Australian Government
Department of Health and Ageing

# *BUSINESS PLAN 2013-14*

## Therapeutic Goods Administration (TGA)

*Better health and active ageing for all Australians*

# CONTENTS

# FOREWORD

This 2013-14 business plan was prepared under my direction in accordance with the planning guidelines for the Department of Health and Ageing. All Australian Government policy decisions from May 2013, including material economic or fiscal implications of which I am aware, have been considered in preparing this plan.

Our priorities, as outlined in the business plan, were developed in the context of the Health and Ageing Portfolio Budget Statements, organisational priorities, the delivery of state and territory office services, and the department's corporate plan and related strategies.

I am committed to achieving the objectives of this business plan.

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Prof John Skerritt Date

**National Manager**

# PART 1

# 1 STRATEGIC CONSIDERATIONS

## 1.1 MISSION

As part of the Department of Health and Ageing (DoHA), the TGA safeguards and enhances the health of the Australian community through the effective and timely administration of the *Therapeutic Goods Act 1989.*

This mission is delivered through our contribution to **Outcome 1. Population Health**, specifically in the delivery of Sub-Program 1.4.Regulatory policy - Therapeutic Goods. Through this sub-program, the Australian Government aims to:

- assure that therapeutic goods manufactured or supplied in, or exported from, Australia are of high quality, and are safe and effective to use for their intended purpose; and
- implement further reforms to Australia's regulatory framework.

Our regulatory activities also contribute towards the Department's delivery of:

- **Outcome 2. Access to Pharmaceutical Services** - particularly access to cost effective medicines
- **Outcome 3. Access to Medical Services** - particularly access to medical devices, and to cost-effective medical and allied health services
- **Outcome 14. Biosecurity and Emergency Response** – Preparedness to respond to national health emergencies and risks, including through better surveillance, regulation, prevention and detection

## 1.2 KEY ROLES, OBJECTIVES AND PRIORITIES

### 1.2.1 KEY ROLES:

The role of the TGA is to regulate therapeutic goods through the effective and timely administration of the *Therapeutic Goods Act 1989.* The objects of the Act are to:

(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:
  (i) used in Australia, whether produced in Australia or elsewhere; or
  (ii) exported from Australia;

(b) provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

We undertake this role by applying scientific and clinical expertise to assessments of the evidence of risks compared to the benefits of use of therapeutic goods. We apply this risk-based regulatory process through pre-market assessment before therapeutic goods are marketed and through post-market monitoring and compliance strategies once products are on the market. We assess the suitability of medicines and medical devices for export.

We also regulate manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality.

We work with consumers, health professionals, industry, technical and scientific specialists and our international regulatory counterparts.

Our Business Planning is guided by the TGA Strategic Statement 2012-15 (Attachment A) which outlines an overarching approach to our directions, priorities, performance and risk mitigation.

### 1.2.2 OBJECTIVES:

In maintaining the community's trust in the safety quality and efficacy (performance) of therapeutic goods, we strive to be:

- **Transparent** by clearly communicating our risk management approach to regulation and decision making processes and by supporting our decisions with appropriate evidence
- **Visible** through helping consumers and the community to better understand the role of the TGA
- **Empowering** through assisting consumers and other stakeholders in accessing relevant, meaningful and reliable information
- **Consistent** by fostering an equitable and reliable approach to risk management and decision making
- **Effective** by taking appropriate and timely action to enforce regulatory decisions
- **Efficient** by continually improving quality and productivity in the delivery of all our functions
- **Influential** through having a strong role in informing scientific debate and participating in creation of relevant national and global standards to ensure the safe and effective use of therapeutic goods
- **Responsive** to emerging local and global regulatory issues affecting the Government and the community in Australia

### 1.2.3 PRIORITIES FOR 2013-14:

Our priorities for the next 12 months comprise:

- *Ensuring timely access to therapeutic goods that are safe, effective and of high quality;*
- *Continuing the implementation of the TGA Blueprint Reforms; and*
- *Continuing the work to establish the Australia New Zealand Therapeutic Products Agency (ANZTPA).*

**Ensuring timely access to therapeutic goods that are safe, effective and of high quality**

Critical to application of risk-based processes for Therapeutic Goods assessment is the work of TGA's pre-market and Post-market Divisions, the Market Authorisation Group (MAG) and the Monitoring and Compliance Group (MCG).

The MAG Division is responsible for undertaking evaluations of applications to approve new therapeutic products for supply in Australia. The MAG makes decisions whether to approve or reject market authorisation of medicines, medical devices and blood and tissues that are imported, exported, manufactured and/or supplied in Australia.

The MCG Division is responsible for ongoing monitoring of therapeutic products supplied in Australia to ensure they continue to maintain an appropriate level of quality, safety, efficacy and performance throughout their lifecycle. The way our medicines, medical devices and blood and tissue products are manufactured is also regulated by the TGA. Australian and international manufacturers must operate in a manner that allows products to meet specified standards if they are to be supplied in Australia.

The Regulatory Support Group (RSG) is the TGA Division that provides the regulatory support services that enable us to undertake our regulatory responsibilities. This support includes the delivery of legal, financial, information technology and information management, communications, committee support, parliamentary and human resource management services.

**Continuing the Implementation of the TGA Blueprint Reforms**

We are committed to working collaboratively with our external stakeholders—consumers, health professionals and industry—to ensure the Blueprint reforms are implemented effectively, and that stronger relationships are established for the future.

The Blueprint reforms began in January 2012 and will be implemented over four years, in accordance with the published plan http://www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm.

**Continuing the work to establish ANZTPA**

In 20 June 2011, the Australian and New Zealand Prime Ministers signed a "Statement of Intent" to establish ANZTPA and to progressively implement the joint regulatory scheme for therapeutic products over five years.

Development of regulatory Rules ahead of ANZTPA is only part of the development of a Common Regulatory Framework. A parallel priority is to look at how TGA and Medsafe business and regulatory processes, administration, expertise and datasets can be aligned ahead of the establishment of ANZTPA.

Building on the experience from the five "Business-to-Business" projects started completed in the mid 2013, TGA and Medsafe have identified and agreed on six further activities that will deliver increased regulatory alignment:

1. Pre-market business processes for prescription medicines
2. Pre-market business processes for non-prescription medicines
3. Medicine ingredients
4. Medicines safety
5. Support for a common regulatory framework for medical devices
6. Biological and blood products

The work is being staged to manage workloads and also to accommodate interfaces with linked activities occurring under the Blueprint Reforms program.

## 1.3 SIGNIFICANT CHANGES AND CHALLENGES

The work program planned for 2013-14 is substantial, as it incorporates business as usual, implementation of the Blueprint reforms and progression of the establishment of the ANZTPA. We need to address the challenge of maintaining quality business as usual regulatory services while also delivering on a wide ranging and complex reform program.

TGA is fully cost recovered from fees and charges imposed on Industry. The Government has indicated that the work to establish ANZTPA will be funded through appropriated moneys in the budget. A challenge to fully developing a framework ahead of ANZTPA involves dealing with uncertainty about ANZTPA governance arrangements. Similarly, our ability to actively manage all major risks in the establishment of ANZTPA is impacted by uncertainty about ANZTPA employment arrangements.

The Government has also agreed to new measures in relation to high risk implantable devices. Implementation of these measures is led through the Regulatory Policy and Governance Division with active involvement of TGA. They will implement new public contact arrangements for identified high risk implantable medical devices so as to ensure patients can be contacted if a serious risk to patient safety associated with an implantable medical device is identified. The measures will also develop two clinical quality registers to enhance post-market surveillance for implantable cardiac devices and breast implants so that they have national coverage and enhance the TGA's capacity to monitor the performance of these devices after they have entered the Australian market.

Initial development and implementation of these measures will be cost shared between industry and the Australian Government. Full cost recovery for the patient contact capacity will commence from July 2014. The costs of the clinical registers are to be fully cost recovered from July 2015.

As a regulatory science based organisation, the TGA can face challenges in relation to recruiting specialist staff, including, recruitment for these roles in a competitive market with the medicines and devices industry.

To ensure that we regulate according to risk we also need to ensure that we have the capacity and capabilities to meet emerging challenges in relation to:

- Ensuring our pre market evaluation risk management remains contemporary and continues to reflect international best practice
- Ensuring we have the capacity to appropriately evaluate emerging technologies
- Improving our readiness for a wider roll out of personalised medicine
- Improving our use of post market pharmacovigilance signals
- Improving manufacturing quality through new approaches to audit and inspection processes, and
- Utilising social science and market research to help consumers and healthcare practitioners make informed decisions about therapeutic goods.

### 1.3.1 MANAGEMENT OF CHANGES AND CHALLENGES

Strategies used in implementing and balancing our effort across our priorities during 2013-14, will be to:

1. *Refine our Regulation*
   Maintain an effective regulatory framework that is contemporary and coherent with international best practice and redevelop major guidance documents to provide better information about regulatory processes.
2. *Engage with our Stakeholders and Manage Key Relationships*
   Develop and enhance partnerships, with consumers and healthcare professionals. Maintain appropriate relationships with industry and enhance international regulatory cooperation through better exchange of information, work sharing and regulatory capacity building. Promote and enhance collaborative and cooperative relationships with the rest of the Department and proactive monitoring and management of emerging issues. Ensure communication is strong with the Parliamentary Secretary and Minister.
3. *Enhance our Business Capability*
   Implement cohesive policies, management and processes that utilise the highest quality scientific methods, governance and management skills, and enhance integration across our organisational groups. Manage major strategic, financial and operational risks. Initiate a major technology investment and change program to improve our capability. Support electronic health reform outcomes.
4. *Deliver through our People*
   Maintain a capable workforce that adapts flexibly to changes introduced through the Blueprint reforms, the development of ANZTPA and other priorities of Government. Maintain effective levels of performance and provide for continuous learning to improve our capability. Implement human resource management policies, procedures and systems that promote the *APS Code of Conduct,* and support the reform agenda of the Australian Public Service and TGA's People Strategy 2012 – 2015.

In addition to these strategies, we are also responding to the 2013 Staff Survey results through the implementation of an action plan that includes a range of organisational wide initiatives that focus on major survey outcomes:

- Strengthening leadership, visibility and engagement at all management levels
- Improving our approaches to change management and internal communication
- Providing valuable and valued opportunities for learning and development, and
- Career development opportunities, in particular for Executive Level (EL 1-2) staff.

The Staff Consultative Forum and the TGA Executive will oversee the progress of our response to the 2013 Staff Survey, with the EL2-Medical Officer forum being a valuable reference group.

# 2 OPERATING ENVIRONMENT

## 2.1 PORTFOLIO BUDGET STATEMENTS 2013-14 DELIVERABLES AND PERFORMANCE INDICATORS

| Deliverables | Performance Indicators |
|---|---|
| **Ensure that therapeutic goods are safe, effective and of high quality** | Percentage of evaluations and appeals regarding the entry of therapeutic goods onto the Australian Register of Therapeutic Goods made within legislated timeframes. - (Target 100%).<br>Percentage of licensing and surveillance inspections completed within target timeframes.<br>- (Target Domestic 100%, Overseas 90%).<br>Percentage of prescription medicine evaluations completed within target timeframes. (Target 100%) |
| **Implement the TGA Reform Blueprint** | Implement reforms that enhance TGA's current regulatory processes<br>- (Target: Reforms implemented in accordance with the published plan http://www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm).<br>Number of blueprint recommendations implemented.<br>- (Target: 12 for 2013-14).<br>DoHA will support industry to implement reforms that strengthen self-regulation of the promotion of therapeutic goods.<br>- (Target: Shared information and complaints systems established by June 2014). |
| **Establish the Australia New Zealand Therapeutic Products Agency** | Further progress a program of work sharing and joint operations<br>Commence public consultation on draft Health Rules by February 2014. |

## 2.2 OTHER PERFORMANCE INDICATORS

During 2013-14, in conjunction with key stakeholders, we will finalise and publish agreed Key Performance Indicators to provide quantitative and qualitative information on our organisational effectiveness and operational efficiency. The proposed key performance indicators were presented to the Australian Therapeutic Goods Advisory Council (ATGAC) and TGA-Industry Consultative Council (TICC) in June2013 for their consideration and advice. It is anticipated that these measures of performance will include the monitoring and reporting of:

- High stakeholder satisfaction and participation with our consultative processes
- Business operations are consistent and meet agreed service/timeliness standards
- Non-compliance and safety issues identified by TGA at an early stage and appropriate, effective responses implemented
- Improved community and industry understanding of TGA's regulatory role
- Financial performance aligns with financial targets
- Compliance with statutory reporting obligations and government accountability frameworks
- International cooperation demonstrated to enhance regulatory harmonisation, and
- Regulatory decisions made by TGA are consistent with the Act and Regulations, and risks are managed well in decision making.

## 2.3 Workforce Planning

The development of a workforce planning framework and plan was completed in early 2013. It will help us in:

- categorising the different roles undertaken by our workforce
- forecasting supply and demand
- identifying areas of key risk to workforce capacity through utilising a range of people metrics, and
- developing strategies with priorities for human resource capacity and capability planning.

The TGA Workforce Plan 2013-15, adopts a risk based approach to analysing our current and future workforce develop and maintain a capable workforce that is able to meet current and future objectives.

The key strategies from the plan are to:

- Integrate workforce planning into the annual business planning process
- Actively manage our workforce profile
- Focus capability development activities in alignment with our job family profile
- Mature the workforce planning processes
- Actively manage risks to maintaining a capable workforce and the risks of staff losses in the establishment of ANZTPA
- Reduce reliance on ICT contractors, and
- Actively manage critical job roles to maintain a critical talent pool.

## 2.4 Outputs to deliver

### 1. The regulation of therapeutic goods for safety, effectiveness and quality

| *Strategies Underpinning this priority* |
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| Use a benefit to risk management approach to carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard, and manufactured in accordance with acceptable standards. |
| Ensure that the Australian community has access, within a reasonable time, to therapeutic advances. |
| Maintain an effective regulatory framework that is contemporary and coherent with international best practice. |
| Enhance international regulatory cooperation through better exchange of information, work sharing and regulatory capacity building in our region. |
| Implement cohesive policies, management and processes that utilise the highest quality scientific methods, governance and management skills, and integrate seamlessly across our organisational groups. |
| Maintain a robust risk management approach to all strategic and key operational risks. |
| Maintain and build a sustainable and capable workforce and invest in emerging technology to improve our capability. |
| Maintain adequate expertise on the TGA's statutory advisory committees to ensure the committees continue to effectively assist the TGA's regulatory decision making process |
| Redevelop key guidance documents and provide better information about regulatory decisions and processes. |

| *Lead TGA Group (Division)* | *Major activity or project underpinning this priority* | |
|---|---|---|
| | **Activity** | **Outputs** |
| **MAG** | **Undertake market authorisation for medicines, medical devices, biological and blood and tissue products, together with the exports regulatory function.** | **Complementary Medicines**<br>· Rationalise and expand the number of coded indications available to sponsors of listed medicines<br>· Subject to Government approval of legislative changes, eliminate the use of free text in the ELF (electronic medicines listing) system<br>· Implement risk profiles to inform the compliance program<br>· Implement of a workflow system to support regular reporting on progress of investigations and trends in non-compliance<br>· Update guidelines for levels and kinds of evidence in light of consultations and subject to Government approvals to legislative changes underpin guidelines in regulation<br>· Consider any needed regulatory outcomes/reforms following the CMO's review of homeopathic and other therapies.<br>· Develop policy, consult and implement changes in relation to proprietary ingredients for listed medicines. |

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| | | **Over-The-Counter Medicines (OTC)**<br>· Finalise the development of the reformed OTC pre market evaluation business process and implement systems to support the new process.<br>· Consider relevant issues arising from the Government's response to the Review of Medicines Scheduling<br>**Prescription Medicines**<br>· Continue to streamline the process for the registration of prescription medicines by finalising the implementation of systems to support the streamlined submission process and variation to registered medicines<br>· Update Regulatory Guidelines after taking stakeholder feedback into account<br>· Consider antimicrobial resistance strategies in registration of antimicrobials. Inclusion of risk management strategies and related communication activities<br>· Consider relevant issues arising from the Government's response to the Review of Medicines Scheduling.<br>**Medical Devices**<br>· Finalise the implementation of the transition for reclassification of joint replacement implants<br>· Subject to approval by Government amend the way in which a kind of medical device is included in the register<br>· Provide advice to Government and if approved implement publication of device product information on the TGA website<br>· Finalise the transition to the IVD Framework and develop and implement new requirements for class 4 in house IVDs for donor screening and biological in-house IVDs<br>**Other**<br>· Explore opportunities from eHealth initiatives, including the feasibility for introducing Australian Medicines Terminology in pre market systems<br>· Continue to deliver evaluation capability in the areas of toxicology, pharmaceutical chemistry and biological science<br>· Progress the implementation of the Biologicals transition strategy |
| | **Reducing Regulatory Burden** | · Progress the implementation of digital registered medicines submissions and submission/application monitoring systems<br>· Identify and investigate potential regulatory changes to more closely align assessment with risk in the areas of OTC medicines and Medical Devices<br>· Implement coded indications and provide clearer regulatory guidance in relation to evidence guidelines for complementary medicines<br>· Increased our use of reports from international regulators to support Australian regulatory decisions |
| | **Regulatory Science** | **Modernisation of pre-market evaluation**<br>· More clearly embed benefit-risk methodology and assessments in medicine and device assessments<br>· Explore better use of clinical trial data for assessment of medical devices<br>· Ensure that we have the capacity to appropriately evaluate innovative emerging technologies, focussing on:<br>- rapidly evolving areas of medical therapy (e.g. oncology)<br>- emerging technologies such as nanotechnology, and<br>- device development that is heavily dependent on software and regulation of medical apps as devices.<br>**Improve our readiness for a wider roll out of personalised medicine**<br>· Ensure we have a good understanding of the genetics and diagnostics behind the technologies to enable their appropriate evaluation. |
| | **Medicines Labelling and Packaging** | · After consultation, implement regulatory changes to improve patient safety outcomes for labelling and packaging of medicines. |
| | **Medicine Shortages** | · Develop and implement information sharing approaches for better managing shortages of medicines through agreeing roles between industry and government, providing industry guidance and establishing a website for reporting and tracking shortages. |
| | **Medicines Compounding** | · Following consultation, develop RIS and implement preferred options for reform. |
| **MCG** | **Undertake post-market monitoring and regulatory activities medicines, medical devices and blood and tissue products, together with the recalls and advertising regulatory functions.** | · Provide access to adverse drug reaction and device incidents data, therapeutic goods early warnings and alerts, and more detailed information regarding therapeutic goods recalls<br>· Undertake inspections and assessments of manufacturers, nationally and internationally<br>· Explore the concept of manufacturer based rather than individual sponsor based inspections of manufacturing facilities<br>· Reduce the number of inspections carried out in countries where other major regulators |

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| | | have also been inspecting the same manufacturing facilities<br>· Undertake monitoring and compliance laboratory testing, investigation and reviews<br>· Explore opportunities for electronic health reform including the feasibility for linkages to the PCEHR (personally controlled electronic health record) in relation to enhancing adverse event and incident reporting<br>· Increase our use of post-market signals received from international regulators to trigger appropriate early warnings for the Australian public. |
| | **Reducing Regulatory Burden** | · Introduce advertising reforms that streamlines and clarifies advertising requirements and provides for penalties that are proportionate to the nature of the offence committed. |
| | **Regulatory Science** | · Better use of post-market / pharmacovigilance signals<br>· Integrate feedback loops from recent initiatives such as enhanced reporting<br>· TGA having input into to the identification of international drug and device safety research topics<br>· Input to whole of government efforts for assessing vaccine safety. |
| | **Device Registries** | · Together with RPGD and other stakeholders, undertake developmental work leading to the introduction of patient contact registers for high risk implantable devices and clinical quality registers for implantable cardiac devices and breast implants to systematically track the performance of these devices and improve clinical practice in their use<br>· Undertake consultation and develop a Cost Recovery Impact Statement (CRIS)<br>· If required, draft legislative amendments required to support levies for the ongoing administration of each registry. |
| | **Advertising Reform Project** | · Subject to government approval, continue to develop a more effective advertising complaint handling process and operating procedure for investigating advertising. |
| **RSG** | **Provides support services that enable the TGA to more effectively undertake its regulatory responsibilities** | **Program and Change Management**<br>· Continue to implement governance and program management processes required to deliver the TGA project activity and organisational change management program<br>**TGA Advisory Committees**<br>· Undertake recruitment processes to seek specific clinical or other expertise to fill all 2013/14 statutory advisory committee vacancies<br>· Better target the use of the committee and committee advice to assist TGA decision making<br>· Implementing more comprehensive and timely public reporting of committee outcomes<br>**Human Resources**<br>· Finalise and implement the strategic workforce plan for the TGA, in consultation with People, Capability and Communication Division (PCCD)<br>· Implement the TGA People Strategy 2012 – 2015:<br>- Complete TGA Job profiling and work with offices to define critical job roles and succession capability and ensure capability development aligns with identified job families and job roles<br>- Finalise work health and safety, recruitment and retention and organisational health strategies<br>- Implement 2013-14 training plan and develop recruitment plans for key areas.<br>**Information management**<br>· Development and commence progressive implementation of an integrated information environment and systems that facilitate:<br>- Business performance management and optimisation<br>- Enterprise reporting and business intelligence<br>- Collaboration and co-operation across business areas<br>- Risk management and compliance<br>- Governance<br>- Integrated business processes and methods, and<br>- Modernisation of the Electronic Business services (eBS) System.<br>**Parliamentary Support**<br>· Ensure timeliness in the development of Question Time Briefs, responses to parliamentary questions on notice, FOI requests and Ministerial/ Parliamentary Secretary correspondence.<br>**International Support**<br>· Participation in international harmonisation initiatives that can ensure that the international regulatory framework meets acceptable Australian standards of safety, quality and efficacy<br>· Implement TGA's International Strategy and 2013-2014 work plan<br>· Complete the review of TGA collaborative arrangements. |

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| | | **Regulatory Compliance**<br>· Focus compliance efforts to areas of greatest risk<br>· Continue to develop appropriate responses to target falsified medicines and illegal internet sales of therapeutic goods<br>· Continue co-operation with the Australian Customs Service in the development of targeted approaches to prevent the importation and or export of illegal therapeutic goods.<br>**Finance**<br>· Review of activity based costing and activities that do not generate revenue to cover the cost of the service provided such as orphan drugs and low value turnover (LVT) exemptions and develop policy options for government consideration addressing revenue implications. |
| | **Reducing Regulatory Burden** | · Ensure that simpler and more targeted information available and readily accessible on our website to save phone calls, email and other enquiries<br>· Explore new opportunities for expanding International engagement that leads to international regulatory harmonisation and work sharing projects. |
| | **Regulatory Science** | **Utilise market research to help consumers and healthcare professionals make more informed decisions about therapeutic goods**<br>· Underpin research to drive prioritisation and development of TGA communication and education activities and content.<br>**Strengthen domestic and international collaboration**<br>· Strengthen the collaborations with Australian universities who are funded through Government (e.g. by NH&MRC, Australian Research Council), to undertake regulatory science research<br>· Work to better mobilise external expertise and regulatory science initiatives led by other regulators (who have the mandate and financial resources to drive these initiatives). |

## 2. Implementation of TGA Blueprint Reform

| ***Strategies Underpinning this priority*** |
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| Develop and enhance key partnerships with consumers, healthcare professionals and other regulatory agencies. |
| Develop and enhance engagement with consumers, healthcare professionals. |
| Maintain appropriate relationships with industry. |
| Maintain an effective regulatory framework that is contemporary and coherent with international best practice |
| Maintain a robust risk management approach to all strategic and key operational risks. |
| Maintain a sustainable and capable workforce. |
| Enhance international regulatory cooperation through better exchange of information, work sharing and regulatory capacity building in our region. |
| Invest in appropriate technology to improve our capability. |
| Redevelop key guidance documents and provide better information about regulatory decisions and processes. |

| ***Lead TGA Group (Division)*** | ***Blueprint activities to be delivered in 2013-14*** | |
|---|---|---|
| | **Activity** | **Outputs** |
| **MAG** | **Complementary Medicines Business Process Review** | |
| | Improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods (ARTG) | · Work finalised on development of coded indications project so as to limit the use of inappropriate claims and indications on the ARTG<br>· RIS and legislative amendments drafted for introduction into Parliament |
| | Analyse and develop risk profiles of products and sponsors to better inform the selection of products for post-market reviews | · IT system changes to workflow management implemented to enable data collection and key automated reporting requirements |
| | **Medicines Labelling and Packaging** | |
| | Implement revised medicines labelling and packaging requirements to assist consumers and health practitioners to make informed decisions about the quality use of medicines and to improve safety outcomes | · Revised TGO subjected to industry and broader public consultation to help inform the Regulatory Impact Statement and obtain policy approval. Final TGO registered as a legislative instrument |

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| | **Regulatory Framework and Guidelines** | |
| | Provide user-friendly information on the risk based framework under which we operate, including detailed explanations of how this framework operates for different classes of therapeutic goods | · Development and implementation of a communication and educational plan to communicate our risk based framework more broadly |
| | Explore mechanisms for providing explanations on TGA's regulatory processes, and adopt publication principles on the outcomes of application assessments | · Usability testing of new webpage format for the updated guidelines and format and content refined in response to feedback, prior to publishing the final guidelines |
| | **On-line Applications** | |
| | Report on the feasibility of developing an on-line system for the submission and tracking of all applications for assessment, to enable the sponsor to ascertain the progress of an application | · Complete the evaluation of eCTD systems and selection of appropriate system<br>· After initial improvements to OTC medicines tracking extension to other therapeutic products |
| **MCG** | **Recalls** | |
| | Promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers | · Complete a review and update of Uniform Recall Procedures, consultation with stakeholders and development of a draft revised instrument<br>· Implement the early warnings system and notification system for medical and medical device recalls |
| | **Enhancing Post Market Compliance** | |
| | Explore mechanisms to maintain the currency of Consumer Medicines Information (CMI) and approved Product Information (PI) | · Complete public consultation on options to maintain currency of PI and CMI to inform the development of these proposals<br>· Policy approval on proposals requiring regulatory change will be provided and approved changes will be implemented |
| | **Advertising** | |
| | Improve access and quality of information on the processes for regulation of advertising of therapeutic goods, including the complaint process and the outcomes of complaints<br><br>Enhance sanctions and penalties for repeated breaches of non-compliance (as well as strengthening sanctions and penalties for advertising)<br><br>Apply, enforce and publicise sanctions and penalties, including for advertising breaches and recalling products from the market | · Feedback assessed on consultation RIS and policy approval obtained for proposals for the future regulatory framework for the advertising of therapeutic products<br>· Regulatory changes drafted and submitted for policy approval for implementation |
| **RSG** | **Strategic Engagement and Information Accessibility** | |
| | Work transparently with other key providers of information to enhance the information available to the public (consistent with the principles of the quality use of medicines<br><br>Ensure the TGA website, is current, accurate, relevant, timely and up to date, and meets the needs of its audiences | · Feedback from Australian Therapeutic Goods Advisory Council (ATGAC) deliberations used to shape TGA's stakeholder and communication activities<br>· Following the development of a partnership strategy, partnering with organisations and participate in existing conferences and events. Schedule of events developed and published<br>· Outcomes of stakeholder research used to develop educational materials targeted to consumers, health professionals and industry<br>· Invite key external organisations to link to information on the TGA website and vice-versa<br>· Functionality of the TGA website improved by introducing a new way of presenting, searching and managing content<br>· Continue to manage enquiries to the TGA through the Public Contact Team |
| | Develop and publish agreed Key Performance Indicators to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency | · Develop processes for systematic reporting of agreed KPIs and reporting commenced |
| | Develop and publish a policy on the disclosure of commercially confidential information | · Seek feedback from stakeholders prior to finalising implementation |

## 3. Continuing the work to establish ANZTPA

- Finalisation of the implementation of the Business to Business projects
- Development of the Common Regulatory Framework, including development of the health regulatory Rules and Orders and conduct of Regulatory harmonisation activities between TGA and Medsafe
- Development of a Single Entry Point e-Business web portal for ANZTPA, to streamline processing by progressively covering all business engagement applications for industry
- Liaison with Medsafe and the Australian (and as appropriate New Zealand) industry on regulatory issues
- Participation in Australia/New Zealand Policy Working Groups covering Governance, Information Law and Intellectual Property, Regulatory Sanctions, Enforcement and Penalties, Administrative Law, Transitional Arrangements and Carve out of Natural Health Products.

| ***Strategies Underpinning this priority*** | |
|---|---|
| Develop a responsive and cost-effective scheme for regulating therapeutic products that is consistent with international best practice. Such a scheme aims to :<br>· Apply a level of regulation that is commensurate with the potential risks to public health and safety posed by therapeutic products<br>· Balance the risks and the potential benefits to be obtained by users from the availability of these products in Australia and New Zealand<br>· Ensure consumers and health professionals have sufficient, accurate information to enable them to select and use therapeutic products safely and effectively<br>· Assist New Zealand and Australian states and territories to adopt a uniform approach to controlling consumer access to therapeutic products<br>· As far as possible, harmonise requirements with overseas regulators of equivalent standard. | |
| Maintaining a sustainable and capable workforce. | |
| Enhancing international regulatory cooperation through better exchange of information, work sharing and regulatory capacity building in our region. | |
| ***Major activity or projects underpinning these responsibilities*** | |
| **Activity** | **Outputs** |
| **Harmonisation of regulatory business towards a Common Regulatory Framework** | Completion of implementation of the Business to Business projects.<br><br>Undertake other regulatory harmonisation projects, as follows.<br>· OTC medicines:<br>- implementation of integrated business processes, common sets of guidelines, workflow management systems, advisory label statements<br>- undertake confidence building activities between evaluation teams.<br>· Prescription medicines:<br>- alignment of pre-market evaluation processes between Australia and NZ<br>- Alignment of orphan drugs assessment policy and administrative practice<br>- Harmonise the format requirements for Medicines PI and CMIs.<br>· Medicine ingredients:<br>- Harmonise scope and names for Proprietary ingredients<br>- Harmonise terminology for ingredient names<br>- Develop common list of colouring substances allowed for use in medicines.<br>· Medicine safety:<br>- Harmonise required label warning statements for medicines<br>- Harmonise paediatric dosages for paracetamol and ibuprofen<br>Develop a harmonised recalls code. |
| | · Medical devices regulation:<br>- Scope and identify overlap between the Class III and AIMD devices on the NZ database (WAND) and the ARTG<br>- Review manufacturers' evidence requirements<br>- Identify issues and concerns with transferring WAND entries to DEAL and issuing single market licences. |

| | |
|---|---|
| | · Biologicals and fresh blood components regulation:<br>- Harmonise GMP Codes for Blood and Blood Products/Components<br>- Harmonise Site Master File requirements<br>- Assess the results of the NZ cell and tissues therapies review.<br>· Liaison with Medsafe and the Australian (and as appropriate New Zealand) industry on regulatory issues. |
| **Health Rules Development** | · Development and drafting of "health" Rules in relation to<br>- Medicines, Medical Devices and Biologicals (initially)<br>- Fees and Charges, Administration, Advertising, Scheduling, Transitional Arrangements, Interpretation (subsequently, with some work continuing into 2014/15). |
| **Facilitate the progression to a joint agency** | · Participation in Australia/New Zealand Policy Working Groups covering Governance, Information Law and Intellectual Property, Regulatory Sanctions, Enforcement. |
| **A Single Entry Point<br>- e-Business web portal for ANZTPA** | · Progress the development of a Single Entry point for business, to streamline processing by progressively covering all business engagement applications for industry. |

## 2.5 Information and Communication Technology (ICT)

TGA is undertaking a comprehensive program to develop and progressively implement an integrated information environment and business systems upgrade to support our regulatory and business operations. This upgraded environment will facilitate:

- Business performance management and optimisation
- Enterprise reporting and business intelligence
- Collaboration and co-operation across business areas
- Risk management and compliance
- Strategy and governance
- Integrated business processes and methods, and
- Modernisation of the Electronic Business Services (eBS) System.

Some of the business drivers for the environment come from the transition to ANZTPA and the changes introduced through the Blueprint Reforms Program. In particular by the end of 2013-14 the following projects will be delivered:

- Migration from Lotus Notes to Microsoft Outlook
- Integrated information management strategy
- Single Entry Point e-Business web portal
- International Regulators Information Sharing Portal
- Systematic reporting of agreed KPIs
- Post Market Reforms- Adverse Events and Early Warning systems, Medicines and Devices Recalls projects
- Over-the Counter Reforms – Implementation of the Business Process Review
- Complementary Medicines Reforms- coded indications project and IT system changes to workflow management implemented to enable data collection and key automated reporting requirements
- Support for the Biologicals Regulatory Framework
- Completion of the evaluation of eCTD systems, and
- eLodgement of variations to registered prescribed medicines.

## 2.6 Alliances and shared responsibilities

### 2.6.1 Role of State Offices

Most TGA employees (95%) are based in the ACT. There are currently 18 staff located in Sydney, 23 in Melbourne, 6 staff in Brisbane, and 2 staff in Adelaide. Our Melbourne office staff will be relocating to the DoHA Victorian State Office in August 2013. Staff located outside ACT primarily focus on medicines and devices authorisation (clinical roles and some non- clinical roles) and GMP inspection and support roles.

### 2.6.2 Cooperative work with other Australian Government agencies

The TGA collaborates closely with several of the regulators within the Health and Ageing Portfolio and Agriculture, Fisheries and Forestry Portfolio on common issues. This includes:

- Food Standards Australia and New Zealand (FSANZ), on regulatory issues at the food-medicines interface
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) on radiopharmaceuticals and diagnostic technologies
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS) on chemicals and cosmetics
- Office of Gene Technology Regulator (OGTR) on gene technology in therapeutic goods
- The Department of Agriculture, Fisheries and Forestry (DAFF) on bio-security issues, and
- Australian Pesticides and Veterinary Medicines Authority (APVMA) on veterinary medicines.

A Regulators' forum of the heads of these agencies, including the TGA National Manager meets regularly, and facilitates collaboration on harmonised training and exchange of best practice approaches for regulation in relevant food, agriculture and health areas.

In addition the TGA works closely with the following other government departments and agencies:

- APVMA in relation to chemical and veterinary medicines scheduling issues;
- Departments of Prime Minister and Cabinet, Finance and Deregulation, Treasury and Attorney General's Department on the formation of the ANZTPA;
- Ombudsman's office in relation to provision of information and determination of complaints;
- Australian Customs Service in relation to importation and export of therapeutic goods; and
- Australian Competition and Consumer Commission in relation to fair trading and consumer issues relating to promotion and use of therapeutic goods and health services.

### 2.6.3 Aboriginal and Torres Strait Islander activities

The Department is committed to having a diverse workforce. Targets have been set for all APS agencies to have 2.7% indigenous workforce by 2015.

## 2.7 Funding Allocations

The TGA's input into the DoHA Portfolio Budget Statements (PBS) is in Outcome 1 (Population Health) Program 1.4 Regulatory Policy. Our finances are managed through the Therapeutic Goods Special Account (under Section 21 of the *Financial Management and Accountability Act 1997*).

### 2.7.1 2013-14 Portfolio Budget Statements

The PBS includes expenses (including capital) totalling $148.428 million for the TGA for 2013-14.
The appropriations include funding of the new budget measure on High Risk Implantable devices of $3.577m (to be distributed between RPGD and TGA) and interest equivalency. ANZTPA departmental and administered funding is held separately.

| | 2012-13 Estimated actual $'000 | 2013-14 Estimated expenses $'000 |
|---|---|---|
| **TGA Special Account** | **131,310** | **148,428** |
| **Budgeted increase in expenditure (including capital) comprises:** | | |
| **Estimated Actual 2012-13** | | **131,310** |
| Employee expenses increase (2.5% per DoHA Enterprise Agreement) | | 2,175 |
| Business improvement and general increase (e.g. rent) | | 2,976 |
| New Policy Proposal (NPP) – High Risk Implantable Device Registers | | 3,577 |
| Business Systems Upgrade (reallocation of funding from TGA reserves) | | 8,390 |
| **Budgeted expenses 2013-14 (including capital)** | | **148,428** |

## 2.8 CAPITAL EXPENDITURE

### 2.8.1 APPROVED CAPITAL EXPENDITURE FOR 2013-14

| | | 2013-14 Proposals | 2014-15 Out year 1 | 2015-16 Out year 2 | 2016-17 Out year 3 |
|---|---|---|---|---|---|
| | | ($) | ($) | ($) | ($) |
| **Outcome 1.4 Regulatory Policy: - Therapeutic Goods** | | | | | |
| **Approved Internally Funded Projects)** | | **5,052,500** | **6,507,900** | **5,355,900** | **6,939,000** |
| **TOTAL APPROVED CAPITAL PROJECTS** | | **$** | **$** | **$** | **$** |

Note: Excludes the Business Systems Upgrade project as a business case has not yet been endorsed.

## 2.9 FUTURE ENVIRONMENT

### 2.9.1 ANTICIPATED REVENUE MOVEMENTS

| | 2013-14 | 2014-15 | 2015-16 |
|---|---|---|---|
| **Anticipated revenue ($'000)** | 133,601 | 134,916 | 139,233 |

# 3 RISK ENVIRONMENT

## 3.1 RISK

TGA has identified these risks as it highest rated:

1. **Insufficient capacity to absorb changes across the organisation and maintain business operations**.
   This risk is mitigated by the following strategies:
   - Closely monitor progress TGA Blueprint for reforms
   - Implementation of Change Management Project
   - Workforce plan in place
   - Redevelopment of IT infrastructure and information management systems
   - Communications and education framework and strategies for management of stakeholder expectations.

2. **Failure to meet major Stakeholders' expectations.**
   This risk is mitigated by the following strategies:
   - Implementation of contact strategy
   - Framework for customer, health professional and industry stakeholder engagement
   - Standard procedures in place to address responses for enquiries and customer service and provision of timely and accurate advice to stakeholders, in accordance with Customer Services Charter
   - Clearer articulation of Regulatory guidelines
   - Development of sponsor access to eBusiness
   - Monitoring of international best practice
   - Risk based review and implementation of Audit schedule
   - Risk based review and implementation of Laboratory testing program.

3. **Misalignment between law, processes and guidance documents.**
   This risk is mitigated by the following strategies:
   - Regular review of processes to ensure alignment with legislation and proper administrative good practice
   - Regular review and update of Regulatory guidelines
   - Review of regulatory guidance documents and SOPs
   - Adequate allocation of resources for decision making
   - Training for decision makers
   - Finalise legal e-learning modules
   - Information on the TGA Website updated and reviewed regularly
   - Use of Business Process Management to align process with legislation.

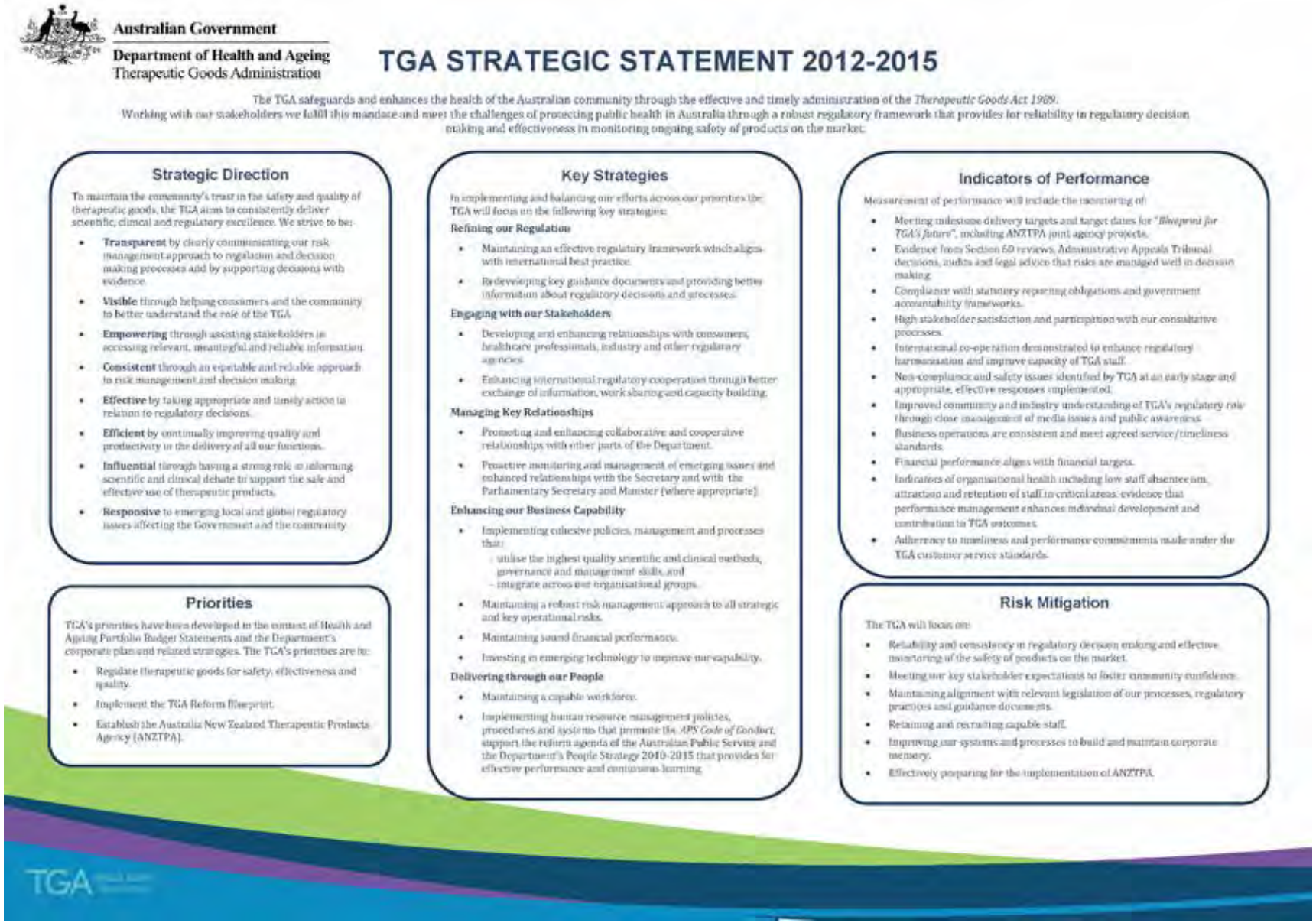
4. **Inability to retain and recruit capable staff.**
   This risk is mitigated by the following strategies:
   - Review of learning and development
   - Regular review of the recruitment model in meeting the TGA's business
   - Proactive approaches to making the TGA a good place to work
   - Adoption of an appropriate change management framework.

5. **Lack of appropriate preparation for ANZTPA.**
   This risk is mitigated by the following strategies:
   - Adequate implementation of agreed projects for which TGA is responsible
   - Contribute to development of options about governance and employment structure
   - Adequate staff consultation and effective communication
   - Adoption of an appropriate change management framework
   - Ensure appropriate expertise is available to the implementation team.

Detailed risk management strategies and treatments can be found in Attachment C - Risk Plan in Part2 of this business plan.

# PART 2

# ATTACHMENT A: TGA STRATEGIC STATEMENT 2012-15



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

## TGA STRATEGIC STATEMENT 2012-2015

The TGA safeguards and enhances the health of the Australian community through the effective and timely administration of the *Therapeutic Goods Act 1989*.
Working with our stakeholders we fulfil this mandate and meet the challenges of protecting public health in Australia through a robust regulatory framework that provides for reliability in regulatory decision making and effectiveness in monitoring ongoing safety of products on the market.

### Strategic Direction

To maintain the community's trust in the safety and quality of therapeutic goods, the TGA aims to consistently deliver scientific, clinical and regulatory excellence. We strive to be:

- **Transparent** by clearly communicating our risk management approach to regulation and decision making processes and by supporting decisions with evidence.
- **Visible** through helping consumers and the community to better understand the role of the TGA.
- **Empowering** through assisting stakeholders in accessing relevant, meaningful and reliable information.
- **Consistent** through an equitable and reliable approach to risk management and decision making.
- **Effective** by taking appropriate and timely action in relation to regulatory decisions.
- **Efficient** by continually improving quality and productivity in the delivery of all our functions.
- **Influential** through having a strong role in informing scientific and clinical debate to support the safe and effective use of therapeutic products.
- **Responsive** to emerging local and global regulatory issues affecting the Government and the community.

### Priorities

TGA's priorities have been developed in the context of Health and Ageing Portfolio Budget Statements and the Department's corporate plan and related strategies. The TGA's priorities are to:

- Regulate therapeutic goods for safety, effectiveness and quality.
- Implement the TGA Reform Blueprint.
- Establish the Australia New Zealand Therapeutic Products Agency (ANZTPA).

### Key Strategies

In implementing and balancing our efforts across our priorities the TGA will focus on the following key strategies:

**Refining our Regulation**

- Maintaining an effective regulatory framework which aligns with international best practice.
- Redeveloping key guidance documents and providing better information about regulatory decisions and processes.

**Engaging with our Stakeholders**

- Developing and enhancing relationships with consumers, healthcare professionals, industry and other regulatory agencies.
- Enhancing international regulatory cooperation through better exchange of information, work sharing and capacity building.

**Managing Key Relationships**

- Promoting and enhancing collaborative and cooperative relationships with other parts of the Department.
- Proactive monitoring and management of emerging issues and enhanced relationships with the Secretary and with the Parliamentary Secretary and Minister (where appropriate).

**Enhancing our Business Capability**

- Implementing cohesive policies, management and processes that:
  - utilise the highest quality scientific and clinical methods, governance and management skills, and
  - integrate across our organisational groups.
- Maintaining a robust risk management approach to all strategic and key operational risks.
- Maintaining sound financial performance.
- Investing in emerging technology to improve our capability.

**Delivering through our People**

- Maintaining a capable workforce.
- Implementing human resource management policies, procedures and systems that promote the *APS Code of Conduct*, support the reform agenda of the Australian Public Service and the Department's People Strategy 2010-2015 that provides for effective performance and continuous learning.

### Indicators of Performance

Measurement of performance will include the monitoring of:

- Meeting milestone delivery targets and target dates for "*Blueprint for TGA's future*", including ANZTPA joint agency projects.
- Evidence from Section 60 reviews, Administrative Appeals Tribunal decisions, audits and legal advice that risks are managed well in decision making.
- Compliance with statutory reporting obligations and government accountability frameworks.
- High stakeholder satisfaction and participation with our consultative processes.
- International co-operation demonstrated to enhance regulatory harmonisation and improve capacity of TGA staff.
- Non-compliance and safety issues identified by TGA at an early stage and appropriate, effective responses implemented.
- Improved community and industry understanding of TGA's regulatory role through close management of media issues and public awareness.
- Business operations are consistent and meet agreed service/timeliness standards.
- Financial performance aligns with financial targets.
- Indicators of organisational health including low staff absenteeism, attraction and retention of staff in critical areas; evidence that performance management enhances individual development and contribution to TGA outcomes.
- Adherence to timeliness and performance commitments made under the TGA customer service standards.

### Risk Mitigation

The TGA will focus on:

- Reliability and consistency in regulatory decision making and effective monitoring of the safety of products on the market.
- Meeting our key stakeholder expectations to foster community confidence.
- Maintaining alignment with relevant legislation of our processes, regulatory practices and guidance documents.
- Retaining and recruiting capable staff.
- Improving our systems and processes to build and maintain corporate memory.
- Effectively preparing for the implementation of ANZTPA.

# ATTACHMENT B: PEOPLE AND CAPABILITY

| People and Capability | | |
|---|---|---|
| **The environment we work in** | **Future Business Changes** | **Workforce Capability** |
| The TGA Business Plan 2013 – 2014 has identified three key priorities are:<br>· regulation of therapeutic goods for safety, effectiveness and quality;<br>· implementing the TGA Program of Reform; and<br>· continuing the work to establish the Australia New Zealand Therapeutic Goods Agency (ANZTPA). | 53% of TGA's workforce is over the age of 45 compared with the APS benchmark of 43%. The APSC have identified that Agencies with a relatively high proportion of older employees may face more critical and complex workforce planning and knowledge management issues than those agencies with a younger age profile.<br><br>Given that over 35% of medical officers are at potential retirement age or older, TGA could face some challenges in maintaining our specialist workforce over the next five years.<br><br>The majority of contract staff is in Information Technology. TGA will implement a plan of reducing reliance on ICT contractors by exploring conversion of contractors to APS staff, documenting key areas of risk to loss of knowledge in TGA's IT systems and developing succession plans for all critical roles undertaken by contract staff. | TGA staff numbers are anticipated to grow over 2013 to 2015 by 5-7 % annually due to increasing demand for regulatory services<br><br>**Areas of Capability Strength**<br>The TGA has 49% of its workforce directly involved in compliance and regulation activity. This area will continue to be a focus for recruitment, capability development and staff retention activities.<br><br>**Areas of Capability Development**<br>The TGA is responding to the 2013 Staff Survey results through the development an action plan that includes a range of TGA-wide initiatives that focus on actions around these survey outcomes:<br>· Leadership, communication, visibility and engagement at all management levels<br>· Change management<br>· Learning and development, and<br>· Career development opportunities. |

## The way we work

| | Critical Positions/Roles | Building Capability |
|---|---|---|
| The *TGA People Strategy 2012 – 2015* has identified the following four areas of focus for the TGA.<br>1. *Recruitment and Retention Strategy*:<br>A streamlined and effective recruitment process that reflects DoHA policies and practices.<br>2. *Work Health Strategy*<br>Implement a tailored Work Health and Safety (WHS) Management System with an appropriate operational WHS Manual; and initiatives that foster Health and Well-being.<br>3. *Organisational Health Strategy*<br>Which fosters effective work practices; adaption to change promotes effective communication and supports the TGA as a good place to work.<br>4. *TGA Capability Development Framework 2013-2015*<br>Build on the existing Capability Map and introduce three core skill categories to training activity:<br>· APS skills<br>· DoHA/TGA skills, and<br>· Appropriate professional/technical/job family skills.<br><br>Incorporate the 70:20:10 model of learning that underpins the APS Leadership Development Strategy and change the focus of learning and development from 'classes and courses' to more effective 'on-the-job' and 'relationship based' approaches to development.<br><br>Implement a strategic process for analysing TGA's training needs and provide an outline of the development priorities for the next two years. | Detailed job profiling will be undertaken for all TGA roles to identify the core skills sets required. These skills sets will assist recruitment and capacity planning across the organisation, inform learning and development activities and used to assist manage current demand for resourcing across the organisation.<br><br>Reporting metrics will be established to assist in developing workforce planning strategies into the future. | We need to continue to ensure capability development alignment with identified job families /functions and roles.<br>**Proposed Learning and Development Activities**<br>1.Project Management<br>Continue to identify skill gaps and develop appropriate targeted training strategies and examine options for introductory Project Management training delivery via eLearning.<br>2.Risk Management<br>Continue to identify skill gaps and develop appropriate targeted training strategies and review and update the existing TGA Risk Management eLearning module.<br>3.Change Management<br>Liaise with PCCD about development options for enhancing change management skills and knowledge within the TGA and develop a training plan for the necessary services required to support TGA organisational change management framework in the implementation of Blueprint recommendations and ANZTPA implementation.<br>4.Legal Awareness<br>Market existing legal awareness eLearning and finalise outstanding modules and review existing face-to-face training to supplement eLearning and provide opportunities for interaction and group activities.<br>5.Coaching, presentation and training skills<br>Liaise with PCCD regarding development options for enhancing coaching, presentation and training skills and knowledge within the TGA and develop a training plan for the necessary services.<br>6.Communication skills<br>Work with the Communications team to identify specific skill gaps and develop appropriate targeted training strategies and liaise with PCCD about development options for enhancing communication skills within the TGA.<br>7.Clinical evaluator training<br>Continue to progress a training strategy for TGA clinical evaluators and examine whether this training would be suited for eLearning.<br>8.Medical Officer CPD Program<br>Continue to work with Medical Officers and other professional staff to schedule and coordinate weekly CPD sessions.<br>9.Technical, job family training<br>Liaise with the Workforce Planning team and the L&D Reference Group on any short to medium term technical development needs and consider the cost benefits of developing a multi-year panel of providers for technical training within TGA. Examine options for laboratory procedures training delivery via eLearning.<br>10. APS Values, Code of Conduct, Bullying and Harassment, Workplace Behaviours<br>Liaise with PCCD about development options for enhancing workplace behaviours within the TGA and examine options for workplace behaviour training delivery via eLearning. |

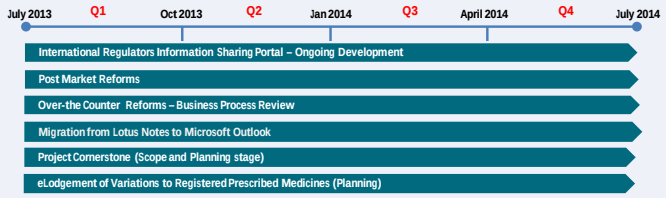
| | Critical Positions/Roles | Building Capability |
|---|---|---|
| | | 11. Workload/time management<br>Liaise with PCCD about development options for enhancing the workload/time management skills and knowledge within the TGA and liaise with Communications about placing handy tips into TGA Daily.<br>12. Leadership and management skills<br>Review the existing TGA management development programs with a view to aligning it with the department's broader manager development strategy.<br>13. Existing eLearning modules<br>Review the existing TGA eLearning modules and liaise with PCCD about module sharing arrangements. If unavailable or unsuitable, develop a procurement plan to update the content.<br>14. Committee meetings and international travel<br>Coordinate debrief sessions by TGA staff following external committee meetings and international travel.<br>15. Organisational and APS awareness<br>Work with the PCCD training team to provide greater accessibility to opportunities for organisational and APS awareness training (e.g. EL Lunchtime learning seminars). |

# ATTACHMENT C: IT DELIVERY WORK PLAN

## THERAPEUTIC GOODS ADMINISTRATION

**FY2013-14 Planned ICT Investment** **$Capital: 00,000,000** **$Operational: 00,000,000** **$Administered: 00,000,000** **$Industry Funded: 00,000,000**

### Key Timeframes




### Key Themes

- **Support for Outcome 1 – Population Heath**
- **Policy Development** and **Program Management** involving **Collaboration Services , Channel Delivery** focusing on **Document Management**, **Inbound** email services and **Online** publishing as well as **Health Promotion and Response** are key priorities for TGA given its regulatory role.
- Significant **lodgement** and **publication** of drugs and devices data leverage **business intelligence**, **data management** and **reporting** tools
- **Funds Management** is delivered through Financial Management Information System – FMIS, provided by Great Plains Financial. HR is provided by Aurion .
- TGA is transitioning some of its functions in preparation for ANZTPA. This includes the Single Entry Point and Joint Recalls Project. The Blueprint Reform program is also underway to provide IT support to the Biologicals Regulatory Framework, eLodgement of Variations to Registered Prescribed Medicines, Over-the-Counter Business Process Review, Complementary Medicines Reforms and Online applications.

### Systems at a glance

| | |
|---|---|
| Divisional Staff | 800 |
| Business Continuity Plan | eBS, Email, EDRMS, FMIS, Internet Publishing, RCUS, Aurion, and Telephones |

| 8 Systems | Age Yrs | Investment $ | Roadmap | Platform |
|---|---|---|---|---|
| E-mail | 9 | <100K | Replace | Domino |
| eBusiness Services - eBS | 5 | >200K | Replace | Domino |
| Surveillance | 6 | <100K | Retain | iLeader |
| Clinical Trials System - CTN | 4 | <100K | Retain | iLeader |
| Special Access Scheme | 4 | <100K | Retain | iLeader |
| Financial Management Information System - FMIS | 6 | ? | Retain | Great Plains |
| Aurion for HR | 6 | 0 | Retain | Cloud |

**Key: Enterprise Capability Model**
- Channel Delivery
- Health Promotion and Response
- Policy Development and Program Management
- Funds Management
- Client and Work Management
- Outcome Improvement
- P Plan and Management Enterprise
- E Enablers

### Governance

**Divisional ICT Governance**
- Combined Reform Steering Committee

**Board Representation for Enterprise Capabilities**
- Information Knowledge and Technology Committee

**Committee Servicing**

Statutory Committees
- Advisory Committee on Biologicals (ACB)
- Advisory Committee on Complementary Medicines (ACCM)
- Advisory Committee on Medical Devices (ACMD)
- Advisory Committee on Non-prescription Medicines (ACNM)
- Advisory Committee on Prescription Medicines (ACPM)
- Advisory Committee on the Safety of Medical Devices (ACSMD)
- Advisory Committee on the Safety of Medicines (ACSOM)
- Advisory Committee on the Safety of Vaccines (ACSOV)
- Therapeutic Goods Committee (TGC)
- Advisory committees on medicines & chemicals scheduling (ACMS & ACCS)

Other advisory committees and forums
- Australian Influenza Vaccine Committee (AIVC)
- Australian Therapeutic Goods Advisory Council
- National Coordinating Committee on Therapeutic Goods (NCCTG)
- Regulatory and Technical Consultative Forum for medical devices (RegTech Forum)

**Divisional Data Steward**
- Peter Bickerton

**Key Data**
- ARTG, Adverse Events, Recalls, Workflow

**Major Stakeholders**

| Stakeholder | Relationship |
|---|---|
| **Medsafe** | ANZTPA |
| **International agencies for medical and therapeutic goods regulation** | Cooperative agreements for GMP auditing and other regulatory activities |
| **Therapeutic Goods industry associations** | Consumer of regulatory services |
| **Drugs and devices manufacturers** | Comply with the regulations and pay fees for listings on TGA registers |
| **Australian Consumers of Therapeutic goods** | Ensuring quality safety and efficacy (where appropriate) of goods |
| **Health Professionals** | Goods QA, incident reporting |
| **Federal & State governments** | Regulatory enforcement & reporting |

### Procurements

| Supplier | Project | $(,000) | Term |
|---|---|---|---|
| **TGA ITS** | Single Entry Point | | 6/2016 |
| **TGA ITS** | Generic Workflow | | 12/2014 |
| **TGA ITS** | Review ARTG | | 12/2014 |
| **TGA ITS** | Executive Reporting | | 12/2014 |
| **Under Tender** | eCTD | 1,000 | 12/2014 |
| **Under tender** | Email migration | 500 | 12/2013 |
| **TGA ITS** | Cornerstone – redevelopment of eBS, workflow, regulation or tracking related items. Scope is not confirmed | 6,000 | 6/2016 |

**By end FY 2013/14**
- Migrate to Microsoft Exchange
- Implement Decision Support System
- ANZTPA Single Entry Point and Joint Recalls project complete and services available
- Medical Device Incident Reporting
- Major components of complementary medicines implemented

**Risks/ Challenges**
- Existing systems can not support emerging business needs
- Internet publishing software is different to DoHA (OpenText and Red Dot)
- Resources and skills constraints, especially project management and change delivery
- Improving information and IT Governance
- Improving stakeholder satisfaction and visibility of ICT performance
- Introduction of electronic submissions
- Further development of information exchange portal

**FY 2014/15**
- 1 Post Market system implemented in the new architecture

*Office of the Chief Information and Knowledge Officer*

# ATTACHMENT D: RISK PLAN

| TGA Risk Management Plan – Risk identification, assessment, evaluation & Reporting | | |
|---|---|---|
| **Division or Branch or Program or Project name** | **THERAPEUTIC GOODS ADMINISTRATION** | (Date of Approval) |
| **Division or Program or Project Ref** | TGA Business Plan 2013-14– Risk Management Plan | |
| **Risk Plan Delegate/Owner** | Dr John Skerritt, National Manager, TGA | |
| **Duration of this plan** | 12 months | Review - February 2014 |
| **Type of activity being assessed e.g. Business Plan, implementation plan, initiation plan** | Business Plan | Review - February 2014 |
| **Business or Program or Project Objective** | Maintaining the community's ongoing trust in the safety, quality and performance of therapeutic goods through regulation of therapeutic goods | |
| **Key outputs milestones (critical Success factors) in the period of this plan** | · Ensuring that therapeutic goods are safe, effective and of high quality;<br>· Continuing the implementation of the TGA Reform Blueprint; and<br>· Continuing the work to establish the Australia New Zealand Therapeutic Goods Agency | |
| **Internal/external stakeholders consulted** | DoHA Risk Manager , TGA Office heads | |

We identified these risks that are rated 'extreme' or 'high':

- Insufficient capacity to absorb required changes across the organisation and maintain business operations
- Failure to meet Key Stakeholders expectations
- Lack of proper alignment between law, processes and guidance documents.
- Failure to retain and recruit capable staff;
- Failure to maintain staff training to ensure skills and competencies are up to date with the current state-of-the-art;
- Lack of appropriate preparation for ANZTPA.

The TGA's treatments to significant risks are outlined in the following table:

| # | Risk Name | Description/Source/Context | Current | Target | Sponsor | Treatment Summary (Owner) |
|---|---|---|---|---|---|---|
| 1 | **Insufficient capacity to absorb required changes across the organisation and maintain business operations** | **Enterprise Risk Category:**<br>· Implementation Risk #1<br>· Delivery Risk #4 | **Current Consequences**<br>Major<br>**Current Likelihood**<br>Possible<br>**Current Rating**<br>High | **Target Consequences**<br>Moderate<br>**Target Likelihood**<br>Unlikely | Heads, MAG and MCG | · Closely monitor progress TGA Blueprint for reforms (Executive, OPM)<br>· Implementation of Change Management Project (OPM)<br>· A TGA wide workforce plan in place (OPSS)<br>· Redevelopment of IT infrastructure and information management systems (OIM)<br>· Communications and education framework and strategies for management of stakeholder expectations (OPSS) |

**Sources:**

- Significant number of Blueprint reforms for implementation
- Project lifecycle
- Lack of clarity in specification of outcomes of reform projects
- Lack of transparency or failure to adequately consult with and/or inform stakeholders
- unrealistic stakeholder expectations
- Increase in complexity in regulatory matters
- Increasing number of new generics and ARTG entries
- Ageing staff profile
- Untimely decision making.
- Lack of predictable timeframes for processing/evaluating applications/submissions across regulatory areas.
- Staff lacking knowledge and understanding of current and new legislative requirements

**Consequences:**

- Delays in making regulatory decisions
- Delays in implementing changes identified in reforms
- Damage to the TGA's reputation
- Adverse scrutiny from media, public and Minister
- Loss of stakeholder confidence

| # | Risk Name | Description/Source/Context | Current | Target | Sponsor | Treatment Summary (Owner) |
|---|---|---|---|---|---|---|
| 2 | **Failure to meet Key Stakeholders expectations** | **Enterprise Risk Category:**<br>· Stakeholder risk #6 | **Current Consequences**<br>Major<br>**Current Likelihood**<br>Possible<br>**Current Rating**<br>High | **Target Consequence**<br>Moderate<br>**Target Likelihood**<br>Unlikely | National Manager | · Implementation of TGA contact strategy (OPSS)<br>· Develop a framework for customer, health professional and industry stakeholder engagement (OPSS)<br>· Standard procedures in place to address responses for enquiries and customer service and provision of timely and accurate advice to customers, health professionals and industry, in accordance with Customer Services Charter (All)<br>· Clearer articulation of Regulatory guidelines (OMA,ODA,OCM, OPR, OMQ)<br>· Development of sponsor access to eBusiness (OIM)<br>· Monitoring of international best practice (OPSS)<br>· Risk based review and implementation of Audit schedule (OMQ)<br>· Risk based review and implementation of Laboratory testing program (OLSS) |

**Sources:**

- Inadequate evaluation or monitoring or manufacturing processes leading to a major public health or safety issue
- Lack of consistency and transparency in decision making
- Ineffective communication on regulatory issues with external stakeholders
- Failure to appropriately manage relations with Departments and/or Ministers or failure to meet Government guidelines
- Lack of timely and accurate information/advice or lack of consistency in decision making and provision of advice
- Staff lacking knowledge and understanding of current legislative requirements and/or non-compliance by staff with legal/regulatory requirements
- Poor record keeping
- Failure to appropriately manage the security of confidential information
- Failure to deliver projects on time and within resources
- Failure to maintain effective information technology systems
- Budget forecasting not accurate
- Backlog of evaluations or inadequate resources allocated
- Inadequate or inappropriate governance arrangements
- Standard Operating Procedures not available or correctly applied in all circumstances

**Consequences**

- Damage to the TGA's reputation
- Loss of stakeholder confidence
- Adverse scrutiny from media, public and Minister
- Potential exposure to or legal action against the TGA
- Increased level of stakeholder complaints
- Unforeseen expenditure is incurred (e.g. litigation costs)
- Decisions in individual circumstances inconsistent with legislation and/or policy
- Decisions based on wrong or inadequate information and/or irrelevant factors
- Breach of Code of Conduct or adverse audit findings

| # | Risk Name | Description/Source/Context | Current | Target | Sponsor | Treatment Summary (Owner) |
|---|---|---|---|---|---|---|
| 3 | **Lack of proper alignment between law, processes and guidance documents** | **Enterprise Risk Category:**<br>· Governance & Accountability risk #3 | **Current Consequences**<br>Major<br>**Current Likelihood**<br>Possible<br>**Current Rating**<br>High | **Target Consequence**<br>Moderate<br>**Target Likelihood**<br>Unlikely | Principal Legal Adviser, Head MAG | · Finalise legal e-learning modules (OLS)<br>· Regular review of processes to ensure alignment with legislation and proper administrative good practice (All)<br>· Regular review and update of Regulatory guidelines (OMA, ODA,OCM, OMQ and OPR)<br>· Review of regulatory guidance documents and SOPs (All)<br>· Adequate allocation of resources for decision making (All)<br>· Training for decision makers (OLS)<br>· Information on the TGA Website updated and reviewed regularly (All).<br>· Use of Business Process Management (BPM) to align process with legislation (MAG) |

**Sources:**
- Staff lacking knowledge and understanding of current legislative requirements
- Lack of consistency and transparency in decision making
- Untimely decision making
- Ineffective communication on regulatory issues with external stakeholders
- Difficulty in accessing specialised expertise to make appropriate decisions
- Lack of an effective record keeping structure and information management system
- Inadequate internal communication including SOPs and published business rules and guidelines
- Legislative clarity or lack of understanding of the legislative basis for the decision
- Conflicts of interest not identified and managed
- Unapproved changes made to policy and/or work practices
- Inadequate resources allocated

**Consequences:**
- Adverse scrutiny from media, public and Minister
- Loss of stakeholder confidence and damage to the TGA's reputation
- Increase in internal review applications (such as s60)
- Potential exposure to successful legal action
- Appropriate therapeutic goods not being made available to the community in a timely manner
- Unsuitable products on ARTG
- Unnecessary regulatory burden on industry
- Further backlogs and problems in service delivery
- Decisions in individual circumstances inconsistent with legislation and/or policy
- Decisions based on wrong or inadequate information and/or irrelevant factors
- Adverse audit findings

| # | Risk Name | Description/Source/Context | Current | Target | Sponsor | Treatment Summary (Owner) |
|---|---|---|---|---|---|---|
| 4 | **Failure to retain and recruit capable staff** | **Enterprise Risk Category:**<br>· Organisational capability risk #7 | **Current Consequences**<br>Major<br>**Current Likelihood**<br>Possible<br>**Current Rating**<br>High | **Target Consequence**<br>Moderate<br>**Target Likelihood**<br>Unlikely | Chief Operating Officer | · Review of learning and development (OPSS)<br>· Regular review of the recruitment model in meeting the TGA's business (OPSS)<br>· Proactive approaches to making the TGA a good place to work (All)<br>· Adoption of an appropriate change management framework. |

**Sources:**
- Poor recruitment processes
- Lack of effective change management process
- Poor systems and processes
- Failure to undertake effective workforce planning, including preparation for future workforce requirements
- Failure to undertake a sufficiently strategic approach to capability development.
- Poor leadership and unattractive working conditions
- Uncertainty about ANZTPA governance and employment structures

**Consequences:**
- Organisation unable to meet its strategic objectives
- Inability to meet performance objectives and revenue projections
- Increase in complaints from stakeholders and closer scrutiny
- Non-compliance with PS Act, Regs and Directions
- Lower capability in the TGA
- Failure to meet statutory obligations under the TG Act

| # | Risk Name | Description/Source/Context | Current | Target | Sponsor | Treatment Summary (Owner) |
|---|---|---|---|---|---|---|
| 5 | **Failure to have systems and processes that establish corporate memory** | **Enterprise Risk Category:**<br>· Organisational capability risk #7<br>· Resilience/Crisis Management risk #8 | **Current Consequences**<br>Moderate<br>**Current Likelihood**<br>Possible<br>**Current Rating**<br>Medium | **Target Consequence**<br>Minor<br>**Target Likelihood**<br>Unlikely | Chief Operating Officer | · Regular update of legal e-learning modules (OLS)<br>· Review of learning and development and more comprehensive training for decision makers (OPSS)<br>· Identification of critical job roles and Implementation of succession planning strategies (OPSS)<br>· Ongoing maintenance and development of IT infrastructure and information management systems (OIM)<br>· Maintaining Quality management systems, procedures and records (OLSS, OMQ) |

**Sources:**
- Lack of an effective record keeping structure and information management system
- Lack of adequate IT systems
- Lack of proper documentation of decision making, legislative clarity or lack of understanding of the legislative basis for the decision
- Staff lacking understanding and knowledge
- Ineffective internal communication on regulatory issues, SOPs and published business rules and guidelines
- Difficulty in accessing expertise to make appropriate decisions.
- Staff turnover

**Consequences**
- Adverse scrutiny from media, public and Minister
- Loss of stakeholder confidence
- Damage to the TGA's reputation
- Potential exposure to successful legal action
- Unsuitable products on ARTG
- Increased workload
- Decisions in individual circumstances inconsistent with legislation and/or policy
- Decisions based on wrong or inadequate information and/or irrelevant factors

| # | Risk Name | Description/Source/Context | Current | Target | Sponsor | Treatment Summary (Owner) |
|---|---|---|---|---|---|---|
| 6 | **Lack of appropriate preparation for ANZTPA** | **Enterprise Risk Category:**<br>· Implementation Risk #1 | **Current Consequences**<br>Major<br>**Current Likelihood**<br>Possible<br>**Current Rating**<br>High | **Target Consequence**<br>Minor<br>**Target Likelihood**<br>Unlikely | National Manager Head TGA-ANZTPA Branch | · Adequate implementation of agreed projects for which TGA is responsible<br>· Contribute to development of options about governance and employment structure.<br>· Adequate staff consultation and effective communication<br>· Adoption of an appropriate change management framework.<br>· Ensure appropriate expertise is available to the implementation team. |

**Sources:**
- Lack of resolution of issues at inter-departmental level
- Lack of staff support for the change
- Staff working concurrently on ANZTPA, Blueprint and BAU
- Change in political environment
- Lack of legislative clarity
- Difficulty in accessing expertise to make appropriate preparation.
- Lack of adequate funding

**Consequences**
- Delay in establishing the Joint Authority
- Adverse scrutiny from media, public and Minister
- Loss of stakeholder confidence
- Damage to the TGA's reputation
- Cost over runs, cross subsidisation

# ATTACHMENT E: FRAUD RISKS

| Description of Fraud Risk | Risk Rating | Mitigation Strategy |
|---|---|---|
| Bribery and corruption in relation to regulatory and compliance powers | Medium | Raise Staff awareness to act in a manner consistent with the Public Service Act 1999 and APS code of conduct and values. |
| Bribery and corruption in relation to, or inappropriate disclosure of, commercially viable information | Medium | Raise Staff awareness to act in a manner consistent with the Public Service Act 1999 and APS code of conduct and values. |
| Bribery and corruption in competitive tendering process for procurement of goods and services | Medium | Any departure from standard procedures constitutes a breach and must be reported.<br><br>Raise Staff awareness to act in a manner consistent with the Public Service Act 1999 and APS code of conduct and values. |

# ATTACHMENT F: WORK HEALTH AND SAFETY

The following table summarises work health safety hazards identified in respect of the activities undertaken by TGA. We are currently undertaking a risk management audit to assess risk ratings and adequacy of existing mitigation controls.

| Activity | Identified hazard | Hazard/risk controls | Responsible person |
|---|---|---|---|
| 1. **Administration Activity- computer based work** | Inappropriate work station setup | · Workers directed to Office wise Comcare for information on correct web site<br>· Manual handling training<br>· Workstation Ergonomic Assessment<br>· Recruitment and Selection – Induction<br>· Ergonomic and manual handling expert<br>· Manual handling risk assessments | PCBU (DoHA), TGA, Managers and Workers |
| **2. Operations within animal services – Activity a range of manual handling tasks**<br><br>**Manual Handling Operations** | Hazardous manual handling tasks/activities that include:<br>- the following characteristics;<br>- repetitive or sustained application of force<br>- repetitive or sustained awkward posture<br>- repetitive or sustained movement<br>- application of high force<br>- exposure to sustained vibration<br>- handling of a person or an animal<br><br>Handling of unstable or unbalanced loads or loads which are difficult to grasp or hold | · Workers directed to Office wise Comcare for information on correct web site<br>· Manual handling training<br>· Ergonomic Assessment<br>· Recruitment and Selection – Induction<br>· Ergonomic and manual handling expert<br>· Manual handling risk assessments<br><br>· Mechanical aids and lifting devices<br>- trolleys<br>- forklifts<br>- pedestrian stackers and walkers<br>- platform ladders<br>- hoists | PCBU (DoHA), TGA, Managers and Workers |
| 3. **Psychological** | Occupational stress<br>Workplace bullying and harassment<br>Fatigue | · Staff training<br>· Employee Assistance Counseling services<br>· Conditions of Employment<br>· Promotional material<br>· Grievance /Review of Actions DoHA intranet site<br>· Harassment Contact Officers DoHA Intranet site<br>· Workplace Bullying and Harassment on DoHA intranet<br>· TGA Human Resources Section | PCBU (DoHA), TGA, Managers and Workers |
| **4. After Hours work** | Working alone<br>Reduction in emergency assistance and support | · Risk assessments<br>· Local area standard operating procedures<br>· Staff training<br>· Restricted access to TGA buildings and property<br>· After hours sign in books<br>· 24 hour security support onsite at Symonston | PCBU (DoHA), TGA, Managers and Workers |

| Activity | Identified hazard | Hazard/risk controls | Responsible person |
|---|---|---|---|
| **5. Purchasing** | Introducing new or uncontrolled hazards into the workplace:<br>· personal protective equipment<br>· office furniture and equipment<br>· chemicals and substances<br>· radiation sources<br>· plant and equipment (including electrical)<br>Introducing new and/or uncontrolled wastes | · Pre-purchasing checklists for:<br>- personal protective equipment<br>- office furniture and equipment<br>- chemicals and substances<br>- radiation sources<br>- plant and equipment (including electrical)<br>· Department Policies and Guidelines<br>· Waste is managed under OL&S S and TGA Property Services | PCBU (DoHA), TGA, Managers and Workers |
| **6. Travel: Domestic /Overseas travel** | Remote locations<br>Working alone<br>Driving and travel arrangements<br>Inadequate communication<br>Security<br>Fatigue<br>Unexpected events/emergencies | · Travel Guides:<br>- Domestic Travel guidelines<br>- International Travel guidelines<br>- Medical declaration<br>· Risk Assessment and Plans<br>· DFAT warnings<br>· Travel Authorising Officers<br>· MHS Travel Doctor<br>· Travel First Aid Kit<br>· Travel to high risk destinations risk assessment<br>· Utilisation of SOS in event of medical emergency | PCBU (DoHA), TGA, Managers and Workers |
| **7. Working Offsite Domestic/International** | Work undertaken in environments that are not under TGA control.<br>Environmental Risks<br>Working in remote international locations<br>Security<br>Working alone<br>Communication<br>Unexpected events/emergencies | · Risk Assessment and Plans<br>· DFAT warnings<br>· Pre risk assessment of work to be undertaken in location and assessment included as part of travel plans.<br>· Communication Plans<br>· Utilisation of SOS in event of medical emergency | PCBU (DoHA), TGA, Managers and Workers |
| **8. Contractors** | Unfamiliar with TGA WHS procedures<br>Work that adversely impacts on the TGA environment and/or staff<br>Conducting work unsafely or in conflict TGA procedures<br>High risk and/or specialised tasks | · Contractor agreed scope of works and/or contracts prior to commencing work<br>· Contractor performance monitoring and reviews<br>· Contractor WHS questionnaire<br>· Contractor WHS plans<br>· Risk assessments<br>· TGA contact person:<br>- Contract Manager<br>- Project Manager<br>· Contractor induction and training | PCBU (DoHA), TGA, Managers and Workers |
| **9. Visitors** | Unfamiliar with TGA WHS procedures<br>Activities that adversely impact on the TGA workers | · Risk assessments<br>· Restricted access to TGA buildings and property<br>· 24 hour security support, onsite at Symonston<br>· Local visitor inductions, checklists and visitor cards | PCBU (DoHA), TGA, Managers and Workers |

| Activity | Identified hazard | Hazard/risk controls | Responsible person |
|---|---|---|---|
| 9. **Legal Compliance** | Injury and/or property damage<br>Prosecution and fines<br>Intervention programs<br>Reputation damage to the TGA | · Work Health and Safety Management System<br>· Risk assessments<br>· Licenses, Permits and Agreements<br>· Authorising Officers<br>· Records management and data control<br>· Health and Safety Committee<br>· WHS management representatives<br>· Health and Safety Representatives and designated work groups<br>· Internal/ External auditing<br>· Incident Reporting, Recording and Management | PCBU (DoHA), TGA, Managers and Workers |
| **10. Emergency Incident** | Uncontrolled emergency incident leading to adverse outcomes:<br>- Loss of life<br>- injury or illness<br>- Property damage<br>Loss of communication<br>Breakdown in emergency procedures | · Trained first aiders and building wardens<br>· Inductions<br>· Scheduled building evacuations<br>· Emergency management exercises –, Wardens<br>· Emergency Management Plans<br>· Building essential services and ongoing maintenance of those services<br>· Building specific emergency procedures and plans<br>· Task/activity specific emergency procedures and plans<br>· Staff training (evacuation drills, fire extinguisher training)<br>· Emergency communication systems | PCBU (DoHA), TGA, Managers and Workers, Contractors |
| **11. Electrical** | Use of faulty equipment/appliances<br>Use of uncertified electrical equipment/appliances<br>Incorrect and/or faulty electrical installation<br>Use electrical equipment/appliances that do not meet relevant Standards and Codes | · Scheduled testing and tagging of portable electrical equipment<br>· Pre-purchase checklist – Electrical Equipment<br>· Certificates of Electrical Safety<br>· Electrical installation by licensed electrician<br>· Use of RCDs<br>· RCD testing | PCBU (DoHA), TGA, Managers and Workers, Contractors |
| **12. Confined Spaces** | Unrestricted access to confined spaces<br>Inadequate risk assessment of confined space<br>Inadequate identification of confined space<br>Poorly ventilated workplaces | · Confined space entry permit system<br>· Confined space entry training<br>· Confined space emergency procedures<br>· Confined Spaces Authorising Officers<br>· Safety signage<br>· Confined space risk assessments<br>· Safe work method statements<br>· Confined spaces register<br>· Restricted access | TGA Property Services /Dalkia |

| Activity | Identified hazard | Hazard/risk controls | Responsible person |
|---|---|---|---|
| **13. Laboratories** | Hazards associated with the work/research undertaken in the laboratory<br>- chemical<br>- microbiological<br>- ionising radiation<br>- non-ionising radiation<br>- mechanical aspects<br>- electrical aspects<br>Refer to specific hazard categories<br>Hazards associated with using plant and equipment. For example:<br>- centrifuge<br>- autoclave<br>- microscope<br>- pipette<br>- fume hoods<br>- biological cabinets<br>- refrigerators/freezers<br>- cage washer<br>Generation of wastes as per specific hazard category | · Laboratory risk assessments<br>· Local area standard operating procedures<br>· Restricted access<br>· Area (laboratory) inductions<br>· Scheduled laboratory inspections<br>· Personal protective equipment<br>· Refer to specific hazard category for required controls | OL&SS |
| **14. Biological Activities** | Biological exposure/contamination<br>Release of biological agent into uncontrolled environment<br>Working with animals<br>Importation and exportation of biological materials<br>Infectious wastes | · Restricted access to authorised workers/contractors/visitors<br>· Risk assessments<br>· Local area standard operating procedures<br>· Biohazard Laboratory Practice Training<br>· Controlled shipping and movement of infectious substances, diagnostic specimens and genetically modified organisms<br>· Engineering controls such as laminar flow cupboards<br>· Scheduled workplace inspections for laboratories<br>· Staff training<br>· Personnel protective equipment<br>· Employee health monitoring<br>· Personal protective equipment<br>· Infectious waste removal is managed under OL&SS and TGA Property Services safety system | OL&SS |
| 15. **Noise** | Noise in excess of the exposure standards<br>Distracting noise | · Purchasing less noisy plant and equipment<br>· Pre-purchasing checklist<br>· Acoustic engineering controls<br>· Noise Risk Assessments<br>· Audiometric screening<br>· Personal protective equipment<br>· Hearing protection training<br>· Signage | TGA Property Services<br>Dalkia<br>OL&SS |

| Activity | Identified hazard | Hazard/risk controls | Responsible person |
|---|---|---|---|
| **16. Hazardous Chemicals** | Chemical exposure - acute or chronic<br>- inhalation<br>- absorption<br>- ingestion<br>- injection<br>Fire and/or explosion through incorrect storage, handling, labeling or mixing of chemicals<br>New chemicals with uncertain properties arising from research and subsequent health affects<br>Time sensitive chemicals that can become unstable during storage<br>Production of hazardous wastes<br>Contamination due to accidental leakage, spills, emissions:<br>- air<br>- water<br>Engineered nanoparticles | · ChemWatch –SDS manifest and inventory system (ChemGold and ChemFFX)<br>· OL&SS Chemical Management System<br>· Chemical Risk Assessments<br>· Risk assessments that include chemical<br>· Local area standard operating procedures<br>· Pre-purchase checklist - chemicals<br>· Licensing agreements and requirements<br>· Engineering controls such as:<br>· fume cupboards<br>· mechanical ventilation<br>· extraction<br>· atmospheric monitoring<br>· Purpose built storage areas for cylinders and compressed gases<br>· Restricted access to authorised workers<br>· Correct labeling, storage and segregation<br>· Scheduled workplace assessments that include chemical assessment<br>· Time sensitive chemicals dated<br>· Emergency procedures for accidental release/spillage<br>· Employee health monitoring<br>· Chemical Management Training<br>· Gas Safety Training<br>· Personal protective equipment<br>· Hazardous waste removal, trade waste agreements etc are managed under the OL&SS and TGA Property Services safety system<br>· Internal chemical expert | OL&SS Property Services Dalkia |
| **17. Workplace Environment and Facilities** | Poor storage and office space<br>Poor environmental characteristics:<br>- thermal discomfort<br>- nuisance noise<br>- inadequate lighting<br>- glare<br>Poorly maintained equipment<br>Office waste<br>Access to facilities including:<br>- toilets<br>- washing facilities<br>- drinking water<br>- dining facilities | · Scheduled workplace inspections<br>· Work station ergonomic assessments<br>· Refer to “Electrical” category for electrical controls<br>· Provision of facilities:<br>- toilets<br>- washing facilities<br>- eating and drinking facilities<br>· Risk assessments<br>· Office waste removal and recycling Recruitment and Selection – Inductions<br>· Induction Compliance Checklist | TGA Property Services Dalkia |

| Activity | Identified hazard | Hazard/risk controls | Responsible person |
|---|---|---|---|
| **18. Animals** | Infectious animals<br>Manual handling<br>Animal and infectious wastes | · Risk assessments<br>· Local area standard operating procedures<br>· Human immunisation<br>· Animal immunisation<br>· Restricted access<br>· Quarantine areas<br>· Restricted access<br>· Appropriate animal housing/farming<br>· Standard operating procedures<br>· Health screening and monitoring<br>· Personal protective equipment<br>· TGA Animal Welfare Committee<br>· Hazardous waste removal is managed under OL&SS and TGA Property Services safety system | OL&SS |
| **19. Machinery and equipment** | Lack of operator competency/training<br>Unassessed plant and equipment<br>Lack of/inappropriate guarding<br>Unrestricted access<br>Poor management of registrable plant<br>Poorly maintained plant<br>Adverse impact on the environment:<br>- waste generation from plant<br>- decommissioning and removal of plant | · Plant Hazard and Risk Assessments<br>· Guarding and engineering controls<br>· Emergency stops<br>· Training and supervision<br>· Restricted access<br>· Scheduled maintenance<br>· Standard Operating Procedures<br>· Plant Registers: Comcare<br>· Pre purchasing checklist – plant and equipment<br>· Personal protective equipment<br>· Waste removal is managed under Chancellery and Common Services, OHS&IM<br>· Removal of decommissioned plant<br>· Internal plant expert | TGA Property Services Dalkia, OL&SS |
| 20. **Hot Work e.g.: welding** | Fire and/or explosion<br>Injury and/or property damage<br>Conducting hot work out doors during a total fire ban | · Hot work risk assessments<br>· Hot work permit system<br>· Safe work method statements<br>· Trained operators<br>· Hot Work Authorising Officers<br>· Hot Work Emergency Plans<br>· Scheduled maintenance for hot work plant and equipment | TGA Property Services/Dalkia/ OL&SS |

| Activity | Identified hazard | Hazard/risk controls | Responsible person |
|---|---|---|---|
| **21. Working at Heights** | Working close to an edge unprotected<br>Unsuitable working environment:<br>- slippery roof<br>- brittle roof<br>- adverse weather conditions (wind and run)<br>Unsecured equipment<br>Inappropriate use of access and/or fall arrest equipment:<br>- ladders<br>- scaffold<br>- elevated work platform<br>- harnesses and lanyards<br>- anchor points | · Roof risk assessments<br>· Risk assessments<br>· Standard operating procedures<br>· Height safety training<br>· Fall arrest training<br>· Fall protection:<br>- handrails and barriers<br>- elevated work platforms<br>- scaffolding<br>- fall arrest and anchor point systems<br>· Accessing heights under suitable weather conditions (e.g. not raining and little/no wind)<br>· Restricted access and entry points<br>· Ladder training<br>· Elevated work platform training<br>· Barricading | TGA Property Services Dalkia |
| 22. **Workplace Design and Construction** | Introduction hazards/risks at design<br>Hazards/Risks associated with construction works:<br>- electrical<br>- plant<br>- fall from heights<br>- chemicals<br>- manual handling<br>- noise<br>- changing environment<br>- unauthorised access<br>Hazardous materials removal | · Project Managers<br>· Risk assessments<br>· Restricted/authorised access:<br>- temporary fencing<br>- signage<br>· Site and contractor induction<br>· Contractor Panel – preferred contractors<br>· Refer to specific hazard category for controls<br>· Hazardous materials removal managed | TGA Property Services Dalkia & OL&SS |