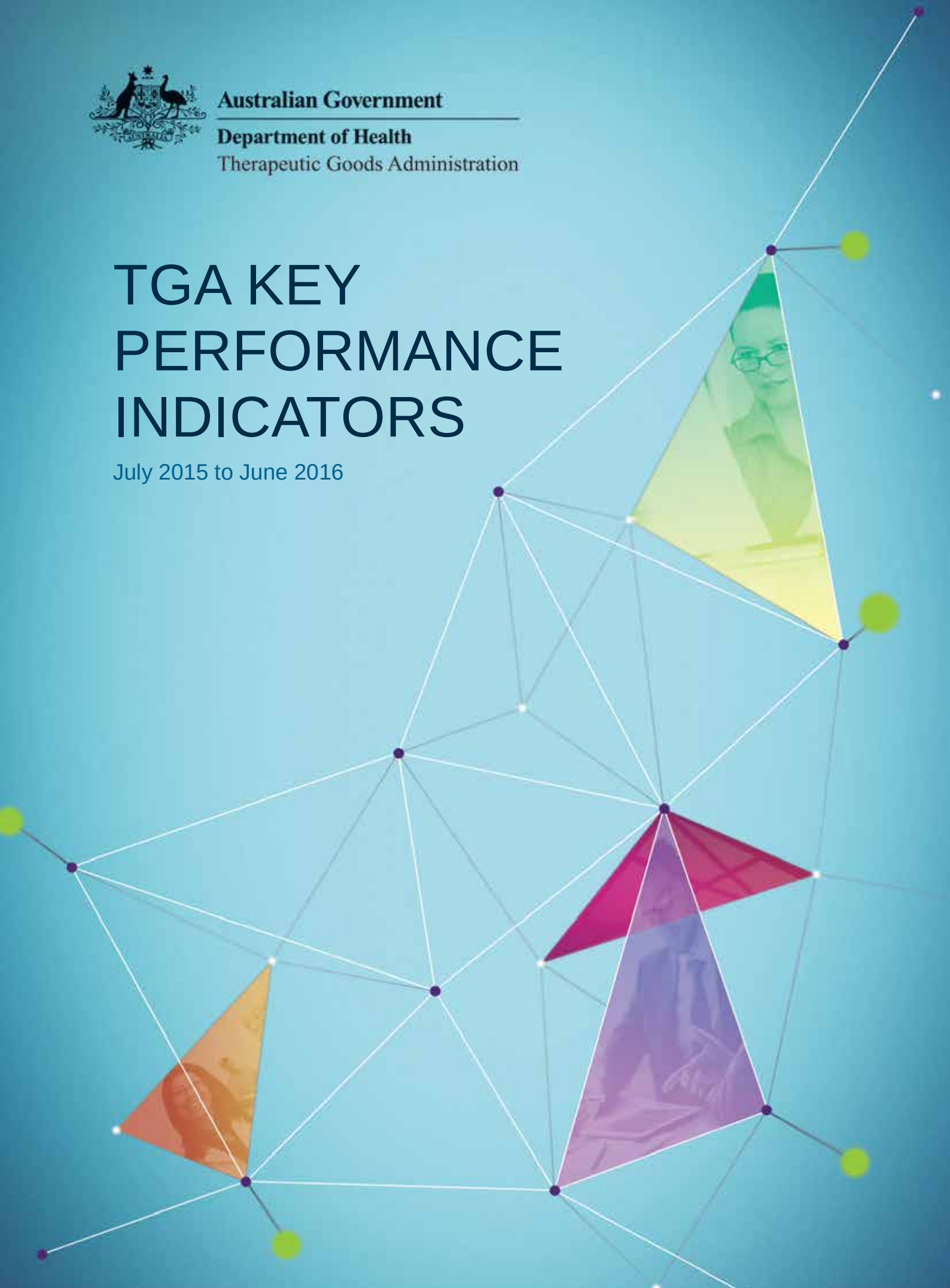
Australian Government

Department of Health

Therapeutic Goods Administration

TGA KEY PERFORMANCE INDICATORS

July 2015 to June 2016



Regulator Performance Framework

The Australian Government has developed a framework to measure the performance of regulators. The Regulator Performance Framework (the Framework) comprises six outcomes-based key performance indicators (KPIs) as listed below to articulate the Government's overarching expectations 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.

These KPIs are supported by measures of good regulatory performance to assist regulators in assessing their achievement of the KPIs.

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. The Framework will allow regulators to report objectively on the outcomes of their efforts to administer regulation fairly, effectively and efficiently.

The Framework has applied since 1 July 2015, with the first assessment period being the 2015-16 financial year. Our reports will be published annually on the Therapeutic Goods Administration (TGA) website. Further information on the Government's Framework is available at: https://www.cuttingredtape.gov.au/resources/rpf.

Assessing our achievement of the KPIs

In consultation with our stakeholders through the TGA Industry Consultative Committee (TICC) and the Australian Therapeutic Goods Advisory Council, an agreed set of TGA specific qualitative and quantitative outputs and evidence against the Government's KPIs were developed to assess our achievement. These KPIs were endorsed by the then Assistant Minister and published on our website in June 2015. The evidence metrics are specified under each of the KPIs and form the basis of our self-assessment.

In preparing our self-assessment against the KPIs multiple data sources were utilised, including:

- published advice on our website
- stakeholder surveys
- public consultations
- market research
- business improvement activities
- international and domestic stakeholder forums.

Our self-assessment was externally validated in September 2016 by the TICC, which comprises industry and consumer representatives.

General feedback from TICC members was positive, supporting our self-assessment overall and agreeing there is sufficient evidence to support our performance ratings for KPIs 2 to 6. In relation to KPI 1, some members suggested that a performance rating of substantially met would be more appropriate, as the evidence did not adequately demonstrate the performance rating of met.

Members noted their appreciation of our efforts in stakeholder engagement, communication and ongoing business improvements.

In terms of feedback on whether the self-assessment process provided sufficient, reliable and current evidence to support our overall performance rating of met, TICC members either agreed or somewhat agreed. Members noted that this is the first report of its kind, and although the majority of the evidence matrices are appropriate and an effective tool for assessing our compliance against the KPIs, the matrices should be subject to continuous improvement to ensure relevance.

Summary of our performance in 2015-16

Self-assessed rating of overall performance

Overall we met the requirements of the Framework through meeting KPIs 1, 3, 5 and 6 with 'strong performance' against these measures and through substantially meeting KPIs 2 and 4. A brief summary is provided below.

SELF-ASSESSMENT RATING AND SUMMARY OF OVERALL PERFORMANCE		
KPI	**Performance rating**	**Comments**
KPI 1. Regulators do not unnecessarily impede the efficient operation of regulated entities	Met	The performance rating of met is supported by successful participation in formal stakeholder forums and participation at industry events. This has led to smaller face-to-face workshops and increased opportunities for our staff to improve their knowledge of emerging technologies and provide industry with an opportunity to increase understanding of our regulatory requirements. Additionally, we have implemented a number of initiatives under the Business Improvement Program aimed at reducing compliance costs to industry.
KPI 2. Communication with regulated entities is clear, targeted and effective	Substantially met	The performance rating of substantially met is based on medical device timeframes for application audits not being met, although these timeframes are not mandated in legislation. The legally-mandated timeframes for medical device conformity assessment were met in 100% of cases.
KPI 3. Actions undertaken by regulators are proportionate to the regulatory risk being managed	Met	The performance rating of met is supported by our risk management approach in regulating therapeutic products, including identifying entities at risk of unintentional or deliberate non-compliance, and the collection of intelligence in relation to alleged breaches of the *Therapeutic Goods Act 1989* and the Therapeutic Goods Regulations 1990. Evidence of actions undertaken by regulators that are proportionate to the regulatory risk is also outlined in our laboratories targeted testing of medicines and medical devices according to the risk they pose to the public, monitoring of the market for signals of potential non-compliance and the scheduling of manufacture inspections based on compliance

		records. Additionally, we can communicate regulatory requirements and compliance expectations quickly and directly to market-entry applicants.
KPI 4. Compliance and monitoring approaches are streamlined and coordinated	Substantially met	The performance rating of substantially met is because we do not yet have a fully mature compliance and enforcement framework with graduated sanctions and penalties. While we have a sound compliance structure in place, we do not yet have a range of regulatory tools which allow us to use the full range of compliance approaches.
KPI 5. Regulators are open and transparent in their dealings with regulated entities	Met	The performance rating of met is demonstrated through our continued efforts towards raising awareness of our regulatory framework through industry workshops and the publication of educational material, as well as maintaining telephone and email based information lines. We also publish regular performance activity reports on our website.
KPI 6. Regulators actively contribute to the continuous improvement of regulatory frameworks	Met	The performance rating of met is supported by our stakeholder engagement through market research, continued business improvements and interactions with other regulators.

Additional reporting

The reporting provided through these KPIs focuses on our performance as a regulator and our engagement with our stakeholders, however we will continue to produce other reports with more detailed information about our regulatory and corporate activities. These reports include the:

- annual Performance Statistics Report
- annual TGA Business Plan
- Half Yearly Performance Report Snapshot – July to December 2015
- Department of Health Annual Report
- Health Portfolio Budget Statements 2015-16.

These reports are publicly available and can be read in conjunction with the KPIs.

KPI 1 Regulators do not unnecessarily impede the efficient operation of regulated entities

KPI 1.1 Regulators demonstrate an understanding of the operating environment of the industry or organisation, or the circumstances of individuals and the current and emerging issues that affect the sector.

1.1a Number of TGA participations in industry formal stakeholder forums, including meetings and working groups and feedback received on TGA presentations.

Within the reporting period we participated in 81 formal stakeholder forums that included attendance and participation at industry events, hosting regulator workshops for stakeholders, staff speaking engagements and bilateral meetings with industry groups.

Examples of these interactions included:

- four stakeholder workshops in Sydney, Melbourne and Canberra in October and November 2015 to consult on communication strategies for implementing changes to medicine ingredient names. The workshops were attended by representatives from the pharmaceutical and medical software industries as well as by health professionals, consumers and other relevant government agencies
- bilateral meetings with nine peak industry bodies to discuss key policy issues, the fees and charges proposal for 2016-17, as well as several other subject specific meetings with each body
- in cooperation with medical device peak bodies, an information day for medical device sponsors in Canberra on 15 October 2015. Nearly 200 people from the medical device industry attended the event, which provided information on the regulatory life cycle for medical devices. Industry feedback indicated this was successful, and there has been significant traffic for the presentations posted on our website following the event (9,724 viewings)
- in cooperation with the Australian Self Medication Industry, presentations at multiple training seminars for advertisers designed to improve awareness and understanding of the legislative requirements that apply to the advertising of therapeutic goods
- regular working groups with industry (e.g. Regulatory Affairs Working Group with Medicines Australia and the Generic and Biosimilar Medicines Association - 9 October 2015 and 6 April 2016) to discuss *inter alia* the predictability and timeliness of the prescription medicine registration process through the provision and discussion of performance data
- participation in meetings with stakeholders in August 2015 (prescription medicines and medical devices) and December 2015 (complementary medicines and advertising) to explore industry priorities and issues relating to the Expert Panel Review of Medicines and Medical Devices Regulation.

Feedback from these interactions, including the above educational seminars and events, has resulted in other smaller face-to-face workshops, as well as increased participation in online education webinars.

1.1b Information on informal interactions with industry and how they are able to build understanding, for example ad hoc meetings between senior TGA staff and industry on specific issues and educational seminars for TGA staff on industry business activities.

We regularly engage with industry to provide guidance on a range of regulatory matters. During the period, these interactions included:

- convening discussions and providing support to sponsors on potential safety and performance issues
- working cooperatively with industry stakeholders by:
  - providing direction on actions required for the finalisation of transition for joint replacement medical devices from class IIb to class III medical devices
  - hosting informal meetings to discuss changes to the prescription medicines registration process. Discussions included shortening the pre-submission timeframes and minimising data requirements
  - holding workshops in Sydney, Melbourne and Brisbane between November 2015 and February 2016 to inform stakeholders on the introduction of a new online submission system for Clinical Trial Notifications (CTNs)
  - providing updates to laboratory stakeholders on the transition period for in-house in vitro diagnostic medical devices (IVDs) and advice on how to comply with regulatory requirements
  - undertaking user testing of the web-based interfaces for the Special Access Scheme and Adverse Event Management System
  - conducting Australian Public Assessment Reports (AusPARs), pre-submission pilot, and TGA Stakeholder 2015-16 surveys.

During these interactions our staff had the opportunity to improve their knowledge of emerging technologies, innovative products and priorities for the regulated industry. These activities also provided industry with an opportunity to increase its understanding of our regulatory requirements.

KPI 1.2 Regulators take actions to minimise the potential for unintended negative impacts of regulatory activities on regulated entities or affected supplier industries and supply chains.

1.2a Evidence of continued compliance with our practice of engagement with industry before a regulation impact statement (RIS) is finalised, to minimise the potential for unintended impacts on regulated entities and product supply.

We engaged with industry stakeholders prior to finalising RISs relating to the International Harmonisation of Medicine Ingredient Names and the Annual Charge Exemption Scheme, along with two sunsetting regulatory instruments that were remade with no changes. For more information see KPI 6.2a. This ensured that any unintended negative impacts were minimised.

KPI 1.3 Regulators implement continuous improvement strategies to reduce the costs of compliance for those they regulate.

1.3a Progress towards implementation of the Australian Government Digital Transition Policy.

Digital record keeping means that the majority of an agency's records will be created, stored and managed digitally and, where possible, incoming paper records will be scanned so that new paper files are not created.

Over the period, 75% of submissions for medicines, devices and biologicals were provided in electronic format. This figure has increased from 72% in June 2015.

A number of initiatives assisted in our transition to digital processes such as:

- the cessation of paper files project which will cease the production of paper-based files
- commencement of the pilot for an internationally standardised structure for conformity assessments for medical devices, known as the Table of Contents pilot
- coinciding with the implementation of electronic Common Technical Document (eCTD), we mandated requirements for industry to cease the production of physical data. This improved the quality of the e-submissions and validation process, and helped to streamline the assessment process
- other business improvement projects e.g. electronic form for minor variations to prescription medicines.

1.3b Progress of the strategies being implemented under the business improvement program and other specific projects aimed at reducing compliance costs for industry.

We have implemented a number of initiatives aimed at reducing compliance costs for industry. We launched the TGA Business Services website (enabling the regulated industry to view and pay invoices, maintain contact details, check the status of applications and respond to requests for additional information) and implemented paperless processes for three quarters of product billing and industry assistance functions (e.g. invoice requests, request for credit notes, write-off approvals).

Further initiatives included:

- we commenced receiving and managing eCTD submissions in addition to non-eCTD electronic submissions for prescription medicine applications. 100% of Category 1 applications (to register a new prescription medicine, other than an additional trade name, or make a variation to an existing medicine), were received electronically. The submission of hard copy dossiers for Category 1 applications is no longer required, resulting in significant savings for industry and the Department in avoided printing and storage costs
- a new corporate Ingredients Repository - a centralised source of ingredient and proprietary ingredient information, referenced by most systems at the TGA. In addition to being easier to maintain (through the auto-population of client details from a validated source), the new Ingredients Repository will improve the Ingredient Summary documents available via our eBusiness Services (eBS) public portal and reduce enquiries from industry stakeholders seeking clarification or additional information
- the ability to more easily develop smartforms through the acquisition and implementation of an eForm development tool
- the commencement of a new adverse event management system which, when completed, will improve processes and reporting

- the new Annual Charges Exemption (ACE) scheme, which has replaced and improved the previous low value turnover (LVT) scheme to exempt goods from annual charges on the basis of low sales turnover, took effect from 1 July 2015
- a pre-submission pilot pathway for prescription medicine applications was introduced in February 2016. The pilot aims to reduce the regulatory burden on industry by removing the need to provide summary information prior to lodgement of a submission for new prescription medicines
- development of policy and implementation design activities ahead of public release of the Government's response to the recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation.

Self-assessed rating of performance against KPI 1 for 2015-16

Met	Substantially met	Not met
P Strong performance against *all* of the measures under the KPI	Strong performance against *most* of the measures under the KPI	Poor performance against *all* of the measures under the KPI

KPI 2 Communication with regulated entities is clear, targeted and effective

KPI 2.1 Regulators provide guidance and information that is up to date, clear, accessible and concise through media appropriate to the target audience.

2.1a Percentage of pages on the TGA website that comply with the Australian Government accessibility requirements.

We have an ongoing program of developing, reviewing and updating regulatory and technical guidance material to comply with Australian Government requirements and international standards for web content accessibility.

Web Content Accessibility Guidelines (WCAG) requirements include the need for the content to be findable, scannable, readable and accessible. A systematic approach to maintaining content is also required. To meet these requirements we have created a new standard database model through which data can be easily discovered, navigated and disseminated.

90% of TGA information on our website is WCAG2.0 compliant. The remaining content includes a large number of third party documents, for example consultation submissions, Product Information (PI) and Consumer Medicine Information (CMI) documents.

We actively monitor and review material on the website to ensure it meets WCAG2.0 compliance requirements, and is user-focused.

We have also delivered a completely new website search platform to improve access to content on the website.

2.1b Improvements made to guidance documents, forms, and information on the TGA website.

Guidance material is intended to lend further clarity to the regulatory processes, to assist industry and other stakeholders to understand and comply with our requirements. We continually develop and update regulatory and technical guidance material. This includes simplified navigation of our website pages.

During the reporting period, we published a range of new and updated guidance documents and material, including:

Prescription medicines

- an evaluation plan estimator for applicants who lodge applications for prescription medicine registrations. This provides estimated dates for the milestones in the registration process to aid in planning applications and was viewed 3,725 times in the reporting period
- prescription medicine guidance, such as Common Technical Document (CTD) Module 1, general dossier requirements, extensions of indications, additional trade names, non-eCTD electronic submissions, preparing applications and requests involving steps in the manufacture of medicines regulated as prescription medicines
- updated guidance for sponsors on evidence of Good Manufacturing Practice (GMP) compliance for prescription medicines
- revised guidance for applicants lodging prescription medicine registration applications to include information on the pre-submission pilot registration pathway, such as questions and answers and a fact sheet to aid planning

- information about changes to medicine ingredient names to align with names used internationally, including to ten pharmaceutical industry organisations, seven medications software/information industry organisations, four consumer organisations and eight government organisations.

Medical devices

- guidance on regulatory requirements for in vitro diagnostic medical devices (IVDs)
- revised guidance on the reduction of assessment fees for conformity assessments of medical devices (including IVDs), providing industry with greater clarity on the assessment fees that may apply
- revised forms to make it easier to collect information from sponsors, including consultation submissions, electronic forms to notify medicine shortages and online forms for clinical trial notifications and custom made medical devices.

Over the counter medicines

- a major revision of the Australian regulatory guidelines for over the counter (OTC) medicines and the TGA approved terminology for medicines, including guides on registration and change processes, CTD Module 1 for OTC medicines, mandatory requirements for effective OTC medicine applications, technical guidance, flowcharts and tools for sponsors

Other

- an application form for sponsors to use when applying for permission to export therapeutic goods for clinical trials.

2.1c Number of educational materials and other documents developed or updated for stakeholders (industry, consumers, health professionals). Number of downloads of these from the website and social media, and data on user satisfaction where available.

We created various educational materials for consumers, health professionals and industry during the reporting period, including:

- two instructional and training videos: a user guide to the new TGA Business Services for industry; and information for consumers about buying medicines online
- 26 presentations for various industry events and 10 presentations for the Devices Sponsor Information Day, providing an overview of the regulatory life cycle for medical devices
- a series of educational materials to raise awareness about upcoming changes to medicine ingredient names.

Additionally, there were 13 fact sheets and frequently asked question (FAQ) documents including:

Industry	Health Professionals	Consumers
Cannabis re-scheduling proposal - questions and answers	Updating medicine ingredient names	Cosmetic injections: beware of 'home based' beauty services
Advertising health services with medical devices	Advertising health services with Schedule 3, Schedule 4 or Schedule 8 medicines	Stem cell treatments and regulation - a quick guide for consumers
Updating medicine ingredient names	Advertising of vaccination services	Weight loss: beware of buying unregulated products online
Annual charges exemption scheme – questions and answers		Can I import it?
Custom made medical devices		
FAQs on Clinical Trial Notification online submissions and the clinical trials scheme		

Significant downloaded or viewed materials for 2015-16 for each stakeholder group are highlighted below.

Consumer & Health professional content: downloads and views through various TGA media channels for the period July 2015 to June 2016

Name of material[1]	New or updated	Format	Publication medium	Number of views/ downloads
Updating medicine ingredient names	New	Posters & website	TGA website & direct email	18,525 views (Website) 1,354 downloads
Cosmetic injections: beware of 'home based' beauty services	New	News item	TGA website	1,132 views
Stem cell treatments and regulation - a quick guide for consumers	New	Questions and Answers	TGA website	704 views
Managing the Challenges and Opportunities of Breakthrough Therapies	New	Presentation	SlideShare	434 views
Buying medicines and medical devices online	New	Video & webpage	YouTube, TGA website	225 views (launched on 26 June 2016)

Industry content: downloads and views through various TGA media channels for the period July 2015 to June 2016

Name of material*	New or updated	Format	Publication medium	Number of views/ downloads
TGA and industry presentations - Devices Sponsor Information Day 15 October 2015	New	12 presentations	SlideShare, TGA website	9,724 views
The new TGA Business Services site	Updated	Video	YouTube, TGA website	1,056 views
Evidence of GMP compliance for prescription medicines	Updated	Webpage	TGA website	2,677 views
Half Yearly Performance Report Snapshot (July to December 2015) and the interactive online summary	New	Report	TGA website	1,227 (between May and June 2016)

The information reported in the above two tables focuses on materials either developed or updated during the reporting period. However, additional materials are made available to stakeholders via the TGA website and social media channels.

These materials can be accessed by stakeholders using various media channels including our website, the TGA Australia YouTube channel and SlideShare.

Education and awareness raising activities were also conducted to support adverse event reporting by consumers and health professionals and improved reporting interfaces were implemented.

KPI 2.2 Regulators consider the impact on regulated entities and engage with industry groups and representatives of the affected stakeholders before changing policies, practices or service standards.

2.2a Details of formal consultations completed during the reporting period, including evidence that the TGA has closely considered submissions from stakeholders.

Some of the activities consulted on during the period included changes to regulatory practices or requirements, reviews of business processes, reviews of standards or guidelines, and fees and charges. For each consultation an internal report is prepared which outlines how submissions have been considered and what action has been taken in response. This forms the basis for our response which is published on our website.

Examples of completed consultations during the reporting period include:

- draft guidelines outlining our expectations for clinical evaluation reports and underlying evidence to be held by medical device manufacturers as part of their conformity assessment procedures
- proposed amendments to the Poisons Standard
- proposed adoption of specific European Union (EU) guidelines in Australia for medicines

- proposal for adoption of Pharmaceutical Inspections Convention Scheme/ Pharmaceutical Inspections Cooperation Scheme (PICs) – GMP standards and revisions and improved consultation process on the adoption of PIC/s guidelines
- updates to medicine advisory statements.

During the reporting period 14 formal consultations were completed. We aim to publish consultation submissions and our response on our website within two weeks following consultation with the Minister.

2.2b Evidence of discussions with affected stakeholders before TGA processes are changed.

In addition to the formal consultation process, we engaged with sponsors and key industry groups that may have been affected by planned changes to regulatory or business processes.

Some examples of topics discussed with affected stakeholders include:

- development and implementation of changes to the prescription medicines process, specifically the pre-submission pilot for new chemical entities and new generic medicines
- introduction of requirements for medicine label advisory statements
- introduction of a revised fee structure for OTC medicine applications
- updates to the Australian Regulatory Guidelines for OTC Medicines, including changes to mandatory requirements and a reduction of target times for processing applications that comply with an OTC medicine monograph
- introduction of a legislative instrument with a single list that specifies the ingredients available for use in listed medicines.

KPI 2.3 Regulators' decisions and advice are provided in a timely manner, clearly articulating expectations and the underlying reasons for decisions.

2.3a Information for consumers, health professionals and industry on the basis for the TGA's decision making, including any work to improve the quality of our decision making.

Information on pre market and post-market regulatory decisions detailing the basis for the decision are published on our website, including:

- ARTG entries: a publicly available online database of information about approved therapeutic goods that can be supplied in Australia, as well as those that have been suspended or cancelled
- AusPARs: information about the evaluation of a prescription medicine and the considerations that led us to a decision
- a list of Australian medicines manufacturers that have been issued with a GMP (manufacturing) licence
- the System for Australian Recall Actions: an online, searchable database containing information about recall actions for therapeutic goods
- outcomes of investigations into complaints about advertising
- outcomes of court actions relating to therapeutic goods.

During the reporting period, improvements to the quality of our decision making were implemented, including:

- updated decision letter templates to provide more consistent information to applicants regarding the legal provisions available to sponsors to review our decisions
- a program to seek ongoing feedback and provide training to internal review delegates.

A public subscription service is available and provides for automatic email notification of updates to the ARTG, safety-related alerts, revised guidelines, medicine shortages alerts, and other notices.

2.3b Percentage of pre-market applications and post-market activities processed in target timeframes.

Applications for market authorisation of therapeutic goods are processed with reference to target timeframes. There are different targets in place for the time taken to make a regulatory decision, depending on the type of therapeutic good being considered. Some of these targets are specified in the legislation. Timeframes exclude 'hold times' where we are waiting for a response from an applicant following a request for information, and include any time for committee consideration.

During the reporting period, the percentage of pre market applications processed within their respective timeframes were:

- 100% of prescription medicine applications (new chemical entity, fixed dose combinations, extension of indications and generic medicines)
- 99% of new over-the-counter medicine applications
- 100% of medical device conformity assessment applications
- 100% of medical device (including IVD) inclusion applications not selected for audit
- medical devices (not-IVD) - 66% of non-compulsory audits, 67% of Level 1 compulsory audits and 15% of Level 2 compulsory audits
- IVD medical devices - 53% of non-compulsory audits and 72% of compulsory audits (mTFR).

In relation to post-market activities, 100% of medical device incident reports were processed within target timeframes.

2.3c Publication of information for health professionals, consumers and industry when medicines are registered and/or new information arises on therapeutic goods.

We regularly issue news updates, tweets and public notices for consumers, health professionals, industry and the community. Some of the publications issued during the reporting period included:

- six editions each of the Medicines Safety Update and the Medical Devices Safety Update, providing health professionals with practical information about safety issues
- 109 web statements regarding safety alerts, shortages, reviews, early warnings or recalls affecting prescription medicines or medical devices.

In the TGA Stakeholder Survey 2015-16, overall reaction to education and publication activities was positive. Standout satisfaction ratings were achieved for the TGA update and TGA guidelines with 95.1% and 94.8% of users rating them useful to extremely useful in their roles respectively.

In November 2015 we launched the TGA Twitter channel to improve our information sharing on social media.

Some specific examples of information published on our website include:

- new prescription medicines and new or extended indications to currently registered products (including a subscription alert)
- AusPARs: reports include information about the evaluation of a prescription medicine and the consideration that led us to a decision
- CMI and PI documents for registered medicines (including any updates)
- a list of new or extended uses or new combinations of registered prescription medicines which is updated monthly

Quantity of information by type published on the TGA website for the period July 2015 to June 2016.

Type of information	Number
Australian public assessment reports (AusPARs)	74
Expert advisory committee meeting statements	19
Scheduling advisory committee interim and final decisions	15
New Chemical Entities (NCE) approvals	35
Extension of Indications (EOI) approvals[1]	18
Web statements: recalls/medicines safety alerts/suspensions	Medicines – 68 Medical devices – 36
Medicines Safety Updates	6
Medical Devices Safety Updates	6
Early warnings – potential safety issues	3
Medicine shortage web statements	4

[1]The publication of new or extended uses for prescription medicines commenced in January 2016.

KPI 2.4 Regulators' advice is consistent and supports predictable outcomes.

2.4a Percentage of substantive regulatory decisions subject to internal review, for which the original decision is revoked and substituted, without consideration of additional information.

Internal reviews are undertaken when a person whose interests are affected by an initial decision requests reconsideration of the decision by the Minister under section 60 of the *Therapeutic Goods Act 1989.*

The decision maker reviewing an initial decision may confirm the initial decision, revoke the initial decision or revoke the initial decision and substitute a different decision.

We make more than 34,000 regulatory decisions every year. During the reporting period, we made decisions on 19 applications for internal review of regulatory decisions. Of these, five initial decisions (26%) were revoked, or revoked and substituted. However, in all five cases, additional information was made available to the internal review delegates that was not submitted at the time of the original application.

2.4b Outcomes of matters referred by sponsors to the Administrative Appeals Tribunal (AAT), including where TGA decisions are upheld, and where the outcome is indicative of an issue about the quality of the decision.

During the reporting period nine matters were referred to the AAT and four of these matters were completed. Of these four, three applicants withdrew their application for a review. In the fourth case the applicant came to an agreement with us about the issues that were before the AAT, based on additional information that was obtained by the applicant after the appeal was lodged to the AAT. Both parties applied for, and were granted, consent orders to reflect the terms of that agreement.

For those matters that have been finalised, none of the outcomes of the AAT review were indicative of an issue about the quality of the initial or reviewable decisions made by us.

Self-assessed rating of performance against KPI 2 for 2015-16

The performance rating of "substantially" met is based on medical device timeframes not being met.

Met	Substantially met	Not met
Strong performance against *all* of the measures under the KPI	**P** Strong performance against *most* of the measures under the KPI	Poor performance against *all* of the measures under the KPI

KPI 3 Actions undertaken by regulators are proportionate to the regulatory risk being managed

KPI 3.1 Regulators apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions.

3.1a Outcomes of completed investigations of alleged offences.

There were no enforceable undertakings entered into during the period.

One matter was referred to the Commonwealth Director of Public Prosecutions (CDPP) for assessment. One court outcome was finalised and published on our website along with the outcomes of other compliance actions.

Of 1,760 completed investigations, 946 warnings were issued and one matter was referred to the CDPP.

Of 2,526 products investigated, prescription medicines comprised 71%, complementary medicines 18%, OTC medicines 1.8%, biologicals 1.9% and medical devices 3.9%.

3.1b Publication of evidence of compliance activities to support the continued availability of safe, effective and high quality therapeutic goods for the Australian public.

We use a staged risk management approach to compliance that attempts to identify entities at risk of unintentional or deliberate non-compliance and collect intelligence in relation to alleged breaches of the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*.

Our Laboratories Branch undertakes targeted testing of medicines and devices according to the risk they pose to the public. The outcomes of samples and products tested by type of therapeutic good and the percentage which failed is reported in the TGA Performance Statistics Report, which is published on our website. Excluding samples tested for accreditation, harmonisation and quality control, 1,696 samples of 761 products were tested. There was a failure rate of 26%, with 30% of medical devices failing, 0.5% of prescription medicines, 19% of OTC medicines and 20% of complementary medicines failing. 76% of unregistered products failed, these often being adulterated complementary medicines or counterfeit products.

We publish details of listed medicines cancelled from the ARTG following compliance reviews, including the provisions under which the cancellation was undertaken. We also publish details of cancellations and suspensions of medical devices (including IVDs).

Additionally, we publish statistics on the proportion of outcomes of inspections in terms of manufacturer performance (satisfactory, marginal and unacceptable) and the timeliness of inspections conducted within prescribed timeframes. Detailed information can be found in our Performance Statistics Report which is published on our website.

KPI 3.2 Regulators' preferred approach to regulatory risk is regularly reassessed. Strategies, activities and enforcement actions are amended to reflect changing priorities that result from new and evolving regulatory threats, without diminishing regulatory certainty or impact.

3.2a Information on the TGA's risk framework published on the TGA website, and regularly kept up-to-date.

The *Therapeutic Goods Act 1989* underpins our work and outlines a risk-based regulatory framework for therapeutic goods.

Some examples of documents describing this include:

- TGA Regulatory Framework – outlines how we regulate according to risk
- TGA Regulatory Compliance Framework.

During the reporting period, advice was provided to the Government in response to the recommendations of the Expert Panel Review of Medicines and Medical Devices Regulation, and a budget measure was published in the May 2016 Budget. Work is currently underway to review and strengthen our regulatory framework and assessment of risk in response to the Review.

3.2b Information on activities undertaken to ensure that a risk-based approach is taken to prioritise complaints and other signals of possible non-compliance with regulatory requirements.

The Regulatory Compliance Committee monitors our compliance actions and practices. Complaints and other signals of possible non-compliance are prioritised for investigation and potential regulatory action based on the level of risk posed. Factors influencing priority include consumer safety and the risk or nature of the regulatory breach. Priority is based on factors that:

- could significantly mislead the Australian public, particularly where there is a health impact
- are likely to become widespread if we do not intervene
- are of national or international significance
- involve a new or emerging issue of concern
- are the subject of public scrutiny and concern
- could lead to a loss of stakeholder confidence in us or therapeutic goods.

For investigations that identify a potential safety or quality risk, testing of samples may be required. The results of testing determine if further action is required, such as a risk assessment, cancellation and/or recall. Appropriate enforcement actions (and appropriate follow-up) are implemented based on the risk assessment and investigation of post-market issues.

For safety reviews, a risk-based process has been developed for the screening and prioritisation of signal investigations. This process provides a rationale for allocation of resources and ensures we can respond to emergent safety issues. All identified issues are recorded and acted upon within a timeframe appropriate to their impact on public health. If a safety concern relating to a medicine or vaccine is identified, a range of regulatory action may be taken.

KPI 3.3 Regulators recognise the compliance record of regulated entities, including using earned autonomy where this is appropriate. All available and relevant data on compliance, including evidence of relevant external verification is considered.

3.3a Information on activities undertaken to ensure that a risk-based approach is taken to monitoring and compliance activities.

Proportionate compliance activities

We monitor the market for signals of potential non-compliance across the range of regulatory areas covered by the *Therapeutic Goods Act 1989* and employ a uniform risk-based approach to determining the significance of any signals detected and the appropriate regulatory response.

We can communicate regulatory requirements and compliance expectations quickly and directly to a market-entry applicant and can deny market access to applicants who cannot demonstrate compliance with these requirements. Providing regulatory education to applicants at or before this point can help to minimise non-compliance once a product is marketed.

Scheduling of inspections based on compliance records

We employ risk-based inspection frequency matrices to guide the frequency of inspections. Manufacturer performance at inspection is categorised as satisfactory, marginal and unacceptable with further granularity provided by applying a high, medium or low risk rating. These ratings are applied when setting the date for reinspection. The matrix also takes into account product and process risks.

Before scheduling inspections, we consider emerging trends, recalls, adverse events, results of laboratory testing, feedback and inspections undertaken by other regulators and manufacturer profiles that have been updated to reflect any significant changes with the company.

Targeted complementary medicine reviews are based in part on the compliance record of the particular sponsor.

During the reporting period, the focus was on raising compliance levels of Australian manufacturers.

Product safety monitoring

All post-market safety-related activities are undertaken using a risk-based approach under our therapeutic product vigilance framework. There were 37 products with a Risk Management Plan (RMP) identified as being a high priority for periodic safety update review, equalling one-third of products approved with an RMP evaluation. The majority of RMP evaluations were conducted for new chemical or biological entities, and applications to extend the indications of registered products.

Recalls

We use a risk-based approach to determine the classification and level to which a recall is undertaken (consumer level, retail level, hospital level or wholesale level) by considering the significance of the hazard, the channels by which the goods have been distributed, and the level to which distribution has taken place.

All recalls are risk assessed and classified into Class I, II and III which aids in the prioritising of actions. Class I and Class II actions are safety related with highest priority given to Class I issues which can result in serious injury or death to patients or users. Class II issues could cause illness, injury or result in mistreatment, but are not Class I. Class III actions occur when issues may not

pose a significant hazard to health, but action may be initiated for other reasons e.g. quality related issues.

Out of the 667 recalls for medicines and medical devices undertaken during the reporting period, 130 were Class I, 463 were Class II and 74 were Class III.

Advertising

Where we receive a complaint regarding advertising it is triaged and prioritised based on the risks that the advertising could pose, primarily to public health and safety, but also our compliance activities and regulatory responsibilities.

During the reporting period, we received 312 complaints about the advertising of therapeutic goods. Where evidence of non-compliance with the legislative requirements is identified, the matter is addressed in the context of our Regulatory Compliance Framework.

Self-assessed rating of performance against KPI 3 for 2015-16

Met	Substantially met	Not met
P Strong performance against *all* of the measures under the KPI	Strong performance against *most* of measures under the KPI	Poor Performance against *all* of the measures under the KPI

KPI 4 Compliance and monitoring approaches are streamlined and coordinated

KPI 4.1 Regulators' information requests are tailored and only made when necessary to secure regulatory objectives, and only then in a way that minimises impact.

4.1a Information on activities undertaken to minimise the need for, or number of, requests for information to sponsors under the relevant legislation.

We continually implement processes to minimise the number of formal requests for information from regulated entities by improving our business processes.

During the reporting period, we worked with the complementary medicines industry to create electronic forms that clearly communicate the requirements of each application category. This is expected to minimise the need for us to seek additional information.

Reform activities have also been introduced over this period to streamline the prescription medicine application processes and engage with sponsors prior to submitting their applications. One of the key elements was the consolidation of regulatory requests issued under section 31 of the *Therapeutic Goods Act 1989* at a single stage in the evaluation process. This has reduced the number of requests sent to sponsors during the evaluation process.

KPI 4.2 Regulators' frequency of information collection is minimised and coordinated with similar processes including those of other regulators so that, as far as possible, information is only requested once.

4.2a Refer to KPI 1.3 – (Progress of business improvements, and other specific projects, so that sponsors will only need to provide some information to the TGA once).

Initiatives to collect information from sponsors, including the new TGA Business Services site, are captured under various business improvement programs as outlined in KPI 1.3b.

Other activities included:

- changes were implemented to streamline systems and processes for registering complementary medicines though the alignment of systems with OTC medicines, and reduce effort, including requests for information, by the consideration of comparable evaluations as part of applications
- streamlined post-market review processes were developed which improve the timeliness of compliance reviews for listed complementary medicines and reduce requests for information within the review process
- a pilot of a simplified pre-submission pathway for prescription medicine registration applications removes the requirement for sponsors to provide summary information to us during the pre-submission phase and then again with the submission dossier. This information is now provided once, in the submission dossier only.

4.2b Information on cooperative activities carried out with international regulators to minimise information collection from industry (such as joint GMP inspections).

We regularly share manufacturer inspection schedules with the United States of America's Food and Drug Administration (US FDA), the European Medicines Agency (EMA) and Health Canada.

This activity aims to identify opportunities for joint inspections with international regulators and therefore minimise the burden on industry. Nine joint GMP inspections were conducted during this period, with agencies including the EMA, EU member state regulators, the European Directorate for the Quality of Medicines and Healthcare (EDQM), the US FDA, Medsafe New Zealand, Health Canada and Medicines Control Council of South Africa.

Collaboration on generic medicines for the reporting period resulted in agreement of a common template for Drug Master Files, new ingredients code tables for eBusiness Services (eBS) and revised guidelines on biosimilar medicines. We also published two OTC medicine monographs that were developed with Health Canada. This will enable more OTC medicines to be processed requiring less information to be provided in the application for registration.

We also have an active role in the development of the international model for a Medical Devices Single Audit Program (MDSAP) through the IMDRF. The pilot is intended to allow MDSAP recognised auditing organisations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the multiple regulatory authorities participating in the pilot program.

KPI 4.3 Regulators utilise existing information to limit the reliance on requests from regulated entities and share the information among other regulators, where possible.

4.3a The use of information from, or in collaboration with, other regulators; for example, development of processes for sharing with international regulators, the number of product evaluation and inspection reports shared.

We have strong active working relationships with major overseas regulators including the United States, Canada, New Zealand, Singapore and European countries. Information sharing with international regulators is further facilitated through participation in forums and consortia such as the International Coalition of Medicines Regulatory Authorities (ICMRA), International Generic Drug Regulators Program (IGDRP), the Australia, Singapore, Switzerland, Canada (ACSS) consortium, International Conference on Harmonisation of Technical Requirments (ICH) and the Regulatory Cooperation Initiative (RCI) with Health Canada.

Examples of collaboration and information sharing with other regulators during the reporting period include:

- chairing the ICMRA Generic Medicines Working Group that developed a draft policy paper proposing information sharing priorities for regulators on generic medicines
- chairing the ICMRA pharmacovigilance working group to progress work in three key areas:
  - how to best utilise ‘big data’ for pharmacovigilance purposes
  - increasing the rates of adverse event reporting, in particular from health care professionals; and
  - linking existing systems in order to improve global pharmacovigilance warnings information sharing
- adopting the IGDRP evaluation templates for our assessment of Biopharmaceuticals Classification System-based biowaivers and Active Substance Master Files/ Drug Master Files to streamline the submission requirements for the medicines industry
- commencing a generic medicine work sharing trial with other regulators in the ACSS consortium and a leading industry stakeholder

- use of foreign review information in assessments of domestic generic drug/medicine applications. Eight generic medicine submissions and four drug master file reports were received from a foreign regulator
- undertaking desktop clearances for manufacturers in place of inspections, taking into consideration regulatory decisions by other comparable regulators. Of the 2,725 approved clearances, 2,590 (or 95%) were based on evidence from other regulatory agencies.

4.3b Collaborative work undertaken with health professionals. For example, interactions on significant medicine shortages, recall actions or safety issues.

At the request of the Council of Australian Governments (COAG) Health Council, we established a working party on medicines shortages. The working party consists of jurisdictional, professional and pharmaceutical industry representation, with the purpose of developing additional strategies to improve the management of medicine shortages. The working party developed the following recommendations for COAG Health Council consideration:

- improve awareness of the Medicine Shortages Information Initiative (MSII) and ensure the shortages are notified to the MSII in a more timely and comprehensive manner, with information kept up to date
- more proactively identify alternative sources of supply of suitable medicines
- ensure appropriate clinical advice is provided when there is a medicine shortage that will significantly affect patient care
- review procurement strategies and protocols on dealing with medicine shortages to ensure consistency in the public health sector
- notification of medicine shortages remains voluntary (with information published on shortages when a pharmaceutical company will not report the shortage).

Further activities include:

- collaboration with ACT Health and NSW Health in undertaking the “inSite” pilot project to educate health professionals about medical device adverse event reporting and encourage reporting to us
- in conjunction with ARCS Australia, several workshops for industry on activities to improve the quality of risk management plans.

KPI 4.4 Regulators base monitoring and inspection approaches on risk and, where possible, take into account the circumstance and operational needs of the regulated entity.

4.4a Refer to KPI 3.3 – (information on activities undertaken to ensure that a risk-based approach is taken to monitoring and compliance activities).

KPI 3.3 outlines the activities undertaken to ensure that a risk-based approach is taken to our monitoring and compliance activities.

In addition to these activities, we have streamlined and coordinated compliance activities so that the circumstances and operational needs of industry are also considered. Information gathered from monitoring and surveillance activities is shared with pre market areas and inspectors. This information is subsequently used in risk assessments for activities such as proactive compliance reviews of therapeutic goods and schedules for inspections of manufacturing facilities.

A Regulatory Intelligence Section has been established to develop and implement strategic, tactical and operational intelligence capability. This intelligence capability is intended to provide intelligence led, risk-based predictive intelligence to support proactive compliance, enforcement and investigatory activity.

Self-assessed rating of performance against KPI 4 for 2015-16

We have self-assessed the result as "substantially" rather than "fully" met as TGA does not yet have a fully mature compliance and enforcement framework with graduated sanctions and penalties. While we have a sound compliance structure in place, we do not yet have a range of regulatory tools which allow us to use the full range of compliance approaches.

Met	Substantially met	Not met
Strong performance against *all* of the measures under the KPI	P Strong performance against *most* of the measures under the KPI	Poor performance against *all* of the measures under the KPI

KPI 5 Regulators are open and transparent in their dealings with regulated entities

KPI 5.1 Regulators' risk-based frameworks are publicly available in a format which is clear, understandable and accessible.

5.1a Refer to KPI 3.2 – (Information on the TGA's risk framework published on the TGA website).

We publish detailed and user friendly information on the way we apply our risk-based frameworks and this information is updated in response to emerging issues. KPI 3.2a outlines how our risk framework is made available to the public.

We have continued to direct efforts towards raising awareness of our regulatory framework through activities such as industry workshops and publication of educational materials.

5.1b Information on the TGA's regulatory compliance framework published on the TGA website, with evidence of systems for regular review and updates.

Our Regulatory Compliance Framework outlines to stakeholders how we manage our compliance function under legislation.

We employ a combination of monitoring strategies to support our compliance program, which enables us to apply flexible and proportionate responses to non-compliance, as well as proactively encourage compliance and manage emerging issues. This is achieved through our continued communication strategies, ongoing publication of safety updates and workshops with industry on effective risk minimisation activities to improve the quality of risk management plans submitted with their applications for high risk medicines or vaccines.

More information about our regulatory compliance framework is provided in KPIs 3.2 and 3.3.

KPI 5.2 Regulators are open and responsive to requests from regulated entities regarding the operation of the regulatory framework, and approaches implemented by regulators.

5.2a Adherence to quantitative standards of service commitments and agreed performance measures in relation to responding to enquiries received through the TGA's public information lines.

We maintain a number of telephone and email based information lines that receive enquiries from industry stakeholders, with our Regulatory Assistance Section (RAS) managing the central telephone, email, fax and letter enquiry lines. During the reporting period 28,035 enquiries were received by the RAS, of which 40% were from industry. Where responses were provided by the RAS, all enquiries from industry were responded to within the timeframes outlined in our customer service standards, i.e. to acknowledge letters and emails within five working days and respond to voice mail messages within two working days.

5.2b Information on interactions with industry.

Please refer to KPIs 1.1a and 1.1b, which provide detailed information on the formal and informal interactions with industry stakeholders during the reporting period.

KPI 5.3 Regulators' performance measurement results are published in a timely manner to ensure accountability to the public.

5.3a Information on ongoing reporting activities including applicable timeframes.

We regularly report on performance activities through:

- Half Yearly Performance Snapshot – July to December 2015
- Performance Statistics Report (annual)
- Regulator Performance Framework KPI report (annual) from 2016
- input to the Health Portfolio Budget Statements (annual)
- input to the Department of Health Annual Report (annual)
- Prescription Medicines Annual Summaries (annual)
- reports for statutory advisory committees (as required).

During the reporting period we commenced a review of our reporting framework, including consultation with industry, to gather a holistic view of the reports that are provided. The aim of this review was to develop a reporting framework that aligns with relevant Australian Government reporting requirements as well as the interests and needs of our stakeholders, and to ensure that the effort required to produce the report is a valuable investment of resources.

Through the review of our reporting framework, we now publish the Half Yearly Performance Report Snapshot – July to December 2015 in digital format. The new digital format offers animation and interactivity to provide users with an improved understanding of the content through the use of plain language.

We have also established a framework of program and project reporting governed by program and project boards to ensure appropriate oversight of key business improvement projects. These reports are delivered on a weekly, monthly, six-monthly and annual basis.

Self-assessed rating of performance against KPI 5 for 2015-16

Met	Substantially met	Not met
P Strong performance against *all* of the measures under the KPI	Strong performance against *most* of the measures under the KPI	Poor performance against *all* of the measures under the KPI

KPI 6 Regulators actively contribute to the continuous improvement of regulatory frameworks

KPI 6.1 Regulators establish cooperative and collaborative relationships with stakeholders to promote trust and improve the efficiency and effectiveness of the regulatory framework.

6.1a Market research conducted on an annual basis to measure consumer, health professional and industry trust in—and engagement with—the regulatory framework.

The information retrieved from our market surveys is utilised to ensure that we help stakeholders make more informed decisions about therapeutic goods and comply with our regulatory requirements.

During the reporting period we surveyed 449 health professionals, 65 consumers and 1,628 members of industry via a public survey to gauge each group's:

- level of awareness of therapeutic goods regulation, the TGA and specific regulatory activities
- perceptions and support for us
- preferred sources of information about the regulatory system
- previous contact with us and use of existing information services.

Key findings in relation to trust in the regulator, based on cooperative and collaborative relationships, for the three major stakeholder groups are outlined below.

	Consumers	Health Professionals	Industry
Trust to perform role ethically and with integrity	71%	83%	87%
Provide safeguards for the health of Australians	58%	74%	77%

Stakeholders were mainly satisfied or very satisfied with our communication and consultation processes, however, overall only 50% of stakeholders felt that the TGA consulted them on relevant issues.

	Consumers	Health Professionals	Industry
Satisfaction with communicating with the TGA	59%	57%	64%
Dissatisfaction with communicating with the TGA	22%	18%	15%
Satisfaction with consultations with the TGA	64%	63%	62%
Dissatisfaction with consultations with the TGA	0%	22%	12%

Between February and April 2016, 40 in-depth one hour interviews were conducted with industry stakeholders, including representatives from large companies as well as small to medium enterprises, to find out more about their experience of dealing with the TGA online. Interviews were conducted with people from prescription medicines, complementary and OTC medicines, devices, and manufacturing sectors.

6.1b Stakeholder engagement and satisfaction with TGA consultative processes.

	2015-16
Percentage of stakeholders who were satisfied or very satisfied with our consultative processes	67%
Percentage of stakeholders who were dissatisfied with our consultative processes	10%

The data for this output was obtained through the annual program of market research reported under KPI 6.1(a).

KPI 6.2 Regulators engage stakeholders in the development of options to reduce compliance costs. This could include industry self-regulation, changes to the overarching regulatory framework, or other strategies to streamline monitoring and compliance approaches.

6.2a Evidence of continuous compliance with our practice of engagement with industry before a RIS is finalised.

Industry was consulted on the two RISs finalised during the reporting period. This minimised the potential for unintended impacts on regulated entities and product supply. Refer to KPI 1.2a for more information on RIS consultation during this period.

We also engage with regulated entities prior to minor or machinery changes that may not require a RIS, such as updates to guidelines, and improvements to forms and systems used to conduct business. These consultative processes are consistent with our commitment to minimise the potential for unintended financial or resource impacts on regulated entities and product supply consultation. Refer to KPI 2.2a for information about our formal consultations during the reporting period.

Detailed information on our consultations can also be found on our website.

6.2b Progress of business improvements and other projects aimed at reducing compliance costs.

We aim to reduce compliance costs to our regulated entities by regularly engaging with our stakeholders and maintaining a cycle of continuous business improvements, including:

- launch of the TGA Business Services website
- transition to eCTD technical files for prescription medicines
- introduction of the ACE scheme
- introduction of the pre-submission pilot pathway for prescription medicines applications
- implementation of electronic lodgement of CTN
- ongoing development of an online application form for minor variations relating to prescription medicine applications

- introduction of regulatory reforms to the IVD Framework (in particular, regulation of in-house IVD tests) with a transition period until 30 June 2017 for in-house IVDs.

During the period, there was progress in implementing digital prescription and OTC medicine submissions and monitoring systems including a new fee model for OTC medicines.

For more information, refer to KPIs 1.3b and 4.2a.

KPI 6.3 Regulators regularly share feedback from stakeholders and performance information (including from inspections) with policy departments to improve the operation of the regulatory framework and administrative processes.

6.3a Information on cooperation and collaboration with policy areas of our Department.

These activities included:

- collaboration with representatives from the Office of Health Protection and Jurisdictional Immunisation Coordinators from the states and territories regarding vaccine safety issues
- liaison with the Medical Benefits Division to support the activities of the Prostheses List Advisory Committee, including alignment of ARTG inclusions and the Prostheses List following the reclassification of joint replacement prostheses
- working with the Best Practice Regulation Branch to provide input on regulatory reform activities, including the Review of Medicines and Medical Devices Regulation
- representation on the World Health Organisation International Non-proprietary Names Consultations. The outcomes of the consultations and implications of the adoption of the biological qualifier were conveyed to the Pharmaceutical Benefits Division
- collaboration with the Pharmaceutical Benefits Division and Medical Benefits Division to utilise datasets to establish mechanisms for effective post-market monitoring
- collaboration with the Preventative Health Policy Branch on the Food-Medicine Interface Protocol
- collaboration, in conjunction with the Pharmaceutical Benefits Division, on improving a mechanism to share information regarding prescription medicines submitted under the TGA-Pharmaceutical Benefits Advisory Committee Parallel Process. This information sharing is intended to minimise requests for information from sponsors.

6.3b Information on interactions with other Australian government departments, regulators and statutory authorities.

As part of the Health Department, we collaborate with other Australian government agencies on a range of regulatory issues to ensure a consistent approach. During the period we engaged with:

- Food Standards Australia New Zealand, on health claims and novel ingredients
- state and territory food authorities, regarding enquiries on products at the food-medicine interface
- the ACCC, on safety related recalls
- the Department of the Environment, on the rapid evaluations templates they use for chemical assessments

- HealthPACT, reviewing new and innovative devices
- the Department of Immigration and Border Protection, to develop targeted approaches to prevent the import and/or export of illegal therapeutic goods
- the Department of Agriculture and the Department of Immigration and Border Protection to collaborate and share information technology design, systems and learnings
- the Productivity Commission, on its public inquiry into Australia's Intellectual Property Arrangements
- the Department of Foreign Affairs and Trade, prior to the Trans-Pacific Partnership negotiations in 2015
- the National e-Health Transition Authority, on Australian medicines terminology and specifically changes to medicines ingredient names
- the National Health and Medical Research Council, to update guidance documents relating to conduct of clinical trials in Australia
- state and territory jurisdictions represented on our committees, e.g. Advisory Committee on Chemicals Scheduling and Advisory Committee on Medicines Scheduling.

Self-assessed rating of performance against KPI 6 for 2015-16

Met	Substantially met	Not met
P Strong performance against *all* of the measures under the KPI	Strong performance against *most* of the measures under the KPI	Poor performance against *all* of the measures under the KPI

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Engagement and Planning Branch	September 2016

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Reference R16/572388