Australian Government

Department of Health

Therapeutic Goods Administration

TGA Business Plan 2015–2016

Therapeutic Goods Administration (TGA)

TGA Health Safety Regulation

Strategic considerations

Overview

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

As part of the Department of Health, our activities contribute towards the Department's delivery of its vision to provide better health and wellbeing for all Australians, now and for future generations. These activities contribute to the first and second of the Department's three strategic priorities, namely:

- Better health outcomes and reduced inequality, by enabling timely access to new medicines, medical devices, blood, cell and tissue therapies.
- Affordable, accessible, efficient and a high quality health system, through regulation that protects the health and safety of the community.

Our work is carried out under a national framework using a risk-based management approach to regulation. Our activities align with the priorities set out in the Department's Corporate Plan 2015-16, which includes the Department's strategic plan, and outlines an overarching approach to setting our directions, priorities, performance targets and risk mitigation strategies.

TGA's regulatory performance for the 2015-16 financial year will be reported through the Australian Government's *Regulator Performance Framework* (the Framework), which came into effect 1 July 2015.

Key roles

The role of the TGA is to regulate therapeutic goods under 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 (including medicines, agricultural and industrial chemicals) in Australia.

We undertake this role by:

- applying scientific and clinical expertise to ensure that the benefits of a product outweigh any risk
- assessing the suitability of therapeutic goods for supply in and export from Australia
- regulating manufacturers of therapeutic goods to enable them to meet acceptable standards of manufacturing quality
- implementing a range of regulatory sanctions for non-compliance that are proportionate to the potential risk arising from the non-compliance
- working with consumers, health professionals, industry, technical and scientific specialists and our international regulatory counterparts
- evaluating this work within the scope of the *Regulator Performance Framework*.

As minimising the impost of the regulatory system on industry is a key component of the Framework, we endeavour to achieve this by:

- applying risk-based processes for both pre-market assessment and monitoring and compliance strategies once the goods are on the market
- promoting regulatory compliance through clear and transparent regulatory guidance
- articulating underlying reasons for regulatory decisions and providing them in a timely manner
- utilising innovative technologies and ideas to streamline business functions and promote effective and timely communication
- reporting on our performance to industry, through regular reporting on performance statistics as well as reporting against the Framework following our annual self-assessments.

Guiding principles

The *Regulator Performance Framework* is comprised of six outcomes-based key performance indicators (KPIs) to articulate the Government's overarching expectation of regulator performance:

1. Regulators do not unnecessarily impede the efficient operation of regulated entities
2. Communication with regulated entities is clear, targeted and effective
3. Actions undertaken by regulators are proportionate to the regulatory risk being managed
4. Compliance and monitoring approaches are streamlined and coordinated
5. Regulators are open and transparent in their dealings with regulated entities
6. Regulators actively contribute to the continuous improvement of regulatory frameworks.

The Framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives and to effect positive, ongoing and lasting change within regulators.

Underpinning these principles, the Minister has endorsed specific key performance indicators and measures for regulation by the TGA, which we will report against on an annual basis. These are available at: http://www.tga.gov.au/tga-key-performance-indicators-and-measures-regulator-performance-framework

Strategic priorities for 2015-16

Our priorities for 2015-2016 are:

1. Regulate therapeutic goods—including their manufacture—for safety, effectiveness/performance and quality
2. Participate in international regulatory convergence, harmonisation and work sharing
3. Promote best practice regulation through business improvement and regulatory reform while abiding by the Australian Government's expectations under the *Regulator Performance Framework*.

1. Regulating therapeutic goods for safety, effectiveness/performance and quality

Our three divisions, the Medicines Regulation Division, the Medical Devices and Product Quality Division and the Regulatory Practice and Support Division, apply risk-based processes to regulating therapeutic goods.

The **Medicines Regulation Division** is responsible for:

- evaluating applications for market authorisation of prescription, over-the-counter and complementary medicines, biologicals, blood components and tissue products that are imported into, exported from, manufactured and/or supplied in Australia
- ongoing monitoring of the quality, safety and effectiveness of medicines supplied in Australia.

The **Medical Devices and Product Quality Division** is responsible for:

- regulating manufacturers of therapeutic goods through an auditing and inspection program
- evaluating applications for market authorisation of medical devices (including in vitro diagnostic tests) that are imported, exported, manufactured and/or supplied in Australia
- ongoing monitoring of the quality, safety, performance and effectiveness of medical devices supplied in Australia
- working closely with the Medicines Regulation Division to ensure the quality of therapeutic goods supplied in Australia and that overseas manufacturers of therapeutic goods meet specified standards.

The **Regulatory Practice and Support Division** is responsible for:

- working closely with the Medicines Regulation Division and the Medical Devices and Product Quality Division to monitor compliance of therapeutic goods and enforce compliance where required
- providing operational regulatory policy advice and support services that ensure efficient, best practice regulatory operations
- the delivery of business process improvement programs and supporting project and change management across the divisions
- providing support to a wide range of business functions which enable the operation of a fully cost-recovered framework
- coordinating interactions and communication with stakeholders
- reporting on our performance against the Framework.

In undertaking these activities, we continuously look for opportunities to reduce regulatory burden on industry and health professionals without compromising patient safety.

2. International regulatory convergence and work sharing

We actively engage with our international regulatory counterparts, as well as with regional and international organisations, to support the implementation of consistent science-based standards that underpin the safety and quality of therapeutic goods throughout the supply chain.

This includes participating in international harmonisation, regulatory convergence and work sharing activities to:

- reduce duplication of work in pre-market evaluation of therapeutic goods
- develop internationally consistent regulatory requirements
- negate the requirement for inspecting overseas manufacturers that have already been approved by a recognised regulatory agency.

These activities enable us to make more informed and consistent regulatory decisions about the safety, quality, effectiveness and performance of therapeutic goods available in Australia.

The benefits of investing resources in building and maintaining these relationships include:

- reducing duplication of work leading to a more efficient and effective regulatory system in Australia
- a better understanding of emerging trends, including regulatory science developments
- better implementation of international standards
- more informed regulatory decisions for industry
- better safeguards for the health of the Australian public.

3. Promoting best practice regulation

In 2015-16, we will continue to implement a quality improvement program around regulatory processes and reforms consistent with the Government's best practice regulation agenda which is supported by the Framework. This will ensure that we target our regulatory efforts and level of regulatory oversight according to the risk of the products being regulated.

We will continue to improve the way we communicate with the public about the benefits and risks of therapeutic goods.

Additionally, we will enhance post-market surveillance capacity by:

- exploring the utilisation of health datasets in monitoring and signal detection
- collaborating with other areas of the Department to establish clinical quality registers for cardiac devices and breast implants and sentinel reporting sites.

We will track our performance against the *Regulator Performance Framework* KPIs and report against them annually after the close of the financial year, following their endorsement by the TGA Industry Consultative Committee, the Secretary for Health and the Minister. In line with these changes to our reporting processes; the latter of the Half Yearly Performance Report, which provides detailed performance statistics, will also be reviewed and reported annually.

Subject to the Government response to the Expert Review of Medicines and Medical Devices Regulation, we will commence work to implement identified reforms. The Review was established to identify areas of unnecessary, duplicative or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia. The panel's recommendations include:

- expanding the pathways by which sponsors can seek marketing approval for a medicine or medical device, including making provision for using assessments made by trusted overseas regulators
- defining circumstances where expedited assessments could be undertaken
- enhancing post-market monitoring of medicines and medical devices
- streamlining, in certain circumstances, access by consumers and health professionals to medicines and medical devices that have not been approved for use in Australia.

Managing priorities

As part of the Department of Health, we will implement and resource priorities during 2015-16 as follows:

1. Refine our regulatory practices by:

- evaluating our performance against the *Regulator Performance Framework* in order to undertake our functions with the minimum impact necessary to achieve regulatory objectives
- adopting international best regulatory practice
- redeveloping regulatory guidance to be more accessible and provide greater transparency about regulatory requirements
- refining the way we communicate regulatory decisions to enable a better understanding of the issues and enhance future compliance.

2. Engage with our stakeholders and manage key relationships by:

- enhancing relationships with consumers and healthcare professionals
- maintaining appropriate relationships with industry
- enhancing international regulatory cooperation and minimising duplication of effort through stronger collaboration with overseas regulators and assessment bodies
- actively promoting and enhancing collaborative and cooperative relationships with other parts of the Department of Health
- monitoring and management of emerging issues and timely proactive communication with the Ministers responsible for the Department's work.

3. Enhance our business capability by:

- implementing cohesive policies, management and processes that utilise the highest quality scientific and clinical methods, governance and management skills, and integrating these across our organisation
- managing major strategic, financial and operational risks in line with the Department's Risk Management Policy
- improving business processes and systems to provide improved client services
- contributing to the Government's regulatory reform and red tape reduction agenda by identifying and progressing opportunities to better regulate according to product risk.

4. Deliver through our people by:

- implementing the Department's Health Capability Blueprint to strengthen leadership and culture; improve strategic capability; effective governance and delivery frameworks; relative risk management and active stakeholder engagement
- maintaining a capable workforce that adapts flexibly to change through regulatory reform, business improvement initiatives and other priorities of Government
- providing for continuous learning to improve our capability
- implementing human resource management policies, procedures and systems that promote the APS Code of Conduct and the Department's *Behaviours in Action*
- responding to the 2015 APS Employee Census results through the implementation of a range of 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's Portfolio Budget Statements 2015-16
- the Department's Corporate Plan 2015-16
- the key performance indicators in the *Regulator Performance Framework*.

We will continue to publish performance information, including:

- a self-assessment against the KPIs set by the *Regulator Performance Framework*
- data in the Department of Health's Annual Report
- reports on performance statistics.

During 2015-16 we will continue to focus on risk in managing our regulatory activities.

Each division of the TGA is responsible for specific outputs relating to these deliverables and measures of success. Details of these outputs are provided in the next section.

Outputs to deliver

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

The specific outputs reported under this priority area are separate to potential refor activities encompassed in the recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation. It is anticipated that government wi respond to the review recommendations in the first half of 2016.

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 ss anches and divisions within the TG and ore broadly in the Department.
- Manage significa str egic and key operational risks.
- Maintain a ure expertise on TGA's statutory advis committees and source specialist dvi to sure there are mechanisms to ctively assist our regulatory decision making pro s.
- Provide improved information to stakeholders about regulatory decisions and processes.

Medicines Regulation Division

Regulation of therapeutic go ds afety, effectiveness/performance and quality	
Activity	**Expected outputs**
Regulate and monitor medicines, biolog als, o components and e products, together w ne exports regu t function	**Prescription medicines** • Evaluation of applications completed within legislated timeframes. • Continued streamlining of systems to support market authorisation of new medicines and variations to existing medicines. • Faster and more efficient processes developed for the evaluation of generic medicines. • Continued updates of regulatory guidelines, taking into account stakeholder feedback. • Potential antimicrobial resistance strategies considered during assessment of antimicrobials. **Over-the-Counter (OTC) medicines** • Evaluation of applications completed within target timeframes. • Finalisation of OTC pre-market evaluation business process reforms and monitoring and ongoing improvement of support systems. • Updated regulatory guidance developed for sponsors of OTC medicines. **Complementary medicines** • Continued market authorisation and post-market activities for listed medicines, registered complementary medicines and new substances.

Regulation of therapeutic goods for safety, effectiveness/performance and quality	
Activity	**Expected outputs**
	• Updated regulatory guidance material provided to assist product sponsors in achieving compliance. • Processes and systems implemented to support streamlined applications to register complementary medicines and evaluate new substances for listed medicines. • Development of streamlined post-market monitoring processes to increase the number and improve the timeliness of compliance reviews. **Biologicals** • Continued market authorisation activities for biologicals. • Processes developed and implemented for varying ARTG entries for biologicals. • Implementation of the Biologicals transition strategy progressed. **Post-market activities** • Post-market safety monitoring and surveillance activities undertaken to ensure medicines remain compliant with regulatory requirements. • Education and awareness raising activities conducted to support adverse event reporting by consumers and health professionals, and improved reporting interfaces implemented. • Public access provided to therapeutic goods adverse event data, early warnings and alerts, and maintained information about therapeutic goods recalls. **Other** • Continued market authorisation activities for export-only therapeutic goods. • Appropriate access to unapproved therapeutic goods provided to health professionals and consumers, through the Special Access Scheme and Authorised Prescriber and clinical trials schemes. • Electronic lodgement of clinical trial notifications (CTN) and clinical trial application (CTX) applications implemented. • Delivery of evaluation capability continued in the areas of clinical, toxicology, pharmaceutical chemistry and biological science. • Continued effective management of import-export processes for controlled and reportable substances. • Implementation progressed for digital prescription and OTC medicines submissions and monitoring systems. • Developing TGA's capacity to appropriately evaluate innovative emerging technologies.
Updating medicine ingredient names for international harmonisation	• Decision to update medicine ingredient names and supporting Regulatory Impact Statement published on the TGA website. • Implementation of ingredient name changes to affected ARTG entries. • Begin four-year transition period for ingredient name changes to affected labels, product information and consumer medicine information documents. • Work closely with pharmaceutical, health and medication software, health and consumer organisations to help inform those affected about the ingredient name changes.
Medicine Shortages	• Review implementation of approaches for communicating and managing shortages of medicines. • Design, negotiate and implement any changes to the protocol.

Medical Devices and Product Quality Division

Regulation of therapeutic goods for safety, effectiveness/ performance and quality	
Activity	**Expected outputs**
Regulate medical devices (including in vitro diagnostic tests)	**Medical devices** • Effective and timely completion of market authorisation activities for medical devices including in vitro diagnostic tests (IVDs). • Continued monitoring and compliance work undertaken for medical devices with a risk-based approach. • Information published about regulatory decisions, safety concerns on device, including decisions to cancel devices for non-compliance with regulatory requirements. • Work cooperatively with industry stakeholders to finalise transition for reclassification of joint replacement medical devices from class IIb to class III medical devices. • Regulatory reforms to the IVD Framework continue to be introduced and implemented (in particular, regulation of in-house IVD tests) with a transition period until 30 June 2017. • Refinement of medical device conformity assessment and application for inclusion processes, as part of the Business Improvement Program. • Provision of advice and guidance to stakeholders on medical device issues, and continued development of new regulatory guidelines. • Consultation on options, and standard protocols developed for requirements for clinical data for pre-market assessment of medical devices.
Regulate manufacturing quality, together with recalls and regulatory functions	**Manufacturing quality and recalls** • Monitoring and surveillance of manufacturers undertaken to ensure medical devices remain compliant with regulatory requirements. • 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. Ongoing process improvements to better deal with increasing numbers of GMP clearance applications. • Implementation of a compliance risk management framework that provides incentives for consistent high level compliance and disincentives for non-compliant behaviours. • Proactive risk assessment strategies applied for the planning of manufacturing quality inspections. • Continued oversight of voluntary recall actions and enforcement of mandatory recalls when required. • Monitoring compliance with public and customer notification of recall actions and ensuring that appropriate corrective and preventive actions have been implemented by Australian sponsors.
Monitor compliance of medicines through laboratory testing	• Monitoring and compliance laboratory testing, investigations and reviews undertaken in response to quality or safety concerns. • Lot release program for vaccines conducted, including the seasonal influenza vaccine. • A risk-based laboratory testing program conducted to monitor compliance with required standards.

Regulatory Practice and Support Division

Regulation of therapeutic goods for safety, effectiveness/ performance and quality	
Activity	**Expected outputs**
Monitor and enforce compliance of therapeutic goods	• Investigate compliance with the provisions of the *Therapeutic Goods Act 1989*, in particular around illegal and counterfeit therapeutic goods using appropriate enforcement measures consistent with the Act and Regula[illegible]s. • Advertising complaints responded to in a timely manner using a risk base[illegible] approach and measures taken to support compliance by advertiser[illegible]. • Continued streamlining of administrative processes for handling [illegible] advertising complaints. • Publish information on the outcomes of investigations into adv[illegible]sin[illegible] of therapeutic goods. • Development of appropriate responses to target ille[illegible]tern[illegible]t sales of therapeutic goods. • Continued cooperation with the Department of [illegible]mig[illegible]ion and Border Protection to develop targeted approaches to prevent t[illegible] imp[illegible] and/or export of illegal therapeutic goods.
Provide support services that enable the TGA to more effectively undertake its regulatory responsibilities	**Program and change management** • Foster innovation through th[illegible]vision of support services for regulatory business initiatives, in[illegible]ludi[illegible] pro[illegible]sion of services to projects through assessment of regulat[illegible]bu[illegible]s initiatives, governance of approved projects and post-pr[illegible]ect[illegible]luation. • Implement the delive[illegible]ategy for business change projects. • Deliver spe[illegible] support services to regulatory improvement projects. • Support delive[illegible]y the Business Improvement Programme. **Regulato[illegible]g[illegible]ce and enquiry management** • Hi[illegible]qua[illegible] and timely management of stakeholder enquiries via email and [illegible]eph[illegible]e. [illegible]t external communication activities by identifying trends and [illegible]eporting on the types of enquiries being made and stakeholders who are [illegible]ontacting the TGA. **TGA advisory committees** • Continued administrative support provided to TGA's advisory committees, subcommittees and working groups. • Continue to target use of the committees and associated advice to assist TGA decision making. • Continue to provide comprehensive and timely public reporting of committee outcomes. • Review conducted of the nature and number of committees, to reduce administrative burden. **Parliamentary support** • Timeliness and provision of accurate and appropriate information in parliamentary support activities. **Regulatory education** • 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.

Regulation of therapeutic goods for safety, effectiveness/ performance and quality	
Activity	**Expected outputs**
	• Simpler and more targeted information provided and redundant, out-dated and trivial content archived or removed from our website. • Support external communication activities by identifying trends and report on the types of enquiries and stakeholders contacting the TGA. • Market research utilised to help stakeholders make more informed decisio about therapeutic goods and comply with our regulatory requirements • Research applied to drive prioritisation and development of TGA's communication and education activities and content. • Effective use made of external expertise and regulatory scienc in atives led by other regulators.

2. International regulatory convergence, harmonisation and work sharing

Strategy underpinning this priority

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

Medicines Regulation Division

International regulatory convergence, harmonisation and work sharing	
Activity	**Expected outputs**
Enhance cooperation and work sharing with international regulators in the pre-market assessment of medicines	**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 collaboration. • Implementation of harmonised technical processes and protocols for work sharing with Health Canada and opportunities identified for work sharing with other trusted international regulators, in particular Swissmedic, HSA Singapore and participation in the International Generic Drug Regulators' Programme. • 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 (NCEs, including orphan drugs)** • Program finalised with Health Canada for exchange of evaluation reports for NCEs, including orphan drugs; and opportunities identified for exchange of information and work sharing with trusted international regulators. • Develop a new program of collaboration with Swissmedic, Singapore and Canada on sharing of information on benefit-risk evaluations for orphan drugs. • Actively participate in information sharing on NCE evaluation for oncology products with USFDA, European Medicines Agency and PMDA Japan. **OTC and complementary medicines** • Opportunities identified for work sharing with Health Canada to support the registration process for OTC medicines and the evaluation of registered complementary medicines and ingredients for use in listed medicines. • Greater use made of safety and quality evaluations of new complementary medicine ingredients performed by overseas regulators, including through the Australia – Canada – Singapore – Switzerland (ACSS) collaboration. **Post-market surveillance** • Undertake work sharing with Health Canada in relation to current periodic safety update report evaluation processes and decisions of overlapping applications. • Exchange information regarding signal investigation activities and risk management plan evaluation processes.

International regulatory convergence, harmonisation and work sharing	
Activity	**Expected outputs**
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, sterilisation, GMP, and non-propriety names through participation in standard setting bodies such as the World Health Organization (WHO), the International Organization for Standardization (ISO) and the International Conference on Harmonisation of technical requirements for Registration of Pharmaceuticals for Human Use (ICH). • 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 and ICH • Influence the international regulatory harmonisation agenda through membership of the Management Committee of the International Coalition of Medicines Regulatory Authorities (ICMRA), and lead ICMRA projects on generic medicines, on pharmacovigilance and GMP equivalency. • Participate in the International Generic Drug Regulators Programme and the ACSS (Australia – Canada – Singapore – Switzerland) Heads of Agency group.
Enhance post-market monitoring	• Continued use of risk communication received from other regulators to trigger safety investigations and appropriate regulatory action if required. • Work sharing with Health Canada on post-market 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.

Medical Devices and Product Quality Division

International regulatory convergence, harmonisation and work sharing	
Activity	**Expected outputs**
Enhance cooperation and work sharing with international regulators in the pre-market assessment of medical devices	• Phased program of confidence building with European Notified Bodies continued.
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 trusted regulators have also been inspecting the same manufacturing sites. • Work sharing with Health Canada increased on GMP inspections and desktop assessments and opportunities for work sharing with other trusted international regulators identified. • Internationally consistent manufacturing quality standards applied.

International regulatory convergence, harmonisation and work sharing	
Activity	**Expected outputs**
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 Cooperation Scheme (PIC/S) and the ISO and continued participation in the International M al Device Regulators Forum (IMDRF). • Contribution to regional capacity building through participation in s such as the Regional Alliance Steering Committee for National Re ato Authorities for Vaccines.

Regulatory Practice and Support Division

International regulatory convergence, harmonisation and work sh ng	
Activity	**Expected outputs**
Coordinate TGA's participation in international activities	• TGA's contribution to influencing t de lopment and harmonisation of international regulatory sta supported through the strategic planning of bilateral and multi teral ork aring and harmonisation activities. • Development of a new International Engagement Strategy for 2016-18, aligned with the bro er artmental strategy. • New opport nities ide ed for expanding international engagement leading to internati l regulatory harmonisation and work sharing projects. • Providing ecre iat and strategic support to TGA's participation in the ICMRA a ment Committee and ACSS Consortium (coordinating TGA's involvem nt in ACSS working groups).
Provide support services that enable the TGA to effectively participate in international collaborati and work sharing initi ives	• arc tecture and supporting protocols developed for sharing confidential i ation with trusted international regulators that incorporate ppropriate security measures to protect information from unauthorised use r accidental modification, loss or release.
Continued tra s-Tas an cooperation b en the two national regu rs and the degre of monisation bet een gula ory schemes	• Enhanced information sharing in relation to pre- and post-market regulatory functions performed by each regulator, such as: – regulatory compliance and pharmacovigilance – laboratory tests – investigations into quality defects or manufacturing errors – recall actions undertaken – evaluation reports – medicines scheduling. • Continued sharing of a common approach to OTC medicine pre-market business processes. • Further mutual recognition of TGA and Medsafe GMP inspections of manufacturers in their respective jurisdictions. • Common adverse event/pharmacovigilance database facilities strengthened.

3. Promoting best practice regulation

The Expert Panel Review of Medicines and Medical Devices Regulation

The reports of the Expert Panel Review of Medicines and Medical Devices Regulation were provided to Government in two stages. The first report, on the regulatory frameworks for medicines and medical devices, was provided to Government on 31 March 2015. The Panel's second report, addressing the regulatory frameworks for complementary medicines and the advertising of therapeutic goods, was delivered on 31 July 2015.

During 2015-16, the Department (through the Strategic Policy and Innovation Group and the Regulatory Services Group, which includes the TGA) has undertaken further stakeholder consultations on the reports and initial design work to support the development of advice to government on its response to the Review.

The activities listed below **do not, in the main**, include work encompassed by the Review of Medicines and Medical Devices Regulation. Depending on the timing of government response to the review, a range of corresponding design and initial implementation activities would also be commenced during 2015-16.

Strategies underpinning this priority

- Enhance partnerships with consumers, healthcare professionals and other regulatory agencies.
- Maintain appropriate relationships with industry.
- Promote 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.
- Invest in innovative technology to improve our capability.
- Develop and maintain clear and transparent guidance for the regulated industry.
- Contribute to the Government's regulatory reform and red tape reduction agenda by identifying and progressing opportunities to reduce red tape.

Medicines Regulation Division

Promoting best practice regulation	
Activity	**Expected outputs**
Improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods (ARTG)	• Continued work on "permitted indications" to potentially limit the use of inappropriate claims and indications on the ARTG. • Enhanced post-market monitoring to more efficiently focus resources towards problem areas. Data collected from listing compliance reviews performed by the TGA analysed to inform risk profiles and prioritisation of subsequent reviews.
Improve the pre-market business processes for registered complementary medicines and new substances	• Implement a statutory instrument creating a single list of all ingredients, and their associated conditions of use, permitted for use in listed medicines. Reduced complexity and improved transparency for ingredients permitted for use in listed medicines. • Finalise an application portal which enables applicants to lodge applications electronically, and guidance documents supporting the new application process.

Promoting best practice regulation	
Activity	**Expected outputs**
Improve medicine labelling requirements to assist consumers and health professionals to make informed decisions about the quality use of medicines and to improve safety outcomes	• Further options to address poor labelling and the associated public health implications subject to public consultation, and new legislative instruments developed to enable implementation of labelling changes. A Regulatory Impact Statement will be developed to consider the feasibility of options and inform the final decision.
Provide advice to government on reform options for orphan drugs that provide more equitable access to people with rare diseases, while managing implications for TGA fee revenue	• Options developed based on feedback from earlier public consultation and discussions with key stakeholder groups.
Provide more user-friendly information on the risk-based framework under which the TGA operates, including additional explanations of TGA's regulatory processes	• Communication and education plan developed and implemented to communicate our risk-based framework more broadly. • Detailed explanations developed on how the framework operates for different classes of therapeutic goods. • 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.
Replace paper dossiers for prescription medicine registrations with electronic submissions that meet international standards	• Work with international stakeholders and industry to implement eCTD format submissions.
Assess approaches for the regulation of autologous stem cells, including aspects related to advertising	• Second discussion paper developed that considers issues and potential options to address them. • Subject to government endorsement, public consultation and potential implementation of regulatory options.
Reform processes surrounding access to unapproved therapeutic products through the Special Access Scheme	• Internal policy paper developed on options for reforming regulations and processes. • Subject to policy approval, Regulatory Impact Statement developed to support government decision making on reform to regulations, including appropriate consultation with stakeholders. • Implementation of preferred options commenced, including systems for electronic applications and/or notifications.

Medical Devices and Product Quality Division

Promoting best practice regulation	
Activity	**Expected outputs**
Examine mechanisms for improving the timely communication of alerts and recalls, to health professionals and consumers	• Review completed and update of Uniform Recall Procedure for Therapeutic Goods, including consultation with stakeholders and development of a draft revised instrument.
Review the contestability of TGA's laboratory functions	• Provide advice to the Departmental Executive and Government on the contestability of all functions of the TGA laboratories management and operations. • Independent review commissioned (overseen by a joint Department of Health-Department of Finance Governance Board) and findings reported to government.
Streamline the application process for medical devices	• Participate in a pilot of the Regulated Product Submission (RPS) for medical devices. • Trial and evaluate the effectiveness and potential to adopt the IMDRF's concept of Medical Device Single Audit Program (MDSAP).

Regulatory Practice and Support Division

Promoting best practice regulation	
Activity	**Expected outputs**
Review the role and responsibilities of TGA in regulatory compliance and enforcement around therapeutic goods, including future structure and workforce requirements	• Independent review commissioned and recommendations considered by the Department and implementation plan developed and commenced.
Work with other key providers to enhance the information available to the public	• The TGA website is current, accurate, relevant, timely, up to date, and meets the needs of its audiences. Functionality of the website improved by introducing new ways of presenting, searching for and managing content, including Product Information and Consumer Medicine Information documents. • Participation in conferences and events continued, including plenary presentations, as well as other educational activities with key stakeholders and partner 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) under the *Regulator Performance Framework*	• Implementation of the new KPI reporting framework completed, to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency (publication of the first self-assessment against the KPIs after the close of the 2015-16 financial year). • KPI reporting continued annually as a business-as-usual activity.
Complete changes to reflect TGA's approach to disclosure of commercially confidential information	• Update of TGA forms and guidance documents to reflect the approach.

People and relationships

Cooperative work with other Government regulators and agencies

We collaborate with a number of similar Australian regulators on common issues. This includes:

- Food Standards Australia and New Zealand
- The Office of Chemical Safety (OCS)
- The Office of the Gene Technology Regulator (OGTR)
- Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
- The Department of Agriculture and Water Resources
- The Australian Pesticides and Veterinary Medicines Authority

A Regulators' forum of the heads of these ag[illegible]es, including the Deputy Secretary responsible fo[illegible]e TGA, OGTR and OCS, meets three times a [illegible]lly and facilitates collaboration on harmo[illegible]ed training and exchange of best prac[illegible]app[illegible]aches for regulation.

In addition, we work closely [illegible]h the following other government depar[illegible]nts and agencies:

- Department of Prime Minister and Cabinet
- Department o[illegible] Fo[illegible]n Affairs and Trade
- Commonw[illegible]lth Ombudsman's office
- Australi[illegible] Bo[illegible]der Force
- A[illegible]tra[illegible]n Competition and Consumer C[illegible]m[illegible]sion.

Aboriginal and Torres Strait Islander activities

The Department is committed to having a diverse workforce. Targets have been se[illegible]o[illegible]t Commonwealth public sector to hav[illegible]2 pe[illegible]nt indigenous workforce by 2018. TG[illegible]s ta[illegible]et comprises part of the broade[illegible]Dep[illegible]nt's target. Indigenous staff comprise o[illegible]0.[illegible]r cent of the workforce within the TGA [illegible]visions.

Financial resources

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.

A government appropriation is provided for the operation of the Drug Control Section and the Medicines and Chemicals Scheduling Secretari

2015-16 Portfolio budget statements

Budgeted expenses

	2014-15 Actual expenditure	2015-16 Estimated expenditure
TGA Special Account	**$142,301,000**	**$140,371,000**
Budgeted decrease in expenditure (including capital) comprises:		
Actual expenditure 2014-15		$142,301,000
Capital expenditure		($962,000)
Supplier expenses		($6,417,000)
Employee expenses		$5,449,000
Budgeted expenses 2015-16 (including capi		**$140,371,000**

Risk

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

Risk name	Risk treatment	Strategic risk theme	New or existing risk?
A product enters the Australian market which poses an unacceptable level of risk	1. TGA to maintain environmental scans to ensure that risks from emerging technologies are mitigated. 2. Expand external evaluation panel to ensure that expertise is available. 3. Maintain post-market compliance monitoring activities to identify safety and quality risks. 4. Continue to build international networks to ensure TGA receives the latest safety and quality alerts from international regulatory agencies.	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 good reforms as identified in the 2015-16 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

Therapeutic Goods Administration

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