Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

TGA Business Plan 2012 - 2013

Therapeutic Goods Administration (TGA)

TGA Health Safety Regulation

Strategic Considerations

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.* By working with our stakeholders (consumers, health professionals, government, industry and international counterparts), we will enhance our processes to ensure that the regulatory framework within which we operate is able to adapt to new scientific developments and emerging community expectations.

The TGA's main contribution is to *Outcome 1 – Population Health* of the Department of Health and Ageing's Portfolio Budget Statement. The Australian Government aims to "*ensure 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 to implement further reforms to Australia's regulatory framework*".

The TGA Business Plan 2012-13 is part of the governance framework that guides the TGA's work and identifies continuing responsibilities and major project initiatives. TGA's Business Plan is also guided by the TGA Strategic statement 2012-15 (Attachment A) which outlines our strategic direction, priorities, performance indicators and how we will mitigate risk.

To maintain the community's ongoing trust in the safety and quality of therapeutic goods, the TGA strives 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 become aware of and 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 in relation to regulatory decisions and issues.
- **Efficient** by continually improving quality and productivity in the delivery of all our functions.
- **Influential** through having a strong role in informing scientific debate 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.

Key roles, responsibilities and priorities

Roles

The role of the TGA is to regulate therapeutic goods. The TGA does this by applying scientific and clinical expertise to an assessment of the evidence of the risks compared to the benefits of use of therapeutic goods. The TGA applies this risk-based regulatory process to therapeutic goods before they are marketed and monitors products once they are on the market. Additionally, it assesses the suitability of medicines and medical devices for export from Australia.

The TGA regulates manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality. It has a team of inspectors that audit manufacturing facilities around the world to ensure that products supplied in Australia are of high quality.

Responsibilities

The Australian Government, through the TGA, will continue to regulate therapeutic goods under a national framework to ensure their quality, safety and efficacy. Thus there are a large number of "Business as Usual" responsibilities to be undertaken during the coming year. In 2012-13, the TGA will implement a comprehensive reform agenda outlined in "*TGA reforms: A Blueprint for TGA's future*" and based on an action plan published in July 2012 (http://www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm). The reforms will:

- Improve the way that the TGA communicates with the public about the benefits and risks of therapeutic goods
- Improve and publicly clarify the TGA's processes used to assess different types of therapeutic goods
- Increase the level of evaluation of higher risk medical devices
- Strengthen the response to unsubstantiated advertising and other breaches of the requirements for advertising of therapeutic goods.

The Australian and New Zealand Governments have agreed to proceed with a trans-Tasman scheme for the regulation of therapeutic goods. A three-stage approach over the next four years will be implemented to create a single regulatory framework to provide health benefits for consumers, reduced regulatory costs for industry and greater efficiency for governments.

Priorities

During 2012-13, TGA will need to balance the delivery of our ongoing regulatory program with the development and implementation of a significant program of reform. Priorities comprise:

The regulation of therapeutic goods for safety, effectiveness and quality

The TGA safeguards and enhances the health of the Australian community through the effective and timely administration of the *Therapeutic Goods Act 1989*.

Implement the TGA Reform Blueprint

On 8 December 2011, the Parliamentary Secretary for Health and Ageing, the Hon Catherine King announced her plan to reform the TGA to ensure that it remains adaptable to community and industry expectations. The plan, outlined in *"TGA reforms: A Blueprint for TGA's future"*, will improve the Australian community's understanding of the TGA's regulatory processes and decisions and enhance public trust in the safety and quality of therapeutic goods.

The table below provides an overview of the implementation of the 2012-13 Blueprint reforms.

Streams	*Work to be completed in 2012-2013*
Governance & Management: Managing and governing projects to deliver an integrated program of reform	• Governance • Program Management • Annual Reviews
Communication & Stakeholder Engagement: Projects that deliver on recommendations for better communications and stakeholder engagement	• Australian Therapeutic Goods Advisory Council • Consultation principles and Communication strategy • Application processing review • Regulatory Risk Framework • Evaluate post-market risk communication scheme • Public access to adverse event data • Publicise compliance outcomes
Advertising: Projects that deliver on recommendations for reform of Advertising	• Consult and provide advice to government
Complementary Medicines: Projects that deliver on recommendations for reform of Complementary Medicines	• Improved guidelines and information • Post market compliance reforms • Procedures for investigating advertising breaches
Medical Devices: Projects that deliver on recommendations for reform of Medical Devices	• Consult on improved device information • Consult and provide advice to government on proposals for increased pre-market scrutiny and third party assessment bodies
Organisation Change: Projects and activities that support reform and deliver sustainable outcomes, including engaging TGA staff to understand, support and adopt reform changes	• Implement organisational change and staff engagement strategy • Identify IT system requirements • Assess implications for regulatory framework and legislation

Progress establishment of the Australia New Zealand Therapeutic Goods Agency (ANZTPA)

The Governments of Australia and New Zealand have agreed to a phased approach to implementing a trans-Tasman regulatory scheme for therapeutic goods. The first stage of implementation will result in more efficient processes for the approval of therapeutic goods through the implementation of the following agreed business to business projects between the TGA and Medsafe:

- Development of a publicly available data base with information on adverse reactions to medicines and medical devices.
- Delivery of a common recalls portal for therapeutic goods.
- A common early warning system will also be delivered to inform the public of potential safety issues concerning therapeutic goods.
- Reform of the business process for the evaluation of over the counter medicines.
- Finalising shared capability to conduct audits to assess good manufacturing practice (GMP).

Areas of particular emphasis

In delivering the 2012-13 priorities, the TGA will put particular emphasis on:

1. Cohesion

Fundamental to cohesion is improved strategy and planning, such that our business-as-usual activities are efficiently integrated with the Blueprint reform process and the move to becoming the Australia New Zealand Therapeutic Products Agency. This will include strengthening of internal communication so that important issues are escalated in a timely manner. A strong effort will be made to improve cohesion among the Executive, so that we operate not just as mangers of our individual areas of responsibility but as a close-knit team carrying out joint planning and leadership. This principle will be applied at all levels of TGA's management structure.

2. Delivery

The Blueprint reforms address five areas:

- governance and management
- communication and stakeholder management
- advertising
- complementary medicines, and
- medical devices

The three-phased plan details how the reforms will be rolled out through to December 2015. The TGA understands that it is essential to demonstrate real improvements because with an increase in fees comes an increase in expectations. We have to show value for money to industry, at least in the medium term. Consumers and health professionals too have performance expectations; this will be especially important as we strive to become more transparent.

TGA's Organisation Chart is shown in **Attachment B**.

3. Communications and strong stakeholder engagement

While the TGA (and the rest of DoHA) will continue to work through specialist media managers for issues management, an overall communication and education strategy will be developed in late 2012 to enable TGA to better address high-profile topics. TGA will place a greater focus on education, explaining clearly how we regulate with an emphasis on effective risk communication so that people understand, for instance, that medical devices will and do fail no matter how well we do our job.

4. Supporting regulatory reform

The TGA will make greater efforts to provide more consistent regulatory decisions under our Act and will assess options for proposal to Government to adjust levels of regulation in different areas according to the level of risk.

5. Strengthening our relationships with the rest of the Department and with the Parliamentary Secretary and Minister

It is important that the TGA see itself in the broader departmental and government policy context. This will require TGA staff to develop closer relationships at all levels with key DoHA areas, involvement in policy discussions where they are relevant to the broader contest of regulation, and exploring further opportunities in coordination areas of common concern. Stronger and more frequent communication will take place with our Parliamentary Secretary, Minister and their staff.

6. Making the TGA a great place to work

Many medical, scientific, legal and administrative staff see the TGA as an attractive place to work, and the TGA will increase its communication with sources of potential staff to enable that reputation to be spread further. The 2012 Staff Survey showed that while many people are happy working at TGA, some issues that were specific to the TGA will be addressed through a specific plan.

Approach to priorities

In implementing and in balancing our effort across our priorities during 2012-13, TGA will focus on the following strategies:

1. Refining our Regulation

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

2. Engaging with our Stakeholders

- Developing and enhancing key partnerships with consumers, healthcare professionals and other regulatory agencies.
- Maintaining appropriate relationships with industry.
- Enhancing international regulatory cooperation through better exchange of information, work sharing and regulatory capacity building in our region.

3. Managing Key Relationships

- Promoting and enhancing collaborative and cooperative relationships with the rest of the Department.
- Proactive monitoring and management of emerging issues and enhanced relationships with the Secretary and the Parliamentary Secretary.

4. Enhancing our Business Capability

- Implementing cohesive policies, management and processes that utilise the highest quality scientific methods, governance and management skills, and integrate seamlessly 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.

5. Delivering through our People

- Maintaining a sustainable and 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.

Significant changes and challenges

The work program planned for 2012-13 is substantial, as it incorporates business as usual, implementation of the Blueprint reforms and progression of the establishment of the Australia New Zealand Therapeutic Products Agency. TGA is fully cost recovered from fees and charges imposed on industry. Activity based costing ensures that the fees and charges imposed on industry remain appropriate. The TGA is facing some significant challenges in maintaining quality business as usual regulatory services while also embarking and delivering on a wide ranging and complex reform program.

It is critical to the delivery of our work program that the TGA develops a disciplined approach to the planning, resourcing and implementation of all of its business activities. Key mechanisms in ensuring that the TGA will meet this challenge will be to enhance our governance and to deliver operational and financial efficiencies. Given the fee and charge increase to industry, TGA in consultation with key stakeholders will develop a set of meaningful measures to assess performance and delivery of this work program.

The TGA has responded to the 2012 Staff Survey results through a range of TGA-wide initiatives that have been developed to improve leadership and management, career development and planning, and workplace behaviours. The action plan for the 2012 staff survey has focussed around four areas:

- Senior management team jointly planning and implementing a TGA wide work program.
- A focus on strategy and planning with clarity regarding priorities and deliverables.
- Engaging with Section Heads and managers.
- How we manage change.

Operating environment

Outputs to deliver

1. The regulation the therapeutic goods for safety, effectiveness and quality (ongoing business requirements)

Strategies Underpinning this priority:

To ensure therapeutic goods available in Australia are of an acceptable standard, and manufactured in accordance with the principles of Good Manufacturing Practice:

A. Appropriate use of risk management to carry out a range of assessment and monitoring activities. At the same time, enabling the Australian community to access therapeutic advances within a reasonable time.

Major activities:

- Undertake market authorisation activities for biological, complementary, prescription and non-prescription medicines, together with the exports regulatory function.
- Complete assessment of prescription medicines applications within statutory timeframes.
- Implement business improvements to reduce the backlog of non-prescription medicines and medical devices applications.
- Undertake market authorisation activities for medical devices, including managing the transition of hip, knee and shoulder implants from Class II to Class III.
- Encourage a greater number of registration applications for newly-regulated therapeutic goods, including biologicals and in vitro diagnostics.
- Implement a comprehensive risk-based laboratory testing and batch release program.

B. Maintaining an effective regulatory framework which is contemporary and aligned with international best practice.

Major activities:

- Undertake post-market monitoring and regulatory activities for prescription and non-prescription medicines, devices, and complementary medicines, together with the recalls and advertising regulatory functions.
- Undertake audits and assessments of therapeutic product manufacturers, nationally and internationally.
- Undertake surveillance, enforcement and related activities, including investigations into import and export, manufacture and supply of unauthorised and counterfeit therapeutic goods.
- Develop standard operating procedure for investigating advertising breaches and communicate timeframes for completing investigations .
- Rationalise and expand the number of coded indications available for listed complementary medicines through the assessment of common indications. Develop policy options for further steps, such as eliminating the free text field, requiring sponsors to use only the available coded indications or to apply for a new coded indication for consideration by government.
- Provide on-line access for reporting of adverse events for medical devices and promote the role of TGA to healthcare professionals, industry and the public in monitoring and assessing adverse events to medicines and medical devices.
- Provide access to Australian adverse drug reaction data through the release of a publicly-searchable database.
- Develop options for the regulation of pharmacy compounding.

C. Enhancing international regulatory cooperation through better exchange of information, work sharing and regulatory capacity building in our region

Major activities:

- Opportunities explored for expanding international regulatory harmonisation through development of a 2012-15 International engagement strategy and work plan.
- Co-ordination of work sharing projects with international regulators in relation to generic medicines, new chemical entities and associated GMP activities.
- Participate in the development of a medical devices single audit program with the US, Canada and Brazil.
- Stong participation in regulatory harmonisation fora such as the International Medical Device Regulators Forum.
- Implement harmonised ingredient names for medicine components.

D. Implementing cohesive policies, management and processes that utilise the highest quality scientific methods, governance and management skills, and integrate seamlessly across our organisational groups

Major activities:

- Develop a TGA-wide monitoring and compliance strategy.

E. Maintaining a sustainable and capable workforce

Major activities:

- Finalise and implement strategic workforce plan for the TGA, in consultation with the broader Department of Health and Ageing.
- Investigate and develop the use of shared services for delivery of TGA HR requirements.

F. Investing in emerging technology to improve our capability

Major activities:

- Provide the business systems and support services that enable the TGA to undertake its regulatory responsibilities, including development of systems for electronic lodgement of variations to prescription medicine registrations.
- Review the capability of TGA's systems to provide sponsors with access to an on-line system for submission and tracking for all applications for assessment.
- Enhancements to TGA's application processing systems including an evaluation of an electronic Common Technical Document review tool capable of allowing dossiers to be lodged by applicants electronically, validation of electronic submissions to occur and provide evaluators with the capability to review submissions on line.

G. Redeveloping key guidance documents for industry and providing better information about regulatory decisions and processes

Major activities:

- Update the Australian Regulatory Guidelines for Prescription Medicines (ARGPM) and the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) using a new format proposed for all TGA regulatory guidelines. Release after taking stakeholder feedback into account.
- Develop and release 'Guidelines for levels and kinds of evidence' for Complementary medicines for public consultation prior to finalisation.
- Propose and implement, after consultation, regulatory requirements for labelling and packaging of medicines.

2. Implement the TGA Reform Blueprint (reform initiatives)

Many of the reforms will be managed as discrete projects

- MAG1: Medical Devices Reform, MAG2: Complementary Medicines Reform, MAG6:Regulatory Framework and Guidelines, MAG7: Labelling and Packaging
- MCG1: Adverse Events, MCG2: Early Warning (ANZTPA B2), MCG3: Recalls (ANZTPA B3), MCG5: Post Market Business Process Reform, and MCG6: Advertising
- RSG2: Strategic Engagement, RSG3: Information Accessibility, RSG5: On-line Applications.

Further detail is provided in the Blueprint implementation plan (www.tga.gov.au/about/tga-reforms-blueprint-implementation.htm)

Strategies Underpinning this priority:

A. Developing and enhancing key partnerships with consumers, healthcare professionals and other regulatory agencies

Major activities:

Communication and partnerships

- Establish the Australian Therapeutic Goods Advisory Council to enable more effective stakeholder input into future directions and program implementation.
- Develop a consistent approach to providing information on the work of TGA statutory advisory committees, including outcomes of meetings.
- Develop and implement a comprehensive communication strategy to better inform consumers, industry and healthcare professionals.
- Make more information available to the public through the TGA website and other channels.
- Conduct a pilot project to trial more effective public contact management.
- Work in partnership with other information providers to develop ways to achieve wider public understanding that listed medicines are not evaluated for effectiveness by the TGA prior to market.
- Work with the National Prescribing Service and other information providers to establish agreement on the provision of information to the public consistent with the principles of the quality use of medicines.
- Consult further with stakeholders on the recommendations for advertising reform including more effective approach to sanctions and penalties and provide advice to Government.

Adverse events

- Develop a strategy to increase consumer and health professional awareness of, and participation in, the adverse event reporting system.
- Review the notifications system and consult consumers and health professionals on potential improvements.

Complementary medicines

- Consult stakeholders on options to amend labelling of complementary medicines to provide consumers with clear information, particularly in relation to explaining the meaning of the listed medicine ('AUST L') category.
- Implement a risk-based approach to undertaking complementary medicines post-market reviews, and include the development and application of risk profiles to inform the selection of post-market reviews.
- Provide the public with information on the complementary medicines that have been subject to post-market reviews and the outcomes of reviews.

B. Maintaining appropriate relationships with industry

Major activities:

- Develop consultation principles to guide regulatory transparency and accountability following consideration and feedback from the Australian Therapeutic Goods Advisory Council and other key stakeholders.
- Public consultation on the disclosure of commercially confidential information, to inform the development of TGA policy and a plan on commercially confidential information.
- Work with stakeholders to develop a proposal to provide device product names.
- Publish all hazard alert and recall notices on the TGA website.
- Examine the feasibility of developing a system to allow public searching of TGA regulatory actions.

C. Maintaining a robust risk management approach to all strategic and key operational risks

Major activities:

- Provide more detailed explanations of TGA's risk framework as it applies to different classes of therapeutic goods, initially focusing on listed complementary medicines.
- Actively 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.
- Conduct an evaluation of an early post-market risk communication scheme for new prescription medicines coming onto the market with consideration of international models.
- For prescription medicines, consider processes and regulatory changes that would help maintain the currency of Consumer Medicines Information (CMI) and approved Product Information (PI). Following public consultation, examine options for improving access to and information about CMIs and PIs, and if appropriate develop regulatory change proposals for Government consideration.
- For medical devices regulation, following industry and public consultation provide advice to Government on options around: recognition processes for third party assessment bodies including potential use for Australian manufacturers and levels of pre-market scrutiny for implantable medical devices.

D. Maintaining a sustainable and capable workforce

Major activities:

- Identify and publish key performance information, to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency.

E. Enhancing international regulatory cooperation through better exchange of information, work sharing and regulatory capacity building in our region

Major activities:

- Conduct an evaluation of an early post-market risk communication scheme for products coming onto the market with consideration of international models.

F. Investing in emerging technology to improve our capability

Major activities:

- Release an improved TGA website search engine.

3. Progress establishment of the Australia New Zealand Therapeutic Products Agency

Strategies Underpinning this priority:

A. Implementing the agreed Australia New Zealand Therapeutic Products Agency (ANZTPA) business to business projects with a view to establishing the ANZTPA joint therapeutic regulatory agency.

Major activities:

- Establish a Database of Adverse Event Notification to release publicly accessible information on adverse event reports to medicines.
- Develop a joint early warning system to inform the public of potential safety issues concerning therapeutic products.
- Investigate the feasibility of a common recalls portal to inform the public of recalls of therapeutic products.
- TGA and Medsafe will establish an integrated capability to conduct audits to assess good manufacturing practice.
- TGA and Medsafe to reform the business process for the evaluation of over the counter medicines, forming the basis for a common approach to lodgement of applications, assessment, evaluation and registration.

B. Enhancing international regulatory cooperation with New Zealand through better exchange of information, work sharing and regulatory capacity building

Major activities:

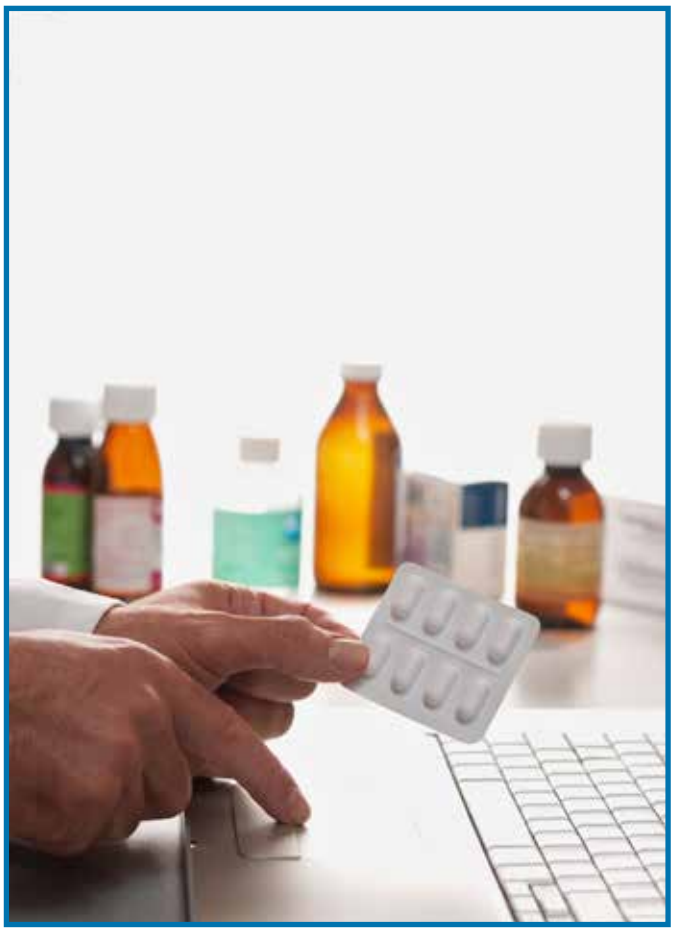
- Work with the ANZTPA task force central agencies and the Attorney-General's Department and New Zealand Counterparts to implement a program of work sharing and joint operations.
- Commence development and implementation of a Common Regulatory Framework for therapeutic goods regulation between Australia and New Zealand.
- Commence development of a Single Entry Point for business, initially as a source of information on ANZTPA regulatory developments.

Personnel

The recruitment of appropriately skilled and experienced staff will continue to challenge the TGA especially in areas requiring medical, project management and legal expertise. While the TGA anticipates an increased demand on resources for business as usual activities such as applications, variations and evaluations, a noted upward trend in FOI requests, S60 reviews and litigation over the last financial year indicates that a further increase in specifically skilled staff will be required to meet the demand. There is also the need to manage succession planning for medical officers who intend to retire or leave the organisation within the next two years.

The program of Blueprint reforms and ANZTPA activities will deliver long term organisational change in the TGA. As a result change management and performance development will continue to be an important priority over the coming year.

There is a strong commitment to the ongoing development of our people through active use of the Performance Development Scheme and broadening of our capabilities through our learning and development programs. The TGA will undertake projects to improve and reform our people management approaches. Human resource priorities will include:



- Develop and implement a TGA People Strategy using the results of the 2012 staff survey as a guide.
- Completion of the implementation of changes introduced in the Work Health and Safety Act (C'wealth) 2011.
- Review of recruitment and learning and development frameworks, and implementation of revised approaches.
- Development of TGA's first formalised Workforce Plan, and establishment of a workforce planning framework.

The 2012 Staff Survey demonstrated a strong commitment and satisfaction of staff to their job and to the TGA more broadly. There was a noted improvement since the 2010 Staff Survey in staff views about internal communication, bullying and harassment and learning and development opportunities.

A number of other results however, highlight areas where improvement is needed. These areas relate to:

- improving leadership and management
- career development progression and planning
- improving workplace behaviours
- balancing workloads.

Supporting technology

TGA has developed a 2012-2015 ICT Strategic Plan. The plan incorporates all major initiatives to be undertaken or supported by the TGA over the next several years. The plan takes account of the demands of operational support that arise from major reforms process over the next 12 months, ANZTPA and technology drivers.

A major task for the organisation over the next year is to make significant inroads towards the reduction of the number of systems in use. The aspiration is to move to a single workflow system which is used to support all product types throughout the pre and post market phases of the product lifecycle.

Alliances and shared responsibilities

Role of State and Territory Offices

The TGA has a small number of staff located in Brisbane, Sydney, Melbourne and Adelaide, and a second site in Fyshwick under the direction of Offices (branches) in TGA Symonston.

Cooperative work with other divisions or Australian Government agencies

The Australian Government continues to work on a range of reforms of the health system. As part of that system, the TGA is an active participant in the overall health reform agenda. Whilst the TGA works cooperatively with all divisions of DoHA it works most closely with the following divisions and portfolio agencies:

Division or Portfolio Agency	*Business Activity*
Chief Medical Officer and Office of Health Protection	Medical and public health advice relating to therapeutic goods and therapeutic goods governance.
Regulatory Policy and Governance Division	Collaboration on therapeutic goods regulation including advertising and implementation of device registries and the formation of the ANZTPA.
Medical Benefits Division	Collaboration on medical devices policy, adverse events and public awareness.
Pharmaceutical Benefits Division	Collaboration with the Pharmaceutical Benefits Advisory Committee, QUM and in dealing with medicines shortages.
Population Health Division	Collaboration on vaccination policy, adverse events reporting and monitoring and working with the ANZTPA taskforce.
People, Capability and Communications	People Strategy and TGA staff capability development and workforce planning.
Australian Commission on Safety and Quality in Health Care (ACSQHC)	Collaboration on QUM issues in relation to safe and appropriate use of therapeutic goods including packaging and labelling.
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)	Collaboration on assessment and therapeutic use of radionuclides.
Food Standards Australia New Zealand (FSANZ)	Collaboration on the Food-Medicine interface, particularly dietary supplements and therapeutic claims.
National Blood Authority (NBA)	Collaboration on regulation of blood and plasma.
National Health and Medical Research Council (NHMRC)	Regulation of clinical trials and issues related to clinical practice guidelines
Office of the Gene Technology Regulator (OGTR)	Collaboration on the regulation of genetically modified therapeutic goods.
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	Collaboration on the cosmetics therapeutics interface, nanotechnology issues and interface issues and scheduling of industrial chemicals.

The TGA also participates in the Regulators' forum, involving the Department of Agriculture, Fisheries and Forestry; FSANZ, ARPANZA; NICNAS, Australian Pesticides and Veterinary Medicines Authority (APVMA); and OGTR. The forum collaborates on harmonised training and exchange of best practice approaches for regulation in food, agriculture and health.

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

- APVMA in relation to medicines and Poisons Scheduling Committees.
- Central Agencies 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 Competition and Consumer Commission in relation to fair trading and consumer issues relating to promotion and use of therapeutic goods and health services.

International cooperation and collaboration

Therapeutic goods are developed and manufactured internationally and sold locally and internationally. The TGA needs to have collaborative arrangements with other international for the whole lifecycle of therapeutic goods to ensure that Australians have access to quality therapeutic goods in the shortest time possible.

The TGA will continue to explore opportunities for expanding international regulatory cooperation, particularly in relation to information exchange and inspection of manufacturing facilities. In 2012-13 The TGA will progress engagement strategies with key international regulatory agency stakeholders. In particular TGA will:

- Develop a framework for international engagement for 2013-15 which aligns our priorities for engagement with our business objectives.
- Develop a strategy for building (regulatory) capacity in our region, in consultation with other areas of the Department and the World Health Organization.
- Develop and implement a strategy for the review and maintenance of TGA's collaborative arrangements with overseas regulatory agencies, including guidelines for the exchange of confidential (regulatory) information.
- Implement the collaborative work program developed by the consortium of four regulators (TGA, Swissmedic, Health Canada and Singapore's Health Sciences Authority).
- Progress bilateral work sharing program developed with Health Canada, in the areas of approval of generic medicines, new prescription medicines, over-the-counter medicines and inspections of manufacturing facilities.

In addition, the significant co-operative effort with colleagues at Medsafe in New Zealand will continue with business to business projects, and a further program of work, to implement a trans-Tasman regulatory scheme for therapeutic goods.

Employees and suppliers

A summary of the TGA's proposed work program and resources allocated for 2012-13:

	Average Staffing Level	Staff Costs ($)	Suppliers Costs ($)
Market Authorisation Group	254.9	33,844,000	5,066,000
Monitoring and Compliance Group	226.7	27,925,000	5,011,000
Regulatory Support Group	178.3	22,245,000	29,176,000
ANZTPA	4.0	775,000	0
Business management			
Executive/leadership	9.0	2,072,000	1,182,000
Totals	672.9	$87,434,000	$40,436,000
TOTAL 2012-13 OPERATIONAL ALLOCATION			**$127,870,000**

Recoveries

A summary of the TGA's proposed cost recovery revenue for 2012-13 is shown below:

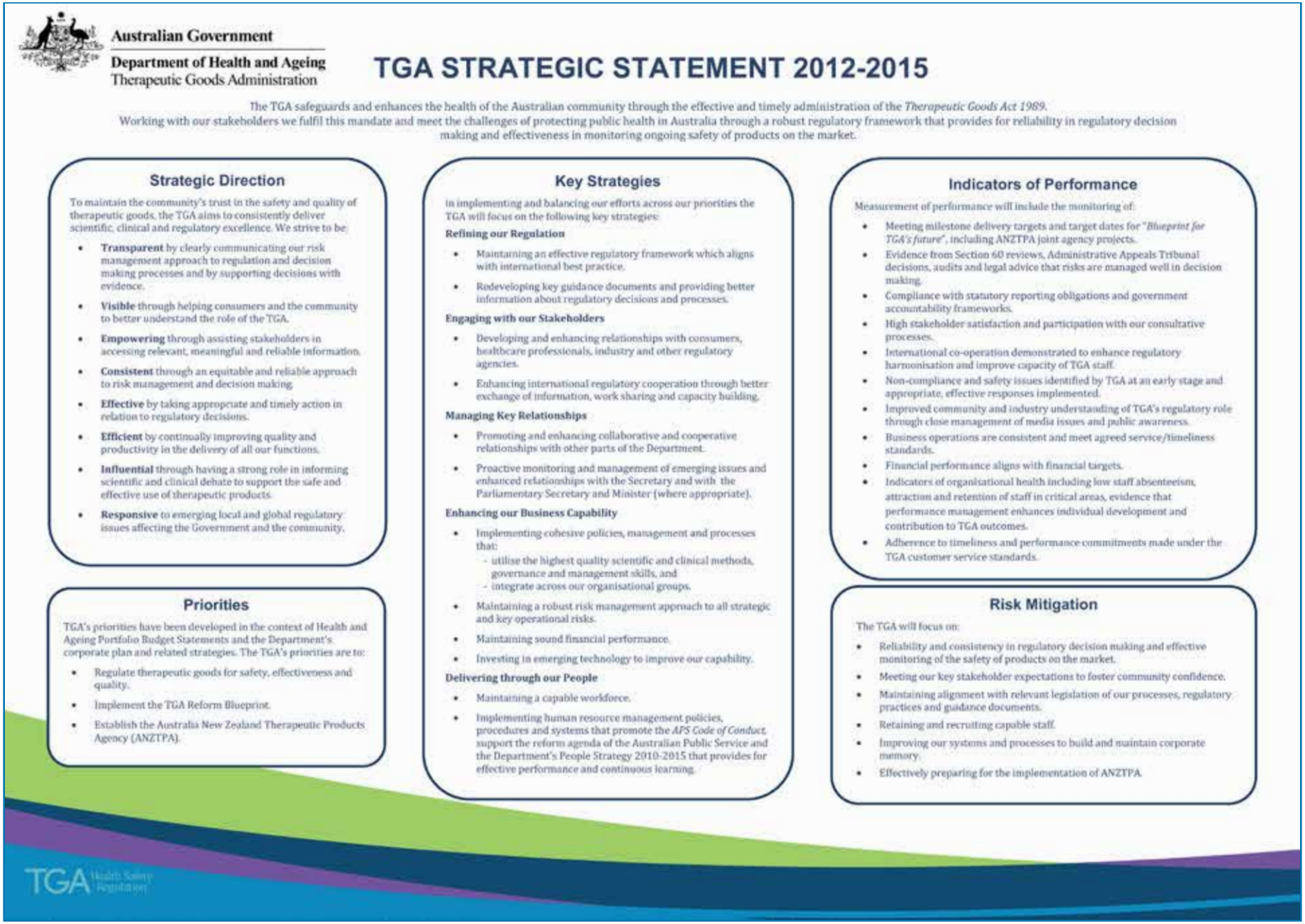
	Revenue ($)
Annual Charges & Licences	51,126,000
Application Fees	13,953,000
Conformity Assessment Fees	4,763,000
Evaluation Fees	41,717,000
Inspection Fees	7,079,000
Desktop & Application Audits	2,602,000
Other Income	6,331,000
TOTAL 2012-13 COST RECOVERY REVENUE	**$127,570,000**

Risk mitigation

The following summarises the strategies TGA will follow to mitigate our exposure to enterprise risks:

- 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.
- Retaining and recruiting capable staff.
- Maintaining alignment with relevant legislation of our processes, regulatory practices and guidance documents.
- Improving our systems and processes to build and maintain corporate memory.
- Effectively preparing for the implementation of ANZTPA.

Attachment A: Strategic Statement



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.

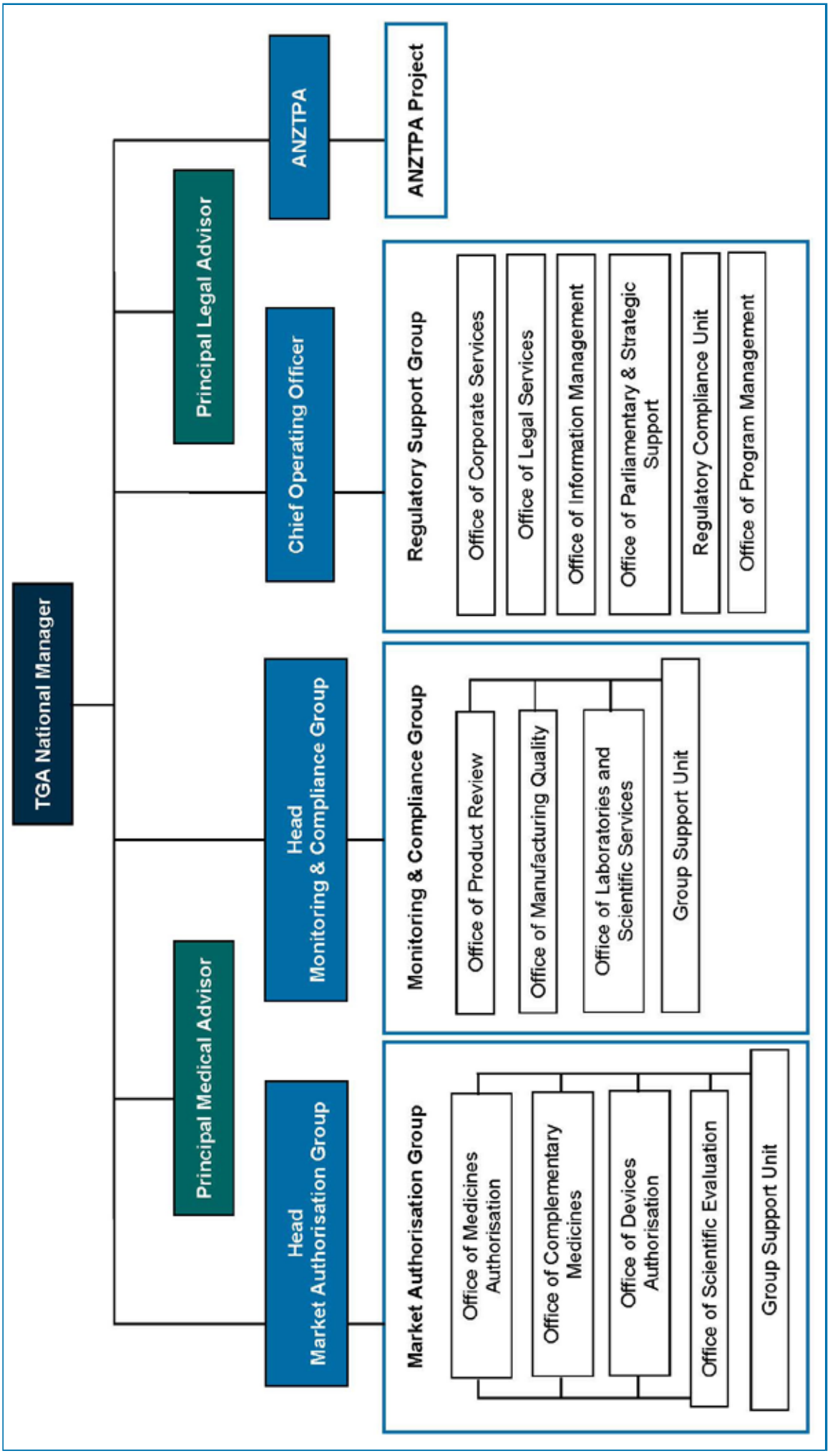
Risk Mitigation

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.

TGA Health Safety Regulation

Attachment B: Organisational Chart



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