk analysis training module • Conduct administrative law training

STRATEGY 2

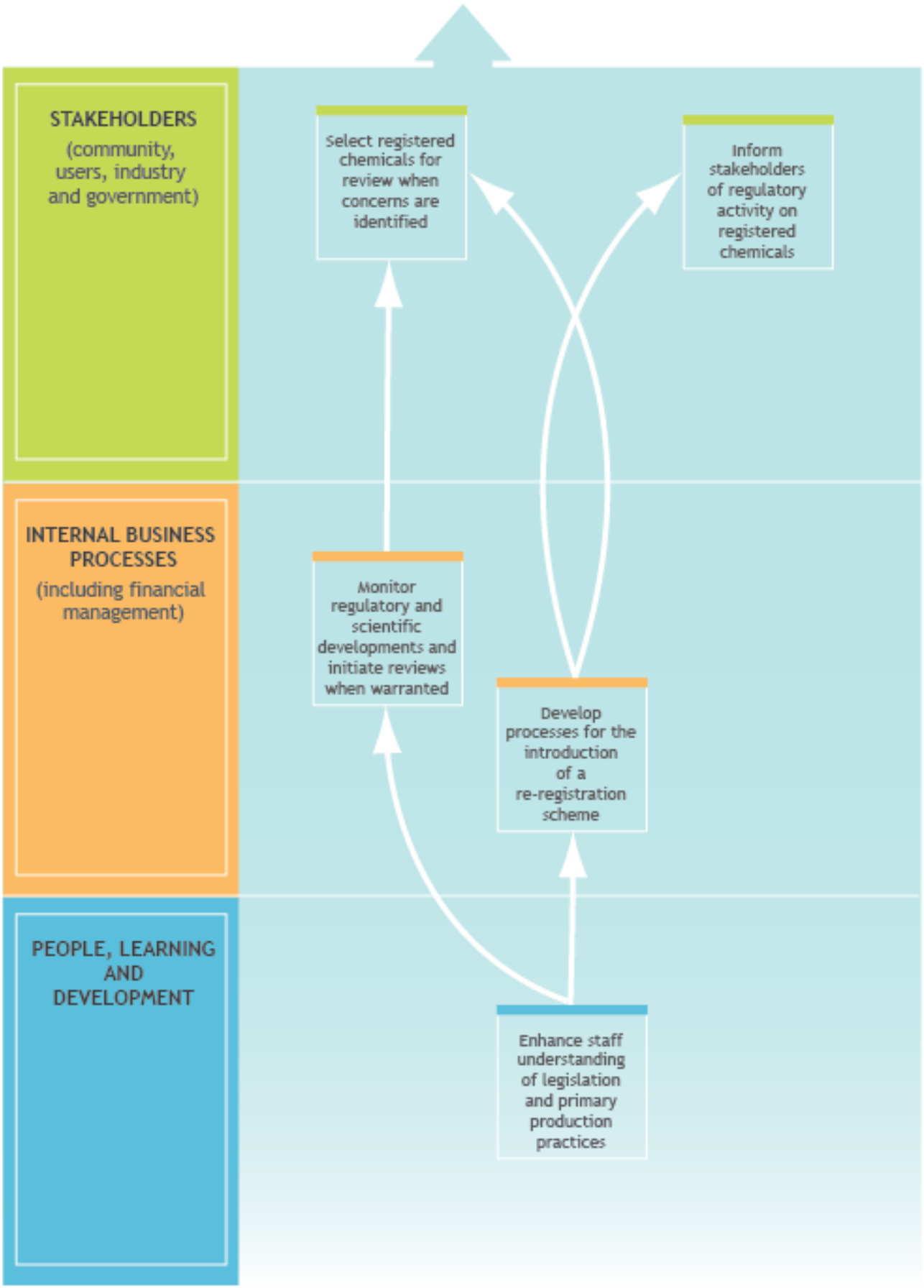
Keep all our stakeholders informed of regulatory matters and consider their views



ACTIVITY	MEASURE	TARGET	INITIATIVES
Understand and address stakeholder needs	• Satisfaction of consultative and liaison committee members • Communicate Reform Agenda implementation • Executive Meetings in regional areas to understand stakeholder issues	• Positive feedback • Quarterly updates provided through Regulatory Updates • One meeting per year held in a regional area	
Provide high quality, targeted and accessible regulatory information	• Accurate website that satisfies stakeholders • Website complies with AGIMO accessibility requirements • Website tailored to different stakeholder needs • Improve consistency of published material	• 100% of operational documents are published and are accurate • Positive feedback from website users • 100% of website meets mandatory government accessibility requirements	• Provide alternate file formats for web site to enhance accessibility • Proactively publish information and further increase transparency through the Information Access Project • Develop templates for all online publications
Enhance stakeholder understanding of regulatory science	• Host a successful Regulatory Science Symposium • Conduct a workshop to develop a regulatory science communication strategy	• 80% overall satisfaction of attendees with science symposium • Develop a regulatory science communication strategy	• Host a Regulatory Science Symposium • Develop partnership with stakeholders on spray drift communication
Enhance capacity to better reach our audiences	• Explore new channels of delivery to/from stakeholders	• Social Media Strategy implemented by 30 June 2012	• Examine opportunities to use social media to engage with stakeholders
Proactively engage with the media	• Ability to inform and represent the APVMA • Pickup of media releases • Stakeholder feedback	• Positive feedback • 70% of media releases picked up	• Target media releases to key outlets
Increase staff awareness of communication channels including social media	• Staff awareness	• All staff aware of communication channels	
Enhance knowledge management across the organisation	• Improved capture of intrinsic knowledge		• Progress the implementation of an EDRMS

STRATEGY 3

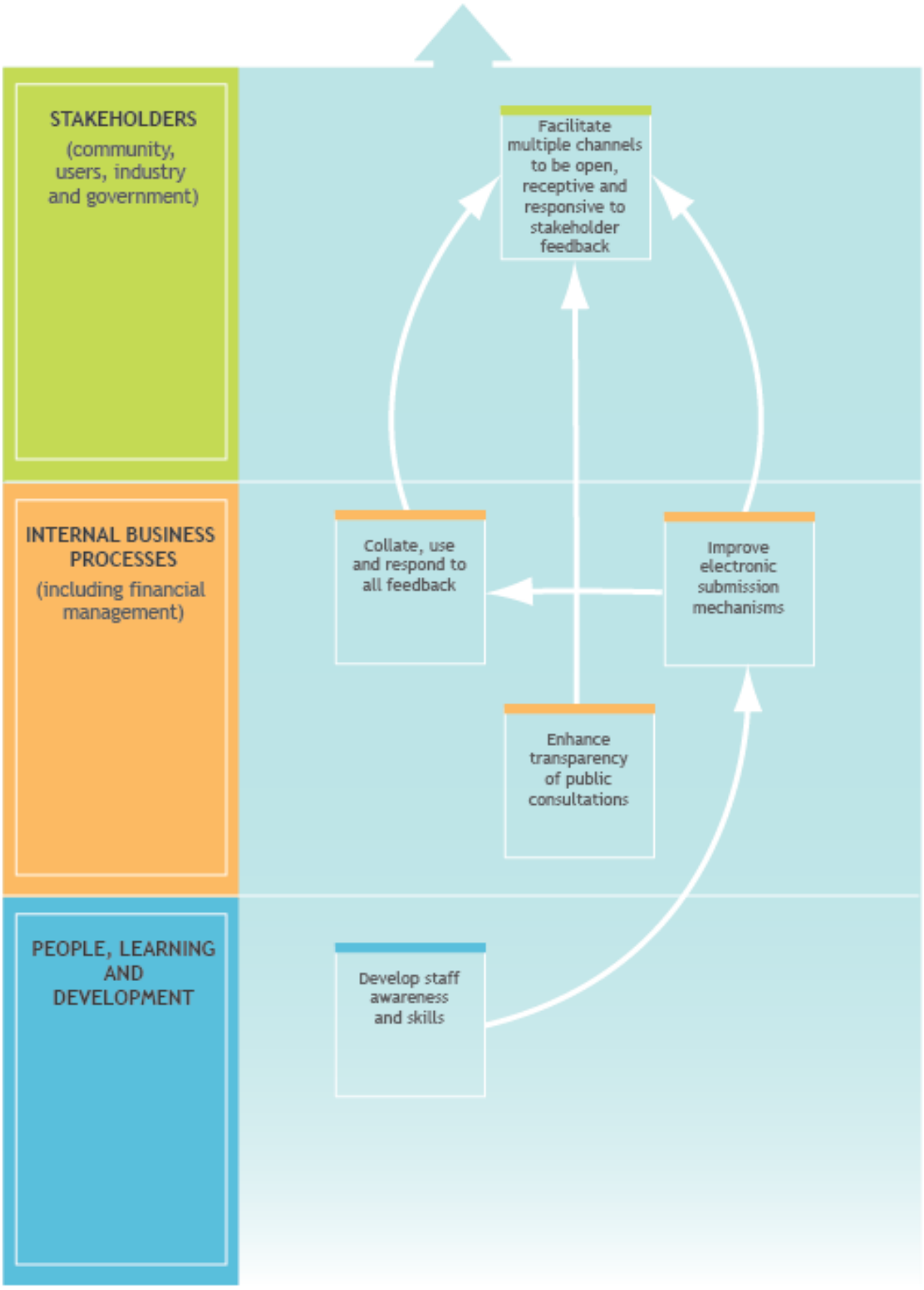
Review registered chemicals to ensure they meet contemporary standards



ACTIVITY	MEASURE	TARGET	INITIATIVES
Select registered chemicals for review when concerns are identified by the APVMA	• Review nominations considered and prioritised • Number of reviews prioritised, commenced and progressed • Regulatory decisions developed • Regulatory decisions implemented	• 6 review or other regulatory decisions taken to mitigate identified risk	• Continue to implement spray drift reviews and encourage utilisation of Drift Reduction Technologies • Increased use of available regulatory tools to manage risks without proceeding to formal legislative review • Increased resources for review 
Inform stakeholders of regulatory activity on registered chemicals	• Use of website, media interactions, and direct stakeholder liaison	• Conduct/participate in 5 review related stakeholder forums • Increased number of review media releases and web page updates	• Enhance chemical review website information and media interactions • Encourage utilisation of best available technology
Monitor regulatory and scientific developments and initiate reviews when warranted	• Information from other regulatory jurisdictions and scientific literature monitored and considered for Australian regulation.	• Issues identified and considered • Responses developed on basis of monitored information and scientific literature • Increase international information exchange and work sharing for review activities	• Increase sharing of regulatory information with national and international regulators
Develop processes for the introduction of a Re-registration Scheme	• Processes developed	• Processes developed by 30 June 2012 • In accordance with project plan	• Re-registration Scheme  • Implement the new Class C Data Protection provisions 
Enhance staff understanding of legislation and primary production practices	• Practical and enforceable regulatory decisions	• Improved access to relevant primary production information • Consider industry feedback to improve our knowledge base	• Deliver training on Administrative Law and primary production practices to raise regulatory science quality

STRATEGY 4

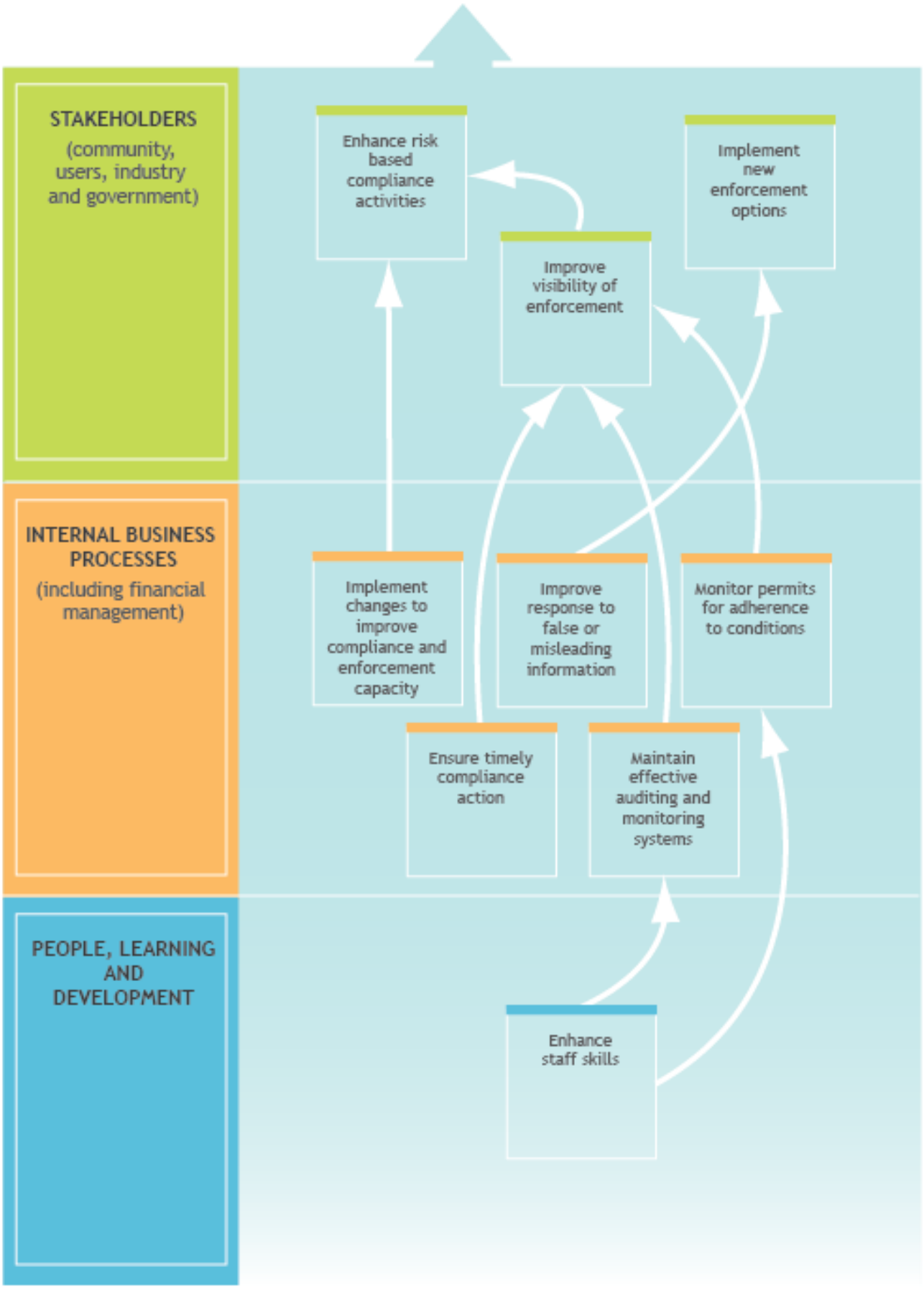
Seek and use stakeholder feedback to inform regulatory activities



ACTIVITY	MEASURE	TARGET	INITIATIVES
Facilitate multiple channels to be open, receptive and responsive to stakeholder feedback	• Develop a Social Media Strategy • Develop new tools to utilise social media	• Social Media Strategy implemented by 30 June 2012 • Social Media tools in place by 30 June 2012	• Social Media Strategy
Enhance the transparency of APVMA operations and public consultations	• Adhere to FOI Information Publication Scheme • Complete a final Public Consultation Policy • Work Instructions relating to consultation amended	• 100% compliance with Information Publication Scheme • Final Public Consultation Policy completed by 30 June 2012 • Work Instructions amended by 30 June 2012	• Implement Final Public Consultation Policy
Collate, use and respond to all feedback	• Feedback acted upon	• 100% of feedback acted upon • Service Charter targets met • Finalise 70% of AERP reports within three months	• Revised Feedback Register processes
Improve electronic submission mechanisms for AERP	• New AERP reporting system developed • Number and quality of AERP reports submitted • AERP system user satisfaction	• New AERP system operational by 30 June 2012 • Increase in number and quality of AERP reports • Survey of users indicates high satisfaction with new system	• New AERP on-line reporting system • Investigate the use of Smart Forms
Develop staff awareness and skills in responding to stakeholder feedback	• Revise Service Charter • Guide staff in conducting public consultations	• Staff understand and adhere to new service standards • 100% of consultations undertaken in line with policy	• Finalise a new Service Charter

STRATEGY 5

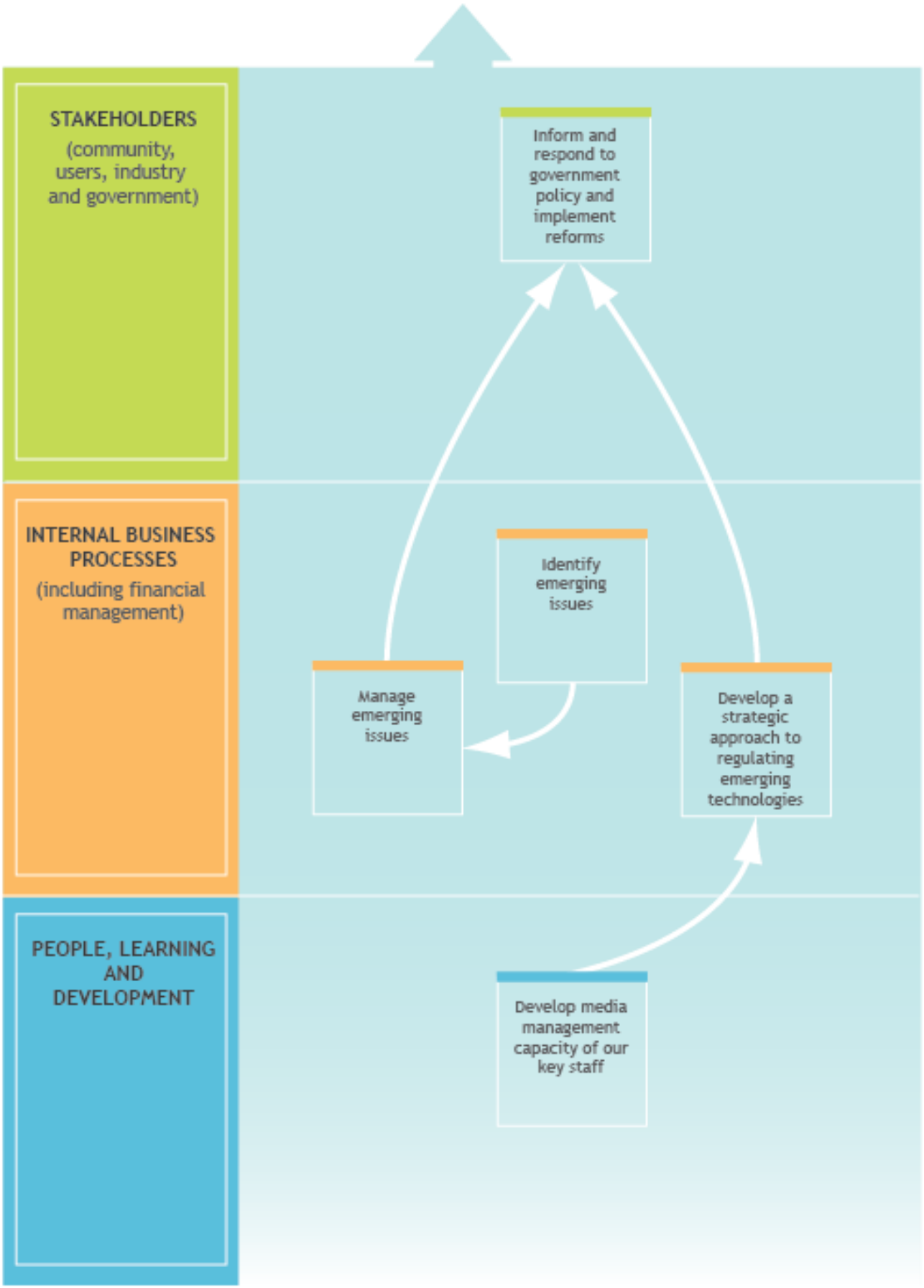
Require and monitor compliance with legislative requirements to maintain confidence in the regulatory framework



ACTIVITY	MEASURE	TARGET	INITIATIVES
Enhance risk based compliance activities	• Effective monitoring and enforcement • Early engagement with non-complying businesses to facilitate compliance	• Minor compliance cases closed within 90 days with minimal complaints • Non-complying companies achieve compliance within 120 days without formal enforcement action	• Develop monitoring procedures and enforcement decision tree for label conditions • Implement Ag QA Scheme review recommendations • Assess enforcement strategies to address globalisation and e-commerce • Work with Customs to improve mechanisms to detect unlawful imports
Improve visibility of enforcement activities	• Stakeholder feedback • Media reporting	• Positive feedback • Positive media reporting of prosecutions	• Publication of compliance outcomes 
Implement new enforcement options flowing from Reform Agenda	• New enforcement options in place	• In place by 30 June 2012 pending legislation	• Implement processes to support a range of new compliance powers such as Penalty Infringement Notices, Enforceable Directions etc  • Investigate processes to support new penalty provisions for manufacturing variations including formulation drift
Improve response to false or misleading information	• Response to false or misleading related cases	• 90% of cases responded to within 3 months	• Implement processes to support new penalty provisions for false or misleading information 
Monitor permits for adherence to conditions	• New penalties in place	• In place by 30 June 2012 pending legislation	• Develop procedures to take regulatory action against permit holders who are non compliant while operating under APVMA permit 
Ensure timely compliance action	• Harmful or non-compliant products are quickly removed from supply • Non-compliant manufacturers and product registrants are brought into compliance or regulatory action is taken	• Harmful or non-compliant products effectively and efficiently removed from the supply chain • All scheduled GMP audits conducted and required evidence of GMP compliance for imported vet products submitted by due date or regulatory action initiated	• Launch Regulatory Strategy Committee
Maintain effective auditing and monitoring systems	• Monitoring system deficiencies identified and addressed	• 100% GMP Audit documentation reviewed • Positive feedback from manufacturers and auditors	• Investigate an IT solution for management of GMP information on overseas manufacturing sites • Examine online access to EUDRA GMP database
Enhance staff skills	• Training on new enhancements to compliance and enforcement provisions undertaken 	• All compliance staff meet AGIS requirements • Training undertaken by 30 June 2012 • GMP Auditors trained	• Undertake Lead Auditor training • Undertake GMP training of new MQL reviewers • Staff trained in new compliance enforcement provisions

STRATEGY 6

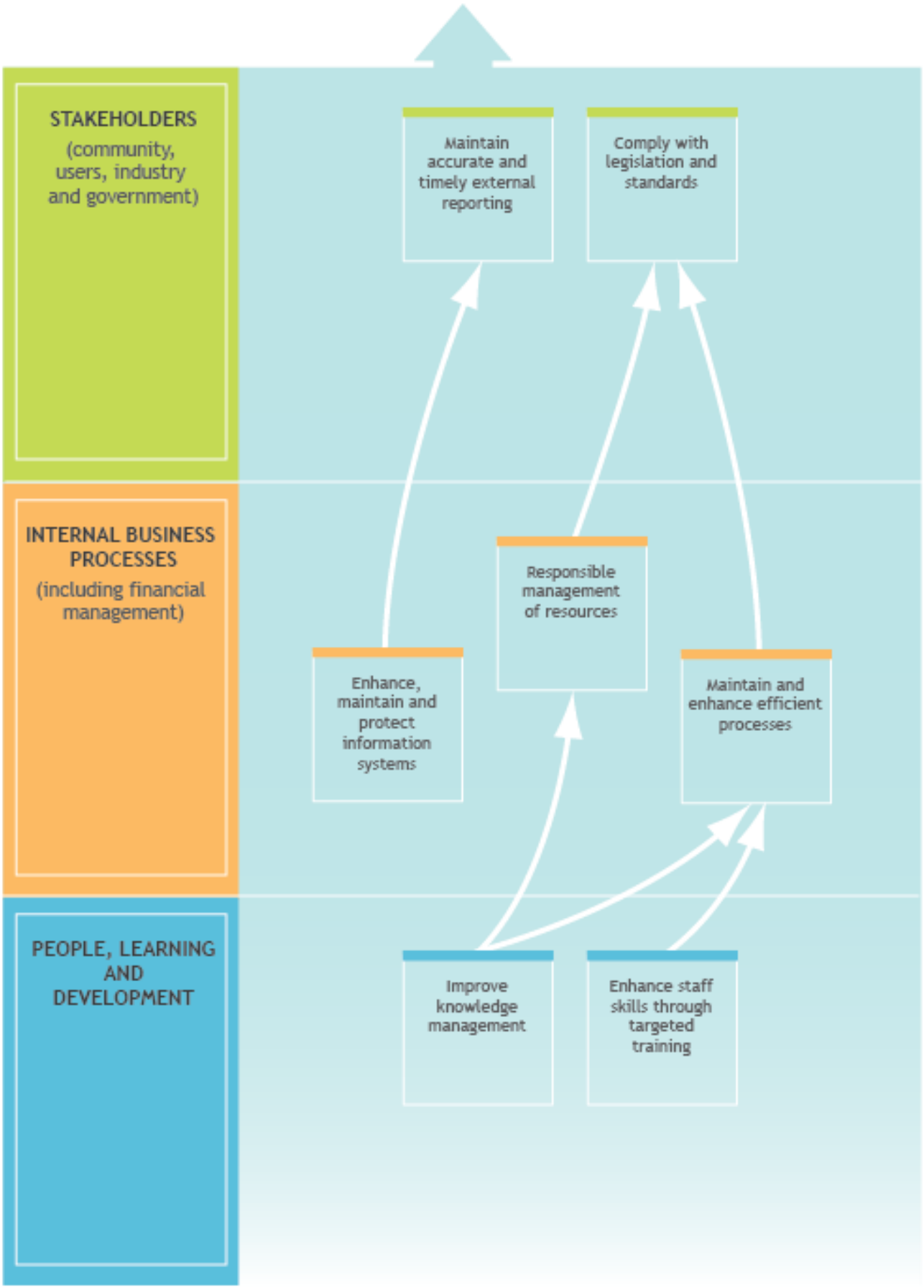
Identify and manage emerging regulatory issues



ACTIVITY	MEASURE	TARGET	INITIATIVES
Inform and respond to government policy and implement reforms 	• Active contribution to high level forums	• APVMA input reflected in outcomes	• Inform Reform Agenda  • Resource a dedicated Reform Agenda Implementation Team  • Participate in the COAG review of chemicals and plastics regulation
Manage emerging issues	• Effective management of issues	• Accurate media reporting of APVMA position • Stakeholder support for issue management initiatives • Web material addresses community questions	
Identify emerging issues of strategic relevance to the APVMA to enhance preparedness	• Regular review and consideration of emerging strategic issues • Strengthen relationships with APVMA international counterparts	• Quarterly reviews undertaken • MOUs in place with international counterparts	
Develop a strategic approach to regulating emerging technologies	• Progress the development of chemistry data requirements for nanoproducts • Develop Terms of Reference and Deeds of Standing Offer	• Finalise Phase 1 of Chemistry Data Requirements	• Develop Nanotechnology Expert Advisory Panel • Co-host a Nanotechnology Symposium with NICNAS
Develop and maintain media management capacity of key staff	• Number of staff with media competencies	• Appropriate staff with media experience	• Media training

STRATEGY 7

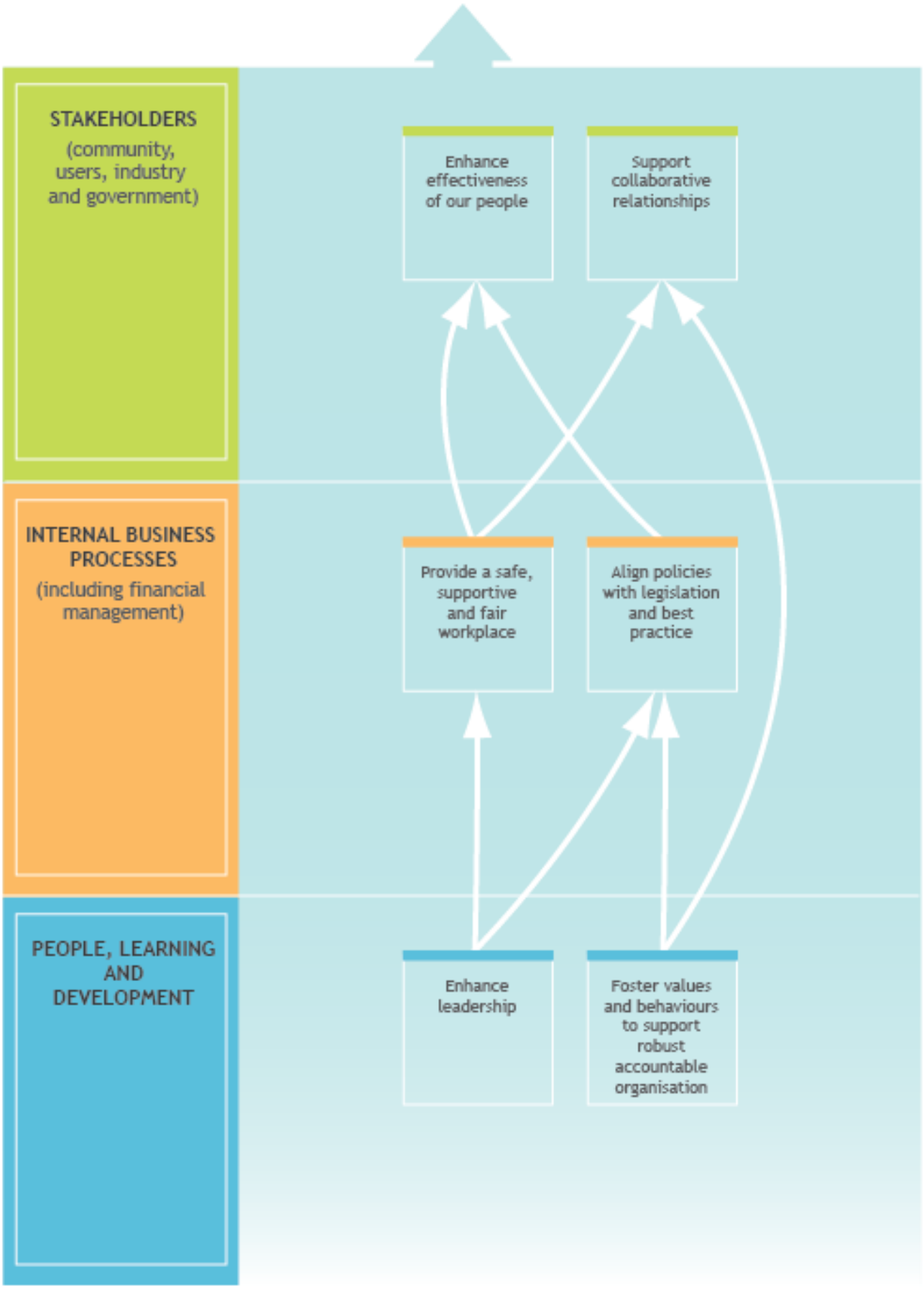
Conduct our business efficiently and effectively



ACTIVITY	MEASURE	TARGET	INITIATIVES
Maintain accurate and timely external reporting	• Annual Financial Statements • Portfolio Budget Statement • Responses to government surveys and questions on notice	• Clearance of audited financial statement by due date • Portfolio Budget Statements submitted by due date • Responses by due date	
Comply with legislation and standards	• Internal and external audit • FOI & IPS compliance • Legislative changes flowing from reform agenda drafted	• No significant audit findings • 100% compliance • Legislation drafted in accordance with project plan 	• Facilitate routine publication of information for the IPS • Undertake a CCI audit • Introduce electronic Certificate of Compliance statements for budget managers
Enhance, maintain and protect information systems	• Up time • Breaches of security • Cyber intrusions • Virus detections	• Maintain up time of 97% or greater • No significant security incidents • Cyber intrusions defeated before damage occurs • Virus attacks defeated before damage occurs	• Implement new IT/IM Strategic Plan • Modify IT systems to support changes flowing from the Reform Agenda  • Progress the implementation of an EDRMS  • Implement EARS internal system • Align IT, Physical, Personnel and Governance security policies to PSPF • Audit cyber intrusion mitigation strategies • Prepare for migration to new gateway provider • Examine Agency Extranet to share application data
Responsible management of resources	• Collection of revenue • Management of budget • Fraud awareness and control	• Collect revenue by due date • Maintain expenditure within 10% of budget (excludes accounting adjustments) • No cases of fraud	• Finalise a new CRIS by 30 June 2012 • Review Levy Collection arrangements  • Develop new Fraud Control Plan 2012-2014
Maintain and enhance efficient processes	• Audit results • PAR resolution timeframes	• No significant audit findings • All PARS resolved within 12 months	• Review non core activities • Review operation of OQS Committee
Improve knowledge management	• New Content Management System • New EDRMS 	• In place by 30 June 2012 • Progressed in accordance with project plan	• Progress the implementation of a EDRMS
Enhance staff skills through targeted training	• Trained staff	• 100% staff complete training	• Training delivered on new processes from Reform Agenda  • Implement on-line Data Protection training module • Develop on-line agvet Chemical Risk Analysis training module • Conduct Fraud Awareness Training

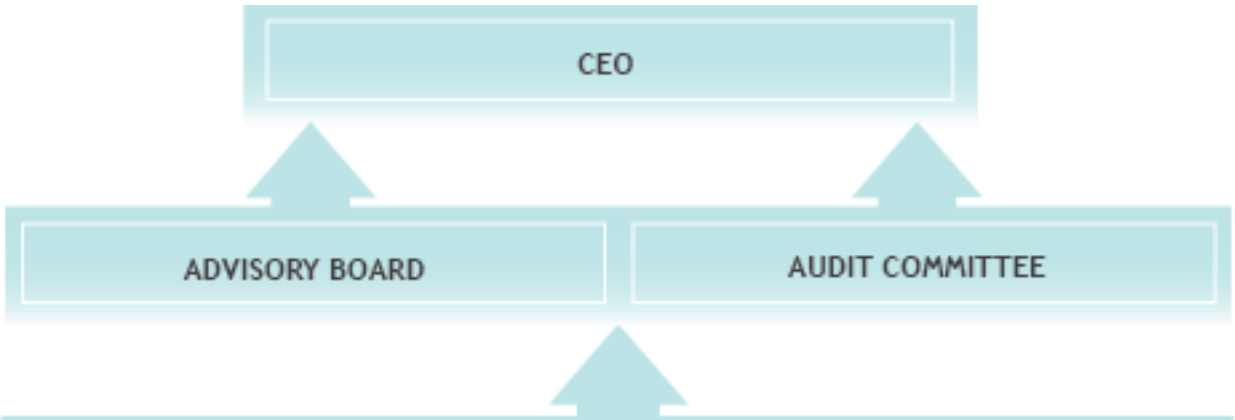
STRATEGY 8

Value our people



ACTIVITY	MEASURE	TARGET	INITIATIVES
Enhance effectiveness of our people	• Performance management outcomes • Stakeholder feedback	• 100% participation in MAAP • Implement mandatory training • Complete 80% of recruitment processes within 45 days • Deliver quarterly stats to EL2s	• Implement a new EA • Review Learning and Development practices
Support collaborative relationships	• Effectiveness of internal committees	• Full membership of all committees • Balanced representation of all programs on committees	• Review Induction processes
Provide a safe, supportive and fair workplace	• Staff feedback • OH&S incidents • Accurate and timely remuneration service	• Positive survey feedback • Nil reportable incidents • Maintain accuracy and timeliness to 100%	• Implement a new EA
Align policies with legislation and best practice	• Annual review of people policies and legislative requirements	• All policies reviewed	• Implement changes flowing from new OH&S legislation
Enhance leadership	• Staff feedback • Performance management	• Positive staff feedback • Staff support for performance management system	• Complete 360 degree feedback for all EL level staff
Foster values and behaviours to support robust accountable organisation	• Grievance rate • Adherence to Code of Conduct	• Low grievance rate • No breaches of the Code of Conduct	

RESPONSIBILITIES OF APVMA PROGRAMS

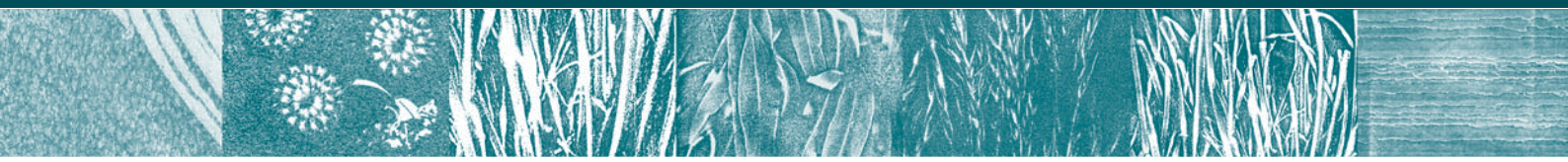


	Veterinary Medicines Program	Pesticides Program	Regulatory Strategy & Compliance Program	Legal Program	Corporate Services Program	Better Regulation Reform
Scientifically evaluate pesticides & veterinary medicines	P	P	S	S	S	S
Keep stakeholders informed	P	P	P	S	S	S
Review existing chemicals	P	P	S	S	S	S
Seek and use feedback	P	P	P	S	S	S
Require and monitor compliance	S	S	P	S	S	S
Identify and manage issues	P	P	P	S	S	S
Conduct our business	S	S	S	S	P	S
Value our people	S	S	S	S	P	S

P — Primary S — Support

GLOSSARY OF TERMS

AERP	Adverse Experience Reporting Program
AGIMO	Australian Government Information Management Office
AGIS	Australian Government Investigation Standard
Agvet	Agricultural and Veterinary
Agvet Code	The schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*
APVMA	Australian Pesticides and Veterinary Medicines Authority
BSC	Balanced Scorecard
CEO	Chief Executive Officer
CCI	Confidential Commercial Information
CMS	Content Management System
COAG	Council of Australian Governments
CRIS	Cost Recovery Impact Statement
EA	Enterprise Agreement
EARS	Electronic Application Registration System
EDRMS	Electronic Document and Records Management System
EL	Executive Level
EM	Executive Management
EUDRA	European Union Drug Regulatory Authorities
FOI	Freedom of Information
GJR	Global Joint Review
GMP	Good Manufacturing Practice
IM	Information Management
IPS	Information Publication Scheme
IT	Information Technology
MAAP	Mutually Agreed Achievement Plan
MORAG	Manual of Requirements and Guidelines
MOU	Memorandum of Understanding
MQL	Manufacturing Quality and Licensing
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
OH&S	Occupational Health and Safety
OQS	Operational Improvement and Quality System Group
PAR	Procedure Amendment Request
PIMC	Primary Industries Ministerial Council
PSPF	Protective Security Policy Framework
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products



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