Australian Government

Department of Health

Therapeutic Goods Administration

TGA Business Plan 2014 - 2015

Therapeutic Goods Administration (TGA)

TGA Health Safety Regulation

Strategic considerations

Mission

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

Our regulatory activities also contribute towards the Health Department's delivery of outcomes. They are carried out under a national framework and using a risk management approach.

Assessment and monitoring are carried out to ensure that therapeutic goods available in Australia are of an acceptable standard, and manufactured in accordance with the standards applicable to the type of product.

At the same time, we continue to ensure that the community has access, within a reasonable timeframe, to therapeutic advances.

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 Act). The objects of the Act are to:

1. provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy (performance) and timely availability of therapeutic goods that are:
   a. used in Australia, whether produced in Australia or elsewhere; or
   b. exported from Australia.
2. 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 premarket assessment before therapeutic goods are marketed and through postmarket monitoring and compliance strategies once products are on the market. We also assess the suitability of medicines and medical and therapeutic devices for export.

TGA also regulates manufacturers of therapeutic goods to enable them to 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 1), which outlines an overarching approach to our directions, priorities, performance and risk mitigation.

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 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 actions in relation to regulatory decisions
- **Efficient** by continually improving quality and productivity in the delivery of all our functions
- **Influential** through informing scientific and clinical debate to enable the safe and effective use of therapeutic products
- **Responsive** to emerging local and global regulatory issues.

Priorities for 2014-15

Our priorities for the next 12 months comprise:

- Continuing to regulate therapeutic goods for safety, effectiveness/performance and quality
- International regulatory convergence and work sharing
- Continuing a program of quality improvement in regulatory processes and reform in key areas, according to government priorities.

Regulating therapeutic goods for safety effectiveness/performance and quality

Critical to application of risk-based processes for therapeutic goods assessment is the work of TGA's premarket and postmarket Divisions, the Market Authorisation Group (MAG) and the Monitoring and Compliance Group (MCG).

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

The MCG is responsible for ongoing monitoring of therapeutic products supplied in Australia to ensure they continue to maintain an appropriate level of quality, safety and efficacy/performance throughout their lifecycle. The MCG is also the division responsible for the regulation of the manufacture of therapeutic goods. 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, project and change management, communications, committee support, parliamentary and human resource management services.

In undertaking our core business of risk-based market authorisation and monitoring and compliance and continuing to meet the objectives of safeguarding and enhancing the health of the Australian community, we will also look for opportunities for reducing regulatory burden on industry and health professionals.

We will continue to publish a six-monthly report detailing measures of business performance and a six-monthly report against Key Performance Indicators (KPIs).

International regulatory convergence and work sharing

We need to engage with regulatory counterparts internationally, as well as with regional and international organisations, to support the implementation of science-based standards that ensure the safety and quality of products throughout the supply chain.

The TGA participates in international harmonisation, regulatory convergence and work sharing activities with international agencies and overseas regulators. These activities will help to reduce effort in premarket evaluation of therapeutic goods, while timely exchange of information on products that are already on the market enables us to make more informed and consistent regulatory decisions about the safety, quality, efficacy and performance of therapeutic goods available in Australia.

Successful relationships with our international regulatory counterparts require the investment of time and other resources. The major return on this investment is a reduction in duplication of effort, leading to a more efficient and effective regulatory system. Other benefits include a better understanding of emerging trends and access to the latest regulatory science developments, more informed regulatory decisions for industry and better safeguards for the Australian public.

Continuing the quality improvement and regulatory reform process

In 2014-15, the TGA will continue to implement a quality improvement program around regulatory processes and reforms in key areas. Consistent with the Government's deregulation and red tape reduction agenda, the main focus will be an examination of premarket processes for different categories of medicines and devices to ensure that TGA targets its regulatory efforts and level of regulatory oversight according to the risk of the products being regulated.

In addition, we will continue to improve the way we communicate with the public about the benefits and risks of therapeutic goods and will optimise a range of regulatory processes in the premarket area. Finally, we will enhance postmarket surveillance capacity:

- through new initiatives to stimulate adverse event reporting for medicines from pharmacists, general practitioners and consumers
- through a collaborative program with the states and territories on enhanced reporting of adverse events following immunisation (AEFI)
- through collaboration in the establishment of clinical quality registers for cardiac devices and breast implants and sentinel reporting sites.

We will continue publishing a half-yearly report on the progress of these improvements and reforms.

Further, we will support the Government's review of medicines and medical devices, and commence work to implement the review panel's recommendations on the following:

- ensuring there is an appropriate balance between risk and benefit in the regulation of prescription, over-the-counter, complementary medicines and medical devices, as well as access for individuals to unapproved medicines and medical devices
- simplifying and streamlining the approval processes undertaken by TGA. This will include recommendations on:
  - fast tracking approvals processes for medicines and medical devices
  - opportunities for working together with trusted regulators in other jurisdictions, including the potential for work-sharing assessments for products marketed in multiple countries; and
  - exploring how risk assessments, standards and determinations of trusted regulators can be used more extensively by Australian regulators when approving the supply of medicines and medical devices
- ensuring regulatory arrangements are sufficiently flexible to accommodate developments in medicines and medical devices, including exploring opportunities to streamline approvals that cross regulatory categories
- improving the processes that assist industry, researchers and consumers to navigate the regulatory system for medicines and medical devices
- supporting work underway on medical device reforms and clinical trial approval arrangements in Australia
- any other matters that the review committee regards as important and relevant to the safe and efficient supply of effective medicines and medical devices to the Australian people.

Significant changes and challenges

In the work program planned for 2014-15, we need to be able to maintain high quality 'business as usual' regulatory services while also identifying opportunities for deregulation and delivering on an extensive reform program.

As a technically-based regulator, we can face challenges in recruiting specialist scientific and medical staff, particularly in a competitive market with the medicines and devices industry. Recruitment must also be carried out in accordance with Australian Public Service (APS)–wide recruitment policies.

We also need to ensure that we have the capacity and capabilities to meet emerging challenges in relation to:

- our premarket evaluation of risks and harms of products remaining contemporary and continuing to reflect international best practice
- having the capacity and capability to investigate problems and complaints with therapeutic goods
- having the capacity and capability to appropriately evaluate emerging technologies
- meeting increasing patient demand for early access to novel therapies, where greater uncertainties about the benefits and risks of products exist
- improving our readiness for a wider roll out of personalised medicine
- improving our pharmacovigilance of medicines and postmarket monitoring of medical devices, including signal detection and analysis
- improving quality of therapeutic goods through wider use of risk-based approaches to manufacturing inspections
- applying social science and market research to better target information to help consumers and health professionals make informed decisions about therapeutic goods.

Management of changes and challenges

Strategies used in implementing and balancing our effort across our priorities during 2014-15 will be to:

1. Refine our regulation

Maintain an effective regulatory framework that is contemporary and in line with international best practice and redevelop major guidance documents and provide more information—in a simple to access style—about regulatory decisions and processes.

2. Engage with our stakeholders and manage key relationships

Develop, enhance and maintain relationships with consumers and healthcare professionals and maintain appropriate relationships with industry. Enhance international regulatory cooperation through better exchange of information, work sharing and capacity building.

Minimise duplication of effort through stronger collaboration with overseas regulators and assessment bodies.

Promote and enhance collaborative and cooperative relationships with the rest of the Department of Health. Proactive monitoring and management of emerging issues and strong communication with the Assistant Minister and Minister.

3. Enhance our business capability

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

Manage major strategic, financial and operational risks. Improve business processes and systems to improve client services.

Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to better regulate according to product risk.

4. Deliver through our people

Maintain a capable workforce that adapts flexibly to changes introduced through regulatory reform, deregulation initiatives 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, support the reform agenda of the APS and TGA's People Strategy 2012–2015.

In addition to these strategies, we are also responding to the 2014 APS Employee Census results through the implementation of an action plan that includes a range of organisation-wide initiatives that focus on major survey outcomes.

Operating environment

Deliverables and measures of success

Our deliverables and measures of their success are derived from the Department of Health's Portfolio Budget Statements 2014-15, namely:

- Continuing the regulation of therapeutic goods for safety, effectiveness/performance and quality
  - percentage of premarket evaluations/ assessments completed within legislated or other target timeframes
  - percentage of alleged breaches of the Act received that are assessed within 10 working days and an appropriate response initiated
  - percentage of domestic and overseas licencing and surveillance inspections completed within target timeframes
  - percentage of other TGA postmarket activities that took place within target timeframes
- Implementing international harmonisation, work sharing and joint operations with comparable international regulators
  - enhanced cooperation and work sharing, including increased use of information from international regulators
- Continuing the reform of regulation of therapeutic goods on the basis of risk, and contributing to the Government's deregulation agenda by identifying and progressing opportunities to reduce red tape.
  - Ongoing implementation of reforms in accordance with the published plan for TGA Reforms.
  - Number of reforms implemented to enhance TGA's regulatory processes.
  - Contribution to a review/s to identify opportunities to reduce regulatory burden.

In addition, we will continue to publish performance information, including six-monthly reports against agreed Key Performance Indicators (KPIs) to provide quantitative and qualitative information on our organisational effectiveness and operational efficiency.

During 2014-15 we will continue to focus on risk in managing our regulatory activity

Workforce planning

Implementation of a workforce planning framework and plan 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
- 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 development and maintaining 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
- actively manage critical job roles to maintain a critical talent pool, for example medical officers and inspectors
- increase capability and capacity in relation to regulatory reform and deregulation
- manage attraction and retention of new staff in light of revised APS recruitment arrangements
- increase mobility and flexibility of existing staff.

Outputs to deliver

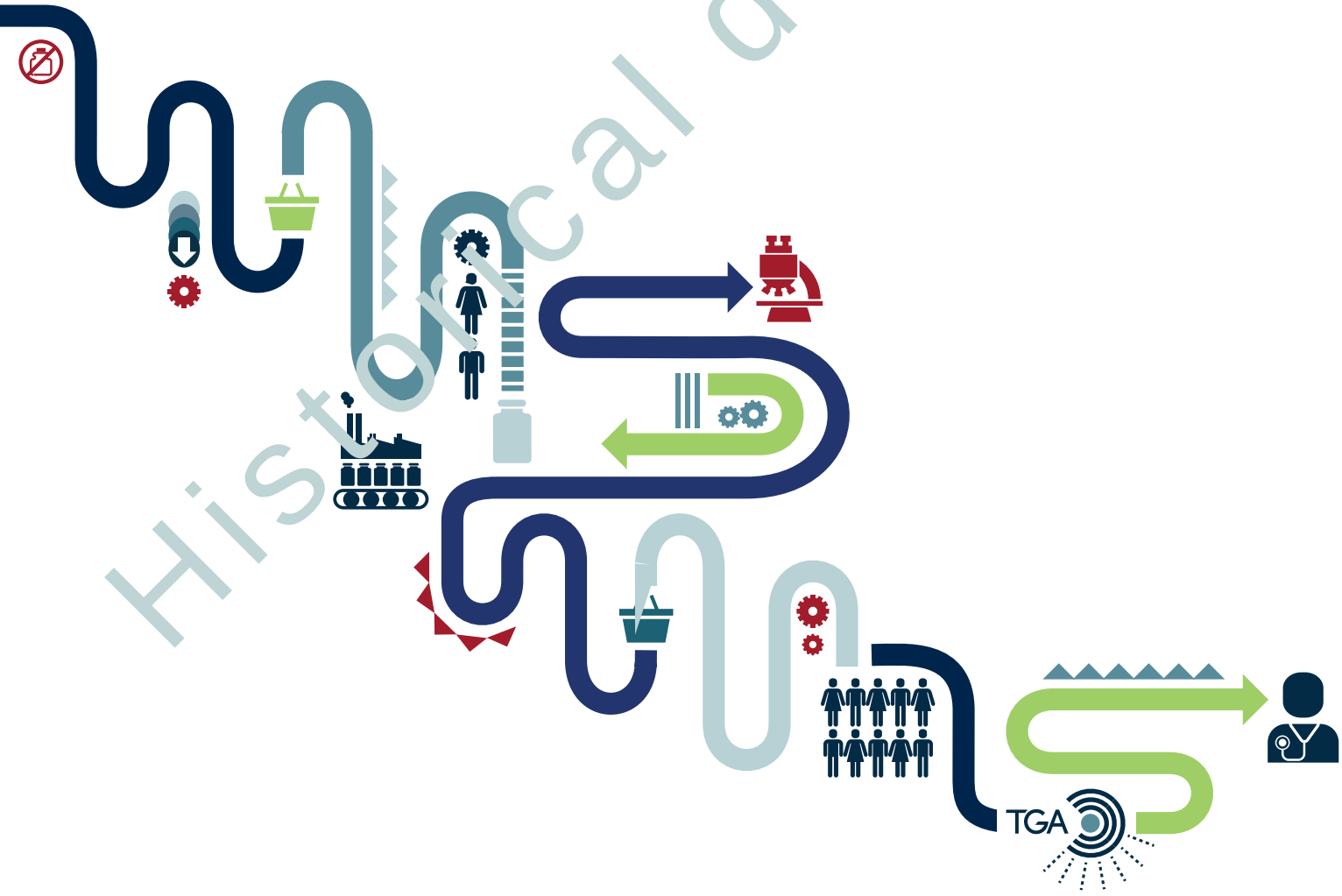
Regulation of therapeutic goods for safety, effectiveness/ performance and quality

Strategies underpinning this priority

- Use a risk management approach to carry out assessment and monitoring to ensure therapeutic goods available in Australia are of an acceptable standard.
- Support the Australian community in having timely access to therapeutic advances.
- Maintain an effective regulatory framework that is contemporary and in line with international best practice.
- Implement policies, management and processes that utilise the highest quality scientific methods, governance and management skills, and integrate seamlessly across our organisational groups.
- Manage significant 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 they continue to effectively assist our regulatory decision making process.
- Provide more information to stakeholders about regulatory decisions and processes.
- Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to regulate according to product risk.

Lead TGA Group:	Market Authorisation Group (MAG)
Activity	**Expected outputs**
Undertake market authorisation for medicines, medical devices, biological and blood and tissue products, together with the exports regulatory function	**Complementary medicines** • Continued market authorisation activities for listed medicines, registered complementary medicines and new substances. • Continued work to update regulatory guidance material to assist product sponsors. • Development of processes and systems commenced to support streamlined registered complementary medicine and new substance applications. **Over-the-Counter (OTC) medicines** • Evaluation/assessment of applications completed within target timeframes. • The reformed OTC premarket evaluation business process finalised and support systems improved. • Improved guidance developed for 'acceptable presentations' of OTC medicines. **Prescription Medicines** • Evaluation/assessment of applications completed within legislated timeframes. • Continued streamlining of systems to support market authorisation of new medicines and variations to existing products. • Faster and more efficient processes developed for the evaluation of generic medicines. • Continued work to update Regulatory Guidelines, taking stakeholder feedback into account. • Potential antimicrobial resistance strategies considered during assessment of antimicrobials. **Medical Devices** • Market authorisation activities for medical devices and in vitro diagnostic medical devices (IVDs) completed within target or legislated timeframes. • Continued implementation of the transition for reclassification of joint replacement implants from class III to class III medical devices. • Transition to the IVD Framework continued and regulatory reforms for IVDs developed and implemented. • Continued refinement of medical device conformity assessment and application for inclusion processes as part of the Business Improvement Program. **Biologicals** • Market authorisation activities for biologicals undertaken. • Processes developed and implemented for varying ARTG entries for biologicals. • Implementation of the Biologicals transition strategy progressed. **Other** • Market authorisation activities for export-only therapeutic goods undertaken. • Appropriate access to therapeutic goods provided to health professionals and consumers, through the Special Access Scheme and other related frameworks. • Opportunities from eHealth initiatives explored. • Delivery of evaluation capability continued in the areas of clinical, toxicology, pharmaceutical chemistry and biological science. • The Drug Control Section from the Office of Chemical Safety integrated within TGA to facilitate continued effective management of import-export processes for controlled and reportable substances and greater alignment with TGA processes for access to unapproved medicines. • Medicines scheduling processes, including the Advisory Committee on Medicines Scheduling, integrated into TGA activities in response to the Review of Medicines Scheduling.

Lead TGA Group:	Market Authorisation Group (MAG)
Activity	**Expected outputs**
Reducing regulatory burden	• Implementation progressed for digital prescription and OTC medicines submissions and monitoring systems. • Potential regulatory changes identified and investigated to more closely align assessment with risk in the areas of OTC medicines and medical devices. • Electronic lodgement of clinical trial notifications (CTN) and clinical trial exemption (CTX) applications implemented
Regulatory science	• Consultation on options, and standard protocols developed for requirements for clinical data for premarket assessment of medical devices. • TGA's capacity to appropriately evaluate innovative emerging technologies assessed, focusing on: – rapidly evolving areas of medical therapy (e.g. oncology) and personalised medicine – emerging technologies such as nanotechnology – device development that is heavily dependent on software.
International Harmonisation of Ingredient Names	• Following consultation, RIS developed and the preferred options for reform implemented.
Medicine shortages	• Implementation of the agreed approach continued for communicating and better managing shortages of medicines. Success of the protocols implementation monitored.
Medicines compounding	• Following consultation, RIS developed and the preferred options for reform implemented.



Lead TGA Group:	Monitoring and Compliance Group (MCG)
Activity	**Expected outputs**
Undertake post-market monitoring and regulatory activities for medicines, medical devices and blood and tissue products, together with the recalls and advertising regulatory functions	• Postmarket monitoring and surveillance activities undertaken across all product types to ensure they remain compliant with regulatory requirements. • Activities relating to recalls and advertising regulatory functions undertaken. • Surveillance, enforcement and related activities undertaken. • Adverse event reporting by consumers and health professionals improved through education and awareness raising activities and improved reporting interfaces implemented. • Public access provided to therapeutic goods adverse event data, early warnings and alerts, and more detailed information provided about therapeutic goods recalls. • Inspections and assessments of manufacturers undertaken, nationally and internationally, while utilising good manufacturing practice (GMP) clearances from international partners to the maximum feasible extent for overseas manufacturers. • Monitoring and compliance laboratory testing, investigation and reviews undertaken in response to quality or safety concerns. • Advertising complaints responded to in a timely manner using a risk based approach. • Continued streamlining of administrative processes for handling of advertising complaints. • Lot release program for vaccines conducted.
Regulatory science	• Early assessment of and response to potential safety signals identified through postmarket monitoring. • Effective triage processes in place to keep pace with an increased flow of adverse event reports as a result of increased rates of reporting. • Input provided to whole of government efforts for assessing vaccine safety by providing timely information on national rates of adverse events following immunisation. • Proactive risk assessment strategies applied for the planning of manufacturing quality inspections. • A risk based laboratory testing program conducted to monitor compliance with required standards.
Device Registries	• Together with the Department's Acute Care Division and other stakeholders, work commenced to develop patient contact registers for high risk implantable devices and clinical quality registers for implantable cardiac devices and breast implants. • Consultation undertaken and a Cost Recovery Impact Statement (CRIS) developed on the preferred option for cost recovery for registries. • Legislative amendments prepared if required to support levies for the ongoing administration of each registry.
Regulatory Compliance	• Compliance efforts focused to areas of greatest risk. • Information published about decisions made to cancel therapeutic goods for non-compliance with regulatory requirements. • Continued development of appropriate responses to target falsified medicines and illegal internet sales of therapeutic goods. • Continued cooperation with the Australian Customs Service and Border Protection Service in the development of targeted approaches to prevent the importation and/or export of illegal therapeutic goods.

Lead TGA Group:	Regulatory Services Group (RSG)
Activity	**Expected outputs**
Provide support services that enable the TGA to more effectively undertake its regulatory responsibilities	**Program and Change Management** • Continued implementation of business improvements to provide a streamlined approach for regulatory case management, reporting and client services, including: – consistent, easy to use and streamlined application processes for conformity assessment – readily accessible and 'real time' information on the status of conformity assessment applications for industry and TGA staff – development of a single source of consistent information available across TGA s[illegible] that stakeholders do not receive conflicting advice – a customer self-service initiative – rollout of the eCTD facility for prescription medicines. • A delivery strategy for the implementation of business change throu[illegible]n p[illegible]jects. • A 'centre of excellence' for change and project management service d[illegible]liver[illegible] maintained. • Timely and accurate information provided on project statu[illegible], i[illegible]sues, [illegible]isks and critical decision points. • Delivery of TGA reforms, the Business Improvement P[illegible]ogram[illegible]nd the deregulatory agenda supported **TGA Advisory Committees** • Continued administrative support provided [illegible]o TGA's advisory committees, subcommittees and working groups. • Recruitment processes undertaken fo[illegible] criti[illegible]al 2014-2015 statutory advisory committee vacancies. • Continued targeted use of the c[illegible]mittees and associated advice to assist TGA decision making. • More comprehensive and timely p[illegible]blic reporting of committee outcomes. • Review undertaken of [illegible]ature and number of committees, to reduce administrative burden. • Advisory Commi[illegible]tee[illegible]r Medicines Scheduling integrated into TGA committee support processes. **Human Resources** • Continued [illegible]R s[illegible]pport provided to the TGA for recruitment, learning and development, payroll, work health and safety and performance management activities. • T[illegible]A's wor[illegible]kforce plan updated. • Con[illegible]nued refinement of recruitment processes in line with whole of government [illegible]rocesses to improve TGA ability to define and fill critical job roles. • [illegible]Continued refinement of the work health and safety management system in alignment with the overall Departmental system and strategies. • 2014-15 training plan developed and implemented. • Strengthened support for active manager assistance in case management of underperformance and of compensation cases. **Information management** • Continued provision of information technology support and communication systems and solutions to support business processes. • Continued development and implementation of an integrated information environment and system. **Parliamentary Support** • Timeliness and provision of accurate and appropriate information in parliamentary support activities.

Lead TGA Group:	Regulatory Services Group (RSG)
Activity	**Expected outputs**
	Communications • Continued provision of internal and external corporate communications for the TGA. • Further development of education materials and social media content targeted to areas of demand. • Migration to a new Content Management System to improve searching and content structure on the TGA website. • Simpler and more targeted information provided and redundant, out-dated and trivial content archived or removed from our website. • High quality and timely responses provided to stakeholder enquiries via email and telephone through the Public Contact Team. **Finance** • Continued provision of financial, procurement and property support to the TGA. • Financial management policy relevant to TGA financial frameworks documented and communicated. • Alignment of business planning with budgeting at the branch and section and project level progressed. • Strengthened financial governance of programs and projects. • Investment funding supported for 2014-15 initiatives on international collaboration, Australia-New Zealand regulatory alignment and implementation of regulatory reforms. • A new activity based costing tool implemented and a report prepared on fees and charges. • TGA is compliant with the Cost Recovery Framework issued by the Department of Finance in July 2014. • Business improvements in financial operations implemented. • Review of the LVT exemption scheme completed with options proposed for Government. • Decision made on the TGA's long-term accommodation requirements in Canberra. **Risk Management and Business Continuity Framework** • Executive kept informed of progress of treatments identified in the TGA Enterprise Risk Plan. • Robust business continuity framework further developed, including regular testing of the framework. **Legal Services** • Legal advice and assistance to the TGA. • Continued improvements to awareness and knowledge within TGA of the legal environment in which we operate. • Assistance provided with the implementation of TGA's reforms and the deregulation agenda.
Regulatory science	• Market research utilised to help stakeholders make more informed decisions about therapeutic goods and comply with our regulatory requirements. • Research applied to drive prioritisation and development of TGA communication and education activities and content. • Effective use made of external expertise and regulatory science initiatives led by other regulators.

International harmonisation and work sharing

Strategy underpinning this priority

- Enhance international collaboration through participation in international regulatory convergence and work sharing initiatives that reduce effort and international duplication in pre- and postmarket evaluation of therapeutic goods.

Lead TGA Group:	Market Authorisation Group (MAG)
Activity	**Expected outputs**
Enhance cooperation and work sharing with international regulators in the premarket assessment of medicines and medical devices	**Generic Medicines** • Increased exchange of, and reliance on, the evaluation reports of trusted international regulators to support Australian regulatory decision making. • Improved understanding of international regulators processes to increase opportunities for harmonisation and work sharing. • Implementation of harmonised processes and protocols for work sharing with Health Canada and opportunities identified for work sharing with other trusted international regulators. • Participation in the European Directorate for the Quality of Medicines and HealthCare's procedure for the Certification of Suitability to the monographs of the European Pharmacopoeia. **New Chemical Entities (including orphan drugs)** • Program developed for exchange of evaluation reports for new chemical entities (NCEs), including orphan drugs, with Health Canada and opportunities identified for exchange of information and work sharing with trusted international regulators. • Exchange of full assessment reports related to marketing authorisations of orphan medicines with the European Medicines Agency. **OTC medicines** • Opportunities identified for work sharing with Health Canada to support the registration process for OTC medicines, including the development of further OTC monographs. **Complementary medicines** • Opportunities identified for work sharing with Health Canada to support the evaluation of registered complementary medicines and ingredients for use in listed medicines. • Greater use of evaluations of new substances performed by overseas regulators explored. **Medical Devices** • Phased program of confidence building with European Notified Bodies completed.
Influence the international regulatory harmonisation agenda through participation in key multilateral fora	• Contribution made to the development of new international regulatory standards in the areas of vaccines, immunisations, medical devices, sterilization, GMP, and non-propriety names through participation in standard setting bodies such as the World Health Organization (WHO) and the International Organisation for Standardization (ISO). • Contribution made to the harmonisation of existing international standards in the areas of evaluation of Active Drug Substance Master Files/Drug Master Files; granting of "biowaivers", and medical devices through participation in multilateral initiatives of international regulators. • Influence the international regulatory harmonisation agenda through membership of the Executive Committee of the International Coalition of Medicines Regulatory Authorities.

Lead TGA Group:	Monitoring and Compliance Group (MCG)
Activity	**Expected outputs**
Engage in activities to reduce duplication and improve efficiencies in inspection of manufacturing sites	• Protocols and criteria developed for exchange of manufacturing inspection information with trusted international regulators. • Reduced number of inspections carried out in countries where other regulators have also been inspecting the same manufacturing sites. • Work sharing with Health Canada increased on GMP inspections and desk top assessments and opportunities for work sharing with other trusted international regulators identified. • Internationally consistent manufacturing quality standards applied.
Enhance postmarket monitoring	• Increased use of risk communication received from other regulators to trigger safety investigations and appropriate regulatory action if required. • Work sharing with Health Canada on postmarket monitoring—evaluations undertaken of Periodic Safety Update Reports and Risk Management Plans where products are common to both jurisdictions. • Database for collecting and analysing adverse events upgraded to allow more effective international sharing of information and improved signal detection.
Influence the international regulatory harmonisation agenda through participation in key multilateral fora	• Contribution to the development of new international regulatory standards and regulatory requirements through participation in initiatives of regulators (for example, Medical Device Single Audit Program) and standard setting bodies such as the WHO, Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the ISO. • Contribution to regional capacity building through participation in forums such as the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines and potentially through greater involvement in regulatory capacity development for medicines in the Mekong region.

Lead TGA Group:	Regulatory Support Group (RSG)
Activity	**Expected outputs**
Coordinate TGA's participation in international activities	• TGA's contribution to influencing the development and harmonisation of international regulatory standards supported through the strategic planning of bilateral and multilateral work sharing and harmonisation activities supported. • Implementation of TGA's International Engagement Strategy 2013-2015 continued. • New opportunities identified for expanding international engagement leading to international regulatory harmonisation and work sharing projects. • TGA's participation in the International Coalition of Medicines Regulatory Agencies (ICMRA) Management Committee and GMP Inspections Project supported; leading in the implementation of the ICMRA generic drugs work plan and sub-project on GMP data requirements.
Coordinate the development of revised collaborative arrangements with trusted international regulators	• Strengthened collaboration and formalised work sharing arrangements in place with overseas regulators.
Provide support services that enable the TGA to effectively participate in international collaboration and work sharing initiatives	• IT architecture and supporting protocols developed for sharing confidential information with trusted international regulators that incorporate appropriate security measures to protect information from unauthorised use or accidental modification, loss or release.
Continued trans-Tasman cooperation between the two national regulators and the degree of harmonisation between regulatory schemes	• Enhanced information-sharing in relation to pre- and postmarket regulatory functions performed by each regulator, such as: – regulatory compliance and pharmacovigilance – laboratory tests – investigations into quality defects or manufacturing errors – evaluation reports – medicines scheduling. **Premarket process for medicines** • Continued implementation of a common approach to OTC medicine premarket business processes. • Common electronic platform shared for OTC and prescription medicine applications. • Guidance information developed for industry about requirements for making changes to approved medicines in Australia and New Zealand. • Further mutual recognition of TGA and Medafe GMP audits of manufacturers in their respective jurisdictions or those located in third countries. **Pharmacovigilance** • Common adverse events/pharmacovigilance database facilities strengthened.

Continuing the therapeutic goods reform process

Strategies underpinning this priority

- Develop and enhance key partnerships with consumers, healthcare professionals and other regulatory agencies.
- Maintain appropriate relationships with industry.
- Maintain an effective regulatory framework that is contemporary and in line 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.
- Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to reduce red tape.

Lead TGA Group	Market Authorisation Group (MAG)
Activity	**Expected outputs**
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. • RIS and legislative amendments drafted for introduction into Parliament, subject to Government policy approval.
Enhancing postmarket monitoring so as to more efficiently focus postmarket resources towards problem areas.	• Data collected from listing compliance reviews performed by the TGA analysed to inform risk profiles and prioritisation of subsequent reviews.
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.	• Proposed Therapeutic Goods Order designed to address poor labelling and the associated public health implications subjected to public consultation to help inform the final RIS and decision. Implementation through a new Therapeutic Goods Order.
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.	• A communication and education plan developed and implemented to communicate our risk based framework more broadly.
Explore mechanisms for providing explanations of 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.
Electronic submissions	
Replace paper dossiers for prescription medicines registrations with electronic submissions that meet international standards.	• Worked with internal stakeholders and industry to implement eCTD format submissions.

Lead TGA Group	Market Authorisation Group (MAG)
Activity	**Expected outputs**
Medical Device Reforms	
Develop regulatory definition of hip, knee or shoulder joint replacement implants to clarify the range of medical devices captured by the reclassification.	• RIS developed to support government decision making on options, including appropriate consultation. • Appropriate regulatory amendments sought.
Provide advice to Government on a modified package of medical device reforms, building on previous proposals and consultation, and taking into account the Government's deregulation policy.	• RIS developed to support government decision making on options, including appropriate consultation with stakeholders.
Biologicals	
Assess approaches for the regulation of autologous stem cells, including aspects related to advertising. Consult publicly on regulatory options and consider whether changes to current regulatory frameworks are warranted.	• Discussion paper developed that considers issues and potential options to address them. Subject to Government endorsement, public consultation on regulatory options.
Experimental products	
Reform regulations and processes surrounding access to unapproved therapeutic products through the Special Access Scheme, including development of electronic submissions.	• Internal policy paper developed on options for reforming regulations and processes. • RIS developed to support Government decision making on options, including appropriate consultation with stakeholders • Implementation of preferred options commenced, including systems for electronic applications and/or notifications.
Toxicology	
Review the way in which the TGA undertakes regulatory toxicology to ensure that priorities, approaches and staffing resources are aligned with contemporary international standards and commensurate with risk.	• Review of the toxicology section completed.
Reducing regulatory burden	
Contribute to the Government's deregulation agenda by identifying and progressing opportunities to reduce red tape.	• Subject to government approval, this could include work towards the following activities: • providing greater flexibility of pathways to market authorisation for prescription medicines, medical devices and breakthrough therapies • considering allowing notification and/or self-certification for some processes: – minor variations to existing approved products and export-only medicines – health professional authorisation for use of medicines and medical devices not yet approved in Australia • reviewing the regulatory requirements for certain low-risk medicines and medical devices, including through possible alignment with comparable food, cosmetic or other consumer product regulatory regimes.

Lead TGA Group	Monitoring and Compliance Group (MCG)
Activity	**Expected outputs**
Recalls	
Promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health professionals and to consumers.	• Review completed and update of Uniform Recall Procedure for Therapeutic Goods, including consultation with stakeholders and development of a draft revised instrument.
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. Enhance sanctions and penalties for repeated breaches of non-compliance (as well as strengthening sanctions and penalties for advertising). Apply, enforce and publicise sanctions and penalties, including for advertising breaches.	• Subject to Government approval, revised RIS developed and approval sought for proposals for the future regulatory framework for the advertising of therapeutic goods that streamline and clarify advertising requirements and provides for penalties that are proportionate to the nature of the offence committed. • Subsequent regulatory changes drafted and submitted for policy approval for implementation. • Subject to Government approval, continued development of a more effective advertising complaint handling process and operating procedure for investigating non-compliance with advertising requirements.
Reducing regulatory burden	
Contribute to the Government's deregulation agenda by identifying and progressing opportunities to reduce red tape.	Subject to government approval, this could include work towards the following activities: • reviewing the advertising requirements for non-prescription medicines, including the need for pre-approval of advertisements • reviewing certain fee structures and administrative processes to ensure barriers are removed for businesses to maintain contemporary and effective product registrations and corresponding information for health professionals and consumers.

Lead TGA Group	Regulatory Services Group
Activity	**Outputs**
Strategic engagement and information accessibility	
Work transparently with other key providers of information to enhance the information available to the public. Ensure the TGA website, is current, accurate, relevant, timely and up to date, and meets the needs of its audiences.	• Functionality of the TGA website improved by introducing new ways of presenting, searching and managing content, including Product Information and Consumer Medicine Information documents. • Feedback from Australian Therapeutic Goods Advisory Council deliberations used to shape TGAs stakeholder and communication activities. • Participation in conferences and events continued, including plenary presentations, as well as other educational activities with key stakeholders and partnered organisations. • Continued dissemination of communication and education materials and testing new materials that are audience-centred, based on outcomes of research into the needs of major stakeholders.
Implement agreed Key Performance Indicators (KPIs) to provide quantitative and qualitative information on the TGAs organisational effectiveness and operational efficiency.	• Implementation of KPI reporting completed with the publication of the full set of reporting measures in the January to June 2014 report. • KPI reporting continued as a business-as-usual activity.
Complete changes to reflect TGAs approach to disclosure of commercially confidential information.	• Update of TGA forms and guidance documents to reflect the approach.
Reducing regulatory burden	
Contribute to the Governments deregulation agenda by identifying and progressing opportunities to reduce red tape.	Subject to government approval, this could include work towards the following activities: • implementing a new business environment to improve engagement with business and other regulators: – electronic submission using pre-populated forms – review of information requirements – applicant access to milestone dates and expected completion dates • enabling streamlined data sharing to make TGA information directly available to the Pharmaceutical Benefits Scheme.

Alliances and shared responsibilities

Cooperative work with other Australian Government agencies

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

- Food Standards Australia and New Zealand, on regulatory issues at the food-medicines interface
- The Office of Chemical Safety, particularly relationships with the National Industrial Chemicals Notification and Assessment Scheme on chemicals and cosmetics
- Office of Gene Technology Regulator on gene technology in therapeutic goods
- The Department of Agriculture on biosecurity issues
- Australian Pesticides and Veterinary Medicines Authority on veterinary medicines and in relation to chemical and veterinary medicines scheduling issues.

A Regulators' forum of the heads of these agencies, including the TGA National Manager, meets three times annually 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:

- Departments of Prime Minister and Cabinet and Foreign Affairs and Trade on the deregulation agenda and international regulatory collaboration
- Commonwealth Ombudsman's office in relation to provision of information and determination of complaints
- Australian Customs and Border Protection Service in relation to importation and export of therapeutic goods
- Australian Competition and Consumer Commission in relation to fair trading and consumer issues relating to promotion and use of therapeutic goods and health services.

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. TGA's target comprises part of the broader Health Department's target. Indigenous staff comprise 0.4% of the TGA workforce.

Funding, capital expenditure and anticipated revenue

Our finances are managed through the Therapeutic Goods Special Account (under Section 80 of the *Public Governance, Performance and Accountability Act 2013* and Section 45 of the *Therapeutic Goods Act 1989*).

TGA's activities are fully cost recovered from fees and charges imposed on industry, with the exception of Government funding provided for the alignment of Australia and New Zealand therapeutic arrangements, and departmental funding for the operation of the Drug Control Section and Medicines Scheduling Secretariat.

2014-15 Portfolio Budget Statements

Budgeted Expenses

	2013-14 Actual expenditure	2014-15 Estimated expenditure
TGA Special Account	**$137,334,000**	**$147,736,000**
Budgeted increase in expenditure (including capital) comprises:		
Estimated actual 2013-14		**$137,334,000**
Capital expenditure		$5,587,000
Supplier expenses		($782,000)
Employee expenses		($121,000)
Government programs		$5,718,000
Budgeted expenses 2014-15 (including capital)		**$147,736,000**

The increase in expenditure (including capital) in 2014-15 relates to funding provided for Government budget measures and capital funding for the Business Improvement Program.

Approved capital expenditure

	2014-15 Proposals	2015-16 Out year 1	2016-17 Out year 2	2017-18 Out year 3
Approved internally funded projects	$15, 231,000	$10,621,000	$7,710,000	$5,710,000

Capital expenditure includes funding for the Business Improvement Program, funding for Government budget measures and standard lifecycle replacement programs for property, information technology and laboratory equipment.

Anticipated revenue movements

	2014-15	2015-16	2016-17
Anticipated revenue	$138,658,000	$135,260,000	$136,593,000

Risk

The table below summarises the risks faced by TGA that are rated as high:

Risk name	Risk treatment	Strategic risk theme	New or emerging risk?
A product is released onto the Australian market which poses an unacceptable level of risk.	1. TGA Offices to maintain environmental scans to ensure that risks from emerging technologies are mitigated 2. Expand external evaluation panel to ensure that expertise is available	Delivery[1]	Existing risk
Public access to therapeutic products is restricted or delayed.	1. Expand external evaluation panel to ensure that expertise is available 2. Identify critical job roles and implement succession planning to ensure corporate knowledge is retained 3. Implement therapeutic goods reforms as identified in the 2014-2015 TGA Business Plan	Stakeholder[2]	Existing risk

[1]Department fails to meet expectations for delivery of medium to long term health policy reform agenda

[2]Effective engagement with other government agencies is not maintained and/or engagement with other external stakeholders is not effective.

Australian Government
Department of Health
Therapeutic Goods Administration

Attachment 1: 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, quality and efficacy/performance 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 informing scientific and clinical debate to support the safe and effective use of therapeutic goods.
- **Responsive** to emerging local and global regulatory issues.

Priorities

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

- continue to regulate therapeutic goods for safety, effectiveness/performance and quality
- pursue international regulatory convergence and work sharing.
- continue a program of quality improvement in regulatory processes and reform in key areas, according to government priorities.

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 that is contemporary with international best practice.
- Redeveloping major industry guidance documents and providing more information—in a simple to access style—about regulatory decisions and processes.

Engaging with our Stakeholders

- Developing, enhancing and maintaining relationships with consumers and health professionals and maintaining appropriate relationships with industry.
- Enhancing international regulatory cooperation through better exchange of information, work sharing and capacity building.
- Minimise duplication of effort through stronger collaboration with overseas regulators and assessment bodies.

Managing Key Relationships

- Promoting and enhancing collaborative and cooperative relationships with the rest of the Department of Health.
- Proactive monitoring and management of emerging issues and strong communication with the Assistant Minister and Minister.

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.
- Manage major strategic, financial and operational risks.
- Improve business processes and systems to improve client services.
- Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to better regulate according to product risk.

Delivering through our People

- Maintaining a capable workforce that adapts flexibly to changes introduced through regulatory reform, deregulation initiatives and other priorities of government.
- Maintaining effective levels of performance and provide for continuous learning to improve our capability.
- 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.

Indicators of Performance

Measurement of performance will include the monitoring and reporting of:

- Improved community and industry understanding of TGA's regulatory role and decision-making.
- High stakeholder satisfaction and participation with our consultative processes.
- Adherence to timeliness and performance commitments made under the TGA customer service standards.
- Pre- and postmarket 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.
- Indicators of organisational health including attraction, development and retention of staff who can respond appropriately to both current and emerging regulatory needs.
- Financial performance aligns with financial targets.
- Compliance with statutory reporting obligations and government accountability frameworks.
- International co-operation demonstrated to enhance regulatory harmonisation and improve TGA efficiency
- Evidence from internal reviews and Administrative Appeals Tribunal decisions that TGA is regulating consistently with the legislation.

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 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 continuing the therapeutic goods reform process.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 02 6232 8444 Fax: 02 6232 8605
www.tga.gov.au