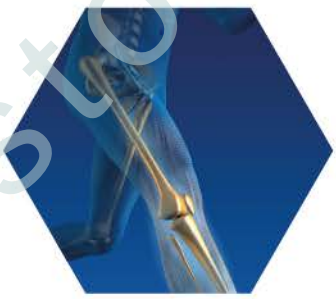
TGA key performance indicators

January to June 2015

Version 1.0, August 2015






Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	August 2015

TGA key performance indicators

As a part of the Department of Health, 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*. Through the TGA, the Australian Government aims to:

- regulate therapeutic goods for safety, effectiveness/performance and quality
- participate in international regulatory convergence and work sharing
- continue quality improvement and regulatory reform processes.

During January to June 2015 we have been guided by the *TGA Strategic Statement: 2012-2015* in delivering these outcomes.

Our performance against our broad strategic intent for this period is measured through eight key performance indicators (KPIs):

1. Stakeholder communication, education and satisfaction
2. Pre-market business operations
3. Post-market business operations
4. Organisational health
5. Financial performance
6. Statutory obligations
7. International cooperation
8. Decision making.

The KPIs and the specific measures that are used to report against each KPI have been endorsed by the Australian Therapeutic Goods Advisory Council, following consultation with the TGA Industry Consultative Committee.

This KPI report covers aspects of our performance between January and June 2015.

Progress has been made in a number of areas since the last KPI report. In particular, in the number of manufacturing clearances issued, and work sharing arrangements with international regulators. There was a steady rise in stakeholder engagement with the TGA website, and progress towards the Australian Government's Digital Transition Policy is increasing and on target to reach 100 per cent by December 2015.

Regulator Performance Framework

The Australian Government has developed a framework to assist regulators to measure their performance. The Regulator Performance Framework (RPF) comprises six outcomes-based KPIs that reflect the Australian Government's overarching expectations of regulator performance.

The RPF KPIs came into effect on 1 July 2015, and will replace the TGA's KPI framework. The January to June 2015 report will be the final KPI report to be published in the current format.

The first report against the new RPF will cover the period July 2015 to June 2016 and the TGA's performance against the RPF KPIs will be published on the TGA website following Ministerial approval. Further information on the *TGA key performance indicators and measures: Regulator Performance Framework* is available on the TGA website.

1. Stakeholder communication, education and satisfaction

We demonstrate our performance against this KPI in three different areas, as described below.

For this reporting period, website statistics are split into two separate time periods because we upgraded our reporting software in November 2014. There is a difference between how the reporting software captures and analyses the data and therefore there is not a direct correspondence between the new metrics and visitor numbers reported in previous periods.

1.1 Improved community, health professional and industry understanding of TGA's role		
Number of visitors engaged with the TGA website (new reporting software)	**Jan – Jun 2015**	**Nov – Dec 2014**
• Sessions – a period of active engagement by a user with the website	1, 284, 287	370,204
• Users – the total number of unique website visitors	799, 364	242,987
• Page views – a view of a single web page on our website.	3, 313, 113	992,786
Number of visitors to the TGA website (previous software)	**Jul – Oct 2014**	**Jan – Jun 2014**
Number of visitors to the TGA website	1,196,493	1,665,669
Top 5 web pages viewed (2015)	**Jan – Jun 2015**	
Home page	332,320	
Australian Register of Therapeutic Goods	44,465	
The Poisons Standard	40,330	
Prescribing medicines in pregnancy database	28,660	
Recommended Paracetamol doses	27,186	
These web pages represent about 14% of total page views.		
Top 5 web pages viewed (2014)	**Jul – Dec 2014**	**Jan – Jun 2014**
Home page	433,976	371,264
Children's Panadol 1-5 years Colourfree suspension	39,608	N/A
Recommended paracetamol doses	29,427	43,275
Latest news & updates	27,729	37,082
Australian Register of Therapeutic Goods	24,233	35,886

N/A = not applicable. This webpage was created during the current reporting period.

1.1 Improved community, health professional and industry understanding of TGA's role			
TGA participation in stakeholder forums	**Jan – Jun 2015**	**Jul – Dec 2014**	**Jan – Jun 2014**
Number of TGA participations in key stakeholder forums, either as speakers or through exhibits	19[1]	28	22

[1] Several TGA speakers may have presented at a single forum.

Market research on our stakeholders

Consumers, health professionals and industry are surveyed annually to measure whether there are improvements in stakeholder understanding of our role. The next survey will be conducted in late 2015 and therefore no new data is available for this period.

TGA stakeholder consultation

1.2 Stakeholder engagement and satisfaction with TGA consultative processes			
TGA stakeholder engagement	**Jan – Jun 2015**	**Jul – Dec 2014**	**Jan – Jun 2014**
Number of new consultations completed during the reporting period	5	4	1
Median number of submissions received for consultations	36 (range 21–67)	11 (range 5–80)	9
Submissions and TGA responses published on the TGA website in target timeframes[1,2]	100%	100%	100%
Number of subscribers to all TGA email lists	9570	9648	9169
Number of subscribers to consultation email list	780	647	592
Number of stakeholders who were satisfied or very satisfied with our consultative processes	66%	N/A	75%

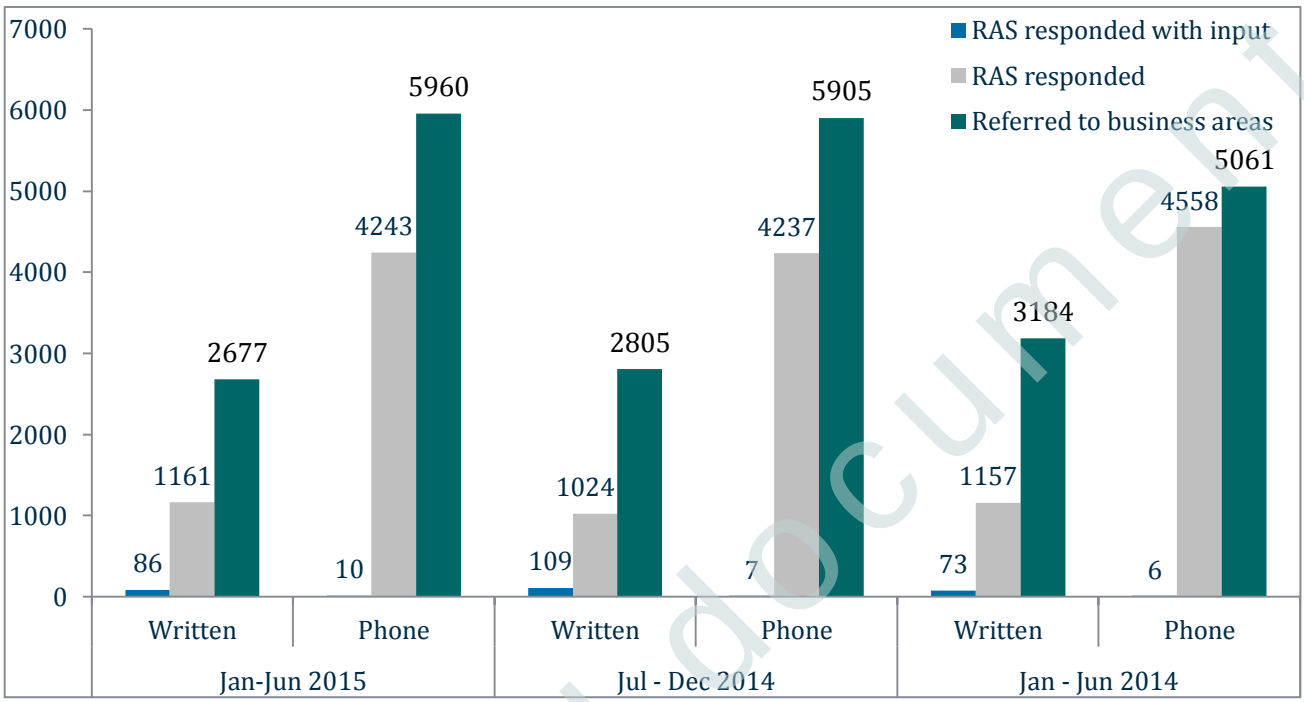
[1] We aim to publish consultation submissions and the TGA response (where appropriate) within two weeks of noting or advice from the Assistant Minister for Health, where applicable.
[2] Submissions and responses to one consultation were published during the reporting period.
N/A = Not applicable. This survey is conducted on an annual basis.

Stakeholder satisfaction with TGA consultation processes decreased during this reporting period due to shorter timeframes provided for consultation responses, and reduction in advanced notice of consultations due to the unavailability of the consultation forecast during the conduct of the *Expert Review of Medicines and Medical Devices Regulation*.

TGA customer service

The Regulatory Assistance Section (RAS) is our first point of contact for enquirers approaching the TGA. Under the TGA's customer service standards, the RAS aims to respond to voicemail messages within two working days, and to respond to emails (either through a direct response or referral to regulatory areas for appropriate action) within five working days.

Figure 1 Regulatory Assistance Section performance



Enquiries received by the RAS are separated into levels depending on how the enquiry is managed:

- RAS responded with input: enquiries that require more than one transaction to finalise, where a response sent by RAS includes input from other regulatory/business areas.
- RAS responded: enquiries finalised by the RAS without needing advice from other areas as the information is publicly available or a similar enquiry has been responded to in the past with appropriate clearance.
- Referred to business areas: Enquiries that are transferred to other work areas for follow up and response.

There were 1955 voicemail messages received during this period. This is an increase from the previous period as a result of staff turnover and training, however the RAS responded to 100 per cent of email and voicemail enquiries within the specified timeframes during the reporting period.

1.3 Performance against TGA customer service standards			
Time taken to respond to complaints	**Jan – Jun 2015**	**Jul – Dec 2014**	**Jan – Jun 2014**
Number of complaints received by email	1	0	5
Median time taken to respond (days)	2	N/A	5
Complaints received by telephone	1	0	2
Time taken to respond (days)	1	N/A	0–2

The TGA customer service standards specify that feedback will either be answered or acknowledged within 5 working days and, where feedback requires further investigation by the TGA, the acknowledgement will provide notification of this and associated timeframes for response.

2. Pre-market business operations

The TGA makes decisions whether to approve or reject market authorisation of medicines, medical devices and blood and tissues that are imported, exported, manufactured and supplied in Australia. This KPI provides evidence about whether we are enabling timely access to therapeutic goods for the Australian public.

We aim to ensure that all of the applications for market authorisation of therapeutic goods are processed within target timeframes. There are different targets in place for the time taken to make a regulatory decision, depending on the type of therapeutic good. Some of these targets are specified in the legislation. Timeframes exclude 'hold times' where the TGA is awaiting a response from an applicant following a request for information, and includes any time for committee consideration.

2. Pre-market business operations	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Prescription medicines			
Applications lodged under the prescription medicines registration process ('Category 1' applications) processed within the legislated timeframe (255 working days)	177 (99%)	164 (100%)	206 (99.5%)
Quality related evaluations ('Category 3' applications) processed within the legislated timeframe (45 working days)	723 (98%)	737 (100%)	754 (100%)
Non-prescription medicines: new applications[1]			
N1 (target timeframe = 45 working days)	56 (100%)	116 (94%)	131 (98%)
N2 (target timeframe = 75 working days)	1 (100%)	8 (100%)	2 (100%)
N3 (target timeframe = 150 working days)	16 (100%)	21 (100%)	38 (100%)
N4 (target timeframe = 170 working days)	15 (100%)	58 (100%)	18 (100%)
N5 (target timeframe = 210 working days)	7 (100%)	17 (100%)	1 (100%)
Non-prescription medicines: change applications[1]			
C1 (target timeframe = 20 working days)	268 (91%)	261 (97%)	184 (84%)
C2 (target timeframe = 64 working days)	136 (100%)	134 (99%)	169 (98%)
C3 (target timeframe = 120 working days)	2 (100%)	3 (67%)	6 (100%)
C4 (target timeframe = 170 working days)	5 (100%)	0[2]	3 (100%)
Complementary medicines			
Registered complementary medicines (mean approval time; working days)	423[3]	160[4]	0[2]
New substances for listed medicines (mean approval time; working days)	127[3]	239	225

2. Pre-market business operations	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Medical devices			
Conformity assessments processed within the target timeframe (255 days)	53 (100%)	95 (100%)	137 (100%)
Non-compulsory application audits processed within the target timeframe[5] (30 working days)[6]	156 (72%)	133 (54%)	478 (38%)[7]
Level 1 application audits processed within the target timeframe[5] (30 working days)	11 (100%)	13 (77%)	16 (60%)
Level 2 application audits processed within the target timeframe[5] (60 working days)	155 (46%)	156 (18%)[8]	205 (60%)
In vitro diagnostic medical devices			
Conformity assessments processed within the target timeframe (255 days)	12 (100%)	25 (100)%	24 (100%)
Non-compulsory application audits processed within the target timeframe (60 working days)	4 (100%)	8 (50%)	6 (33%)
Mandatory technical file reviews processed within the target timeframe (60 working days)	71 (100%)	78 (83%)	69 (91%)

[1] Data for new and change applications were reported differently prior to 2014. The data reported are the total number of applications completed during the reporting period and the percentage that were completed within target timeframes. Further details of the different types of applications for non-prescription medicines are available in the Australian Regulatory Guidelines for Non-prescription Medicines. The different application types for non-prescription medicines are:

- N1: an application submitted as a 'Clone'
- N2: an application which complies with an over-the-counter medicine monograph
- N3: a new application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4
- N4: an application for a 'generic' medicine where the medicine:
  - is included in Appendix X of the Over-the-counter Application Categorisation Framework (but which is not a level N1 application) and/or
  - includes an umbrella branded product name where the umbrella segment is categorised as requiring a higher level of assessment and/or
  - requires supporting safety and/or efficacy (clinical/toxicological) data or a justification for not providing such data.
- N5: an application for a new product that is an extension to a 'Generic category' product or an application for a product containing a new chemical entity as an active ingredient.
- C1: quality and non-quality changes – self assessable requests and safety related requests
- C2: quality changes or non-quality changes – no safety and efficacy data required
- C3: umbrella branding – higher level of assessment or non-quality changes – safety and efficacy data may be required
- C4: non-quality changes – data are required.

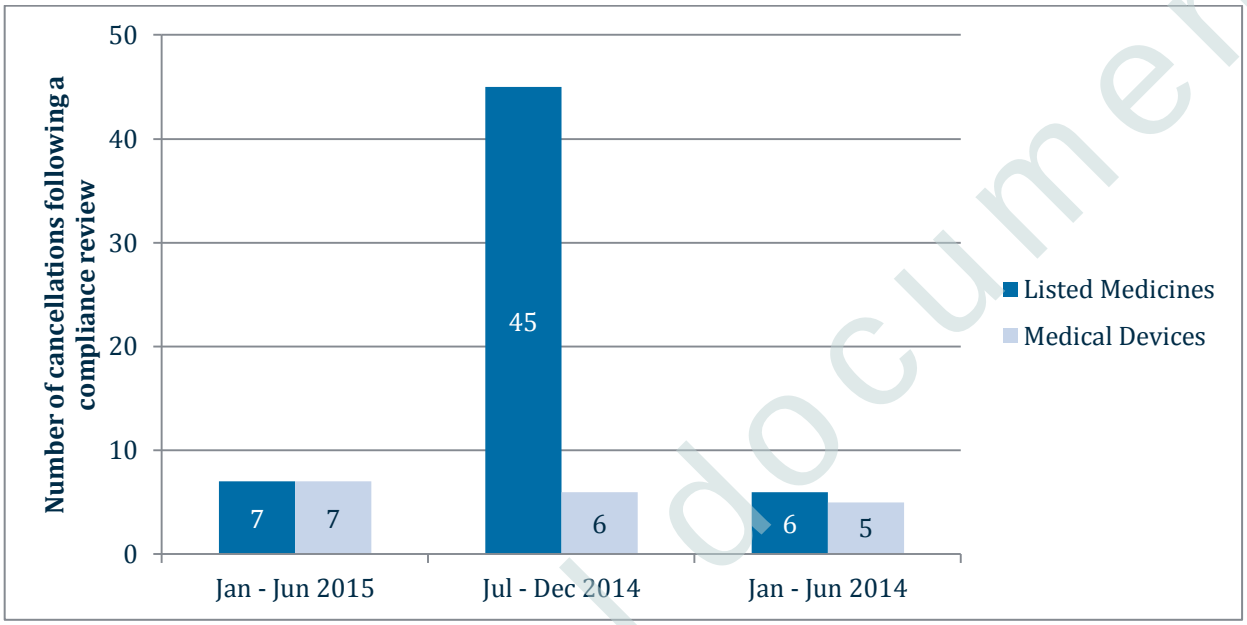
[2] There were no approvals for this application type during the reporting period.
[3] These data are for a single application.
[4] There were three applications approved, which were different dosage forms of the same product line. Thus, the average time for completion of the three individual applications is divided by 3 for reporting purposes.
[5] The audit period commences when the sponsor is notified that the application is selected for audit. Previously, due to certain limitations the target timeframe in this report was calculated inclusive of the 20 working days period from when the application is made (application fee paid) during which time the TGA may select the application for auditing. The figures for the last 6 months (January – June 2015), the report refers to the actual audit time, i.e. excluding initial 20 working days prescribed under the legislation.
[6] The figures for non-compulsory audits do not include applications for reclassification of total or partial shoulder, hip, or knee joint replacement medical devices. These applications are not subject to the agreed target timeframe.
[7] The January-June 2014 figure incorrectly includes numbers for Joint Implant Reclassification applications that are not subject to the agreed target timeframe. The correct figures are: there were 225 non-compulsory application audits processed in January to June 2014, of which 32% were completed within the 30 TGA working day target time frame.
[8] The intricate nature of these audits vary considerably and during this reporting period the majority of audits undertaken were of significant complexity.

3. Post-market business operations

This indicator demonstrates whether TGA's work supports the continued availability of therapeutic goods on the Australian market that are safe, effective and of high quality. The success of many of these measures is underpinned by reporting of adverse events by consumers, health professionals and industry.

3.1 Product cancellations

Figure 2 Cancellations by the TGA of products following a compliance review

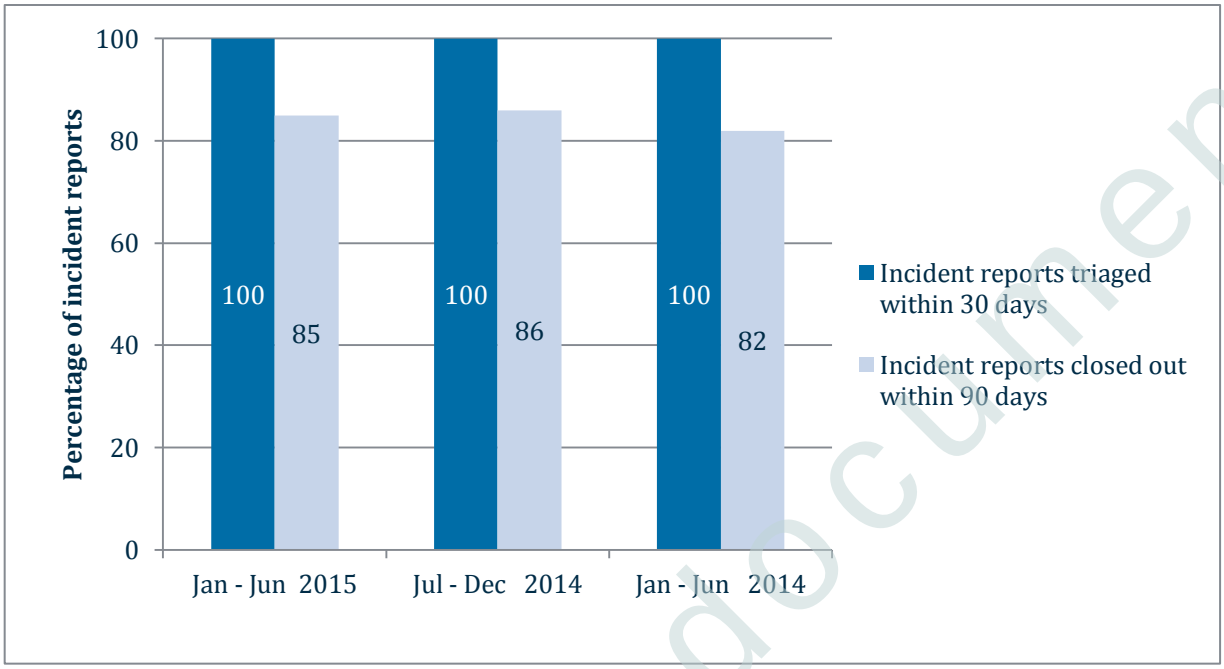


The number of listed medicines cancelled in the July-December 2014 reporting period is higher than comparative periods due to a single sponsor of 36 products failing to comply with a notice requiring information about the goods.

3.2 Medical device incidents

Figure 3 Triage and investigation of medical device incidents

Due to the complex nature of some investigations, it is not expected that all investigations would be completed within the 90 day target. For example, delays can occur while waiting on input from third parties.



3.3 Other post-market activities

3.3 Post-market business operations	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Regulatory compliance			
Outcomes of completed investigations of alleged offences:			
• Warning issued	399	509	371
• Goods released under Personal Import Scheme	46	42	33
• Referred to another part of TGA	3	4	8
• Referred to another department or agency	4	8	8
• Import treated as abandoned goods by Customs	0	0	0
• No offence detected	59	148	100
Cases of deliberate non-compliance referred to the Commonwealth Director of Public Prosecutions for criminal prosecution	1	2	3
Decisions in relation to complaints about advertising of therapeutic goods[1]	0[2]	0[2]	11
Public information on unlisted therapeutic goods	26	18	40
Percentage of TGA actions that took place within target timeframes			
Percentage of priority laboratory testing, identified as a result of safety issues, completed within target timeframes	95%	96%	96%
Class I and II recalls when they are indicative of a safety concern for[3]:			
• Medicines	95%	100%	92%
• Medical devices	95%	98%	97%
• Biologicals	0[4]	0[4]	100%
Non-compliance of listed medicines, where a safety issue has been identified through targeted or random review	0[5]	100%	0[5]
Safety signals identified through adverse event reporting and other surveillance activities for[6]:			
• Medicines and biologicals	100%	96%	95%
• Medical devices	100%	100%	100%

[1] This indicator relates to complaints about the advertising of therapeutic goods that are received via the Complaints Resolution Panel.
[2] In this period, compliance with the advertising requirements was achieved without issuing a formal Regulation 9 Order.
[3] The target timeframe for initial review of Class I and II recalls is two working days.
[4] There were no actions relating to recalls for biologicals during the reporting period.
[5] There were no actions relating to safety issues identified through targeted or random review during the reporting period.
[6] The target timeframe for risk assessment and triage of safety signals for medicines, biologicals and medical devices is 30 days.

4. Organisational health

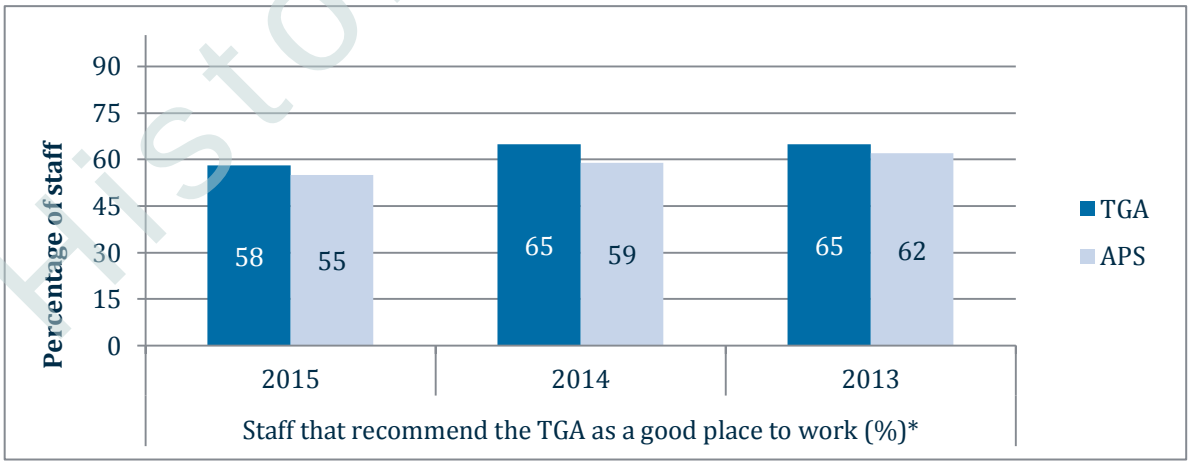
This indicator measures whether we are able to attract, develop and retain a professional workforce that can respond to current and emerging regulatory needs.

4. Performance against measures of organisational health	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Attracting staff: our success in recruiting the right staff to vacant positions			
Number of positions unfilled 90 days after advertising	0[1]	5	0
Developing our staff: the training we provide to develop and maintain the skills of our people, and activities undertaken to keep them informed			
Number of corporate training days per number of full-time equivalent positions	0.9	1.0	1.0
Percentage of medical staff that attended at least one professional development activity in the last six months	100%	100%	100%
We keep staff informed through two primary internal communication channels: the TGA Daily and the TGA Weekly[2]			
Percentage of TGA Weekly disseminated (weekly for 24 weeks during this reporting period)[3]	100%	100%	100%
Percentage of TGA Daily disseminated (five days/week)	100%	100%	100%

[1] Sixteen positions were advertised during this period, eight of which were filled before 30 June 2015. These positions include positions that were advertised internally within the Department of Health, within the Australian Public Service, and some specialist positions that were open to eligible members of the community.
[2] Ad hoc messages are also sent directly to staff outside these two channels as the need arises.
[3] TGA weekly editions are not published during the peak holiday periods after Christmas or over the Easter period. We use other internal communication methods, such as the TGA Daily, to maintain continuity of internal communications.

Figure 4 Surveys of staff satisfaction with the TGA and the work they do

TGA staff are surveyed annually. The previous indicator titled "percentage of staff that agree that the work they do is important for public health" is no longer measured in the staff survey and therefore has been removed from this report.



*Of the 506 survey respondents in 2015, 29% of TGA staff provided a neutral response to this survey question.

5. Financial performance

TGA's activities are primarily cost recovered from industry. However, the TGA received appropriation funding in 2014-15 for aligning Australia's and New Zealand's regulation of therapeutic goods. The function of administering compliance frameworks for controlled drugs was transferred to the TGA Group of the Department of Health in August 2014 and continues to be funded from the departmental appropriation. As a result, TGA now has multiple funding sources for its activities. These activities contribute to Outcome 7 'Health infrastructure, regulation, safety and quality' and Outcome 9 'Biosecurity and emergency response' in the Department of Health's *Portfolio Budget Statements*.

This indicator on our financial performance shows that we are within the target budget range when compared to budget.

5. Financial performance	**Total revenue**			**Total expenditure**		
Time period	**Actual ($'000)**	**Budget ($'000)**	**Variance (%)**	**Actual ($'000)**	**Budget ($'000)**	**Variance (%)**
Jul 2014 – Jun 2015	139,546	138,922	0%	134,905	139,231	-3%
Jan – Jun 2015	71,042	68,850	3%	66,860	68,900	-3%
Jul – Dec 2014	68,504	70,072	-2%	68,045	70,331	-3%
Jul 2013 – Jun 2014	132,564	133,161	-1%	133,065	133,470	0%
Jan – Jun 2014	64,369	65,880	-2%	69,011	65,914	5%

Note: target budget variance is ±5%.

Revenue for the full year was in line with budget overall although annual charges were below budget due to the transition arrangements for the new Annual Charges Exemption scheme and a higher rate of Low Value Turnover applications received during the year. Offsetting this were above-budget application fees and additional appropriation for administering compliance frameworks for controlled drugs.

Expenditure was below budget, mainly in employee expenses due to lower than budget staffing levels and no change in staff pay rates from last financial year.

6. Statutory obligations

6.1 Performance in addressing audit findings	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Financial audits			
Outcome of the financial audit	N/A	Unmodified[1]	N/A
Percentage of category 'A', 'B' and 'C' findings addressed within target timeframes	N/A	100%	N/A
Percentage of management responses completed prior to publication of audit report	N/A	100%	N/A
Performance audits			
Percentage of management responses completed prior to publication of audit report	No performance audits	No performance audits	100%

N/A = not applicable. Financial audits are undertaken annually, at the end of June.
[1] Unmodified means that the auditor expressed an opinion that financial statements were presented, in all material respects, in accordance with applicable financial reporting framework.

6.2 Performance in meeting other statutory obligations	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Compliance with on time payment policy for small business: Relevant invoices paid within 30 days	96%	99%	93%
Compliance with freedom of information legislation: Requests processed to completion within legislated timeframes[1]	100%	100%	100%
Progress towards the Australian Government Digital Transition Policy: applications and submissions received by the TGA that are available in an electronic form[2]	72%	70%	62%
Percentage of compliant regulation impact statements[3] completed by the TGA	N/A	100%	N/A
Percentage of compliant cost-recovery impact statements completed by the TGA[4]	100%	100%	100%

[1] A decision on access to information must normally be advised within 30 days of receipt of the freedom of information request. However, this timeframe may be varied in certain defined circumstances by TGA or the Information Commissioner.
[2] The Australian Government's Digital Transition Policy aims to move all Government agencies to digital recordkeeping. This is an average figure across various product streams on applications and submissions. TGA's target is 100% by December 2015. Compliance is as high as 99% for two of the submission types at 30 June 2015.
[3] Zero (0) Regulation Impact Statements were completed in this period.
[4] Six (6) Cost Recovery Impact Statements were completed in this period.

7. International cooperation

TGA has strong active working relationships with most major overseas regulators. These relationships help us safeguard public health in Australia through harmonisation, information sharing and cooperation.

Many of our efforts towards international cooperation are achieved by collaboration with international regulators through formal forums and consortia.

7.1 Participation in international harmonisation activities

Good Manufacturing Practice inspections

Contributed to a review of Pharmaceutical Inspection Cooperation Scheme (PIC/S) strategies and policies, as the basis for mutual recognition of decisions on Good Manufacturing Practice (GMP) inspections.

Continued regular sharing of inspection schedules with the United States of America's Food and Drug Administration (US FDA), the European Medicines Agency (EMA) and Health Canada, with a view to identifying opportunities for joint inspections.

Conducted nine joint GMP inspections with other regulatory agencies, including the EMA, European Union (EU) member state regulators, the European Directorate for the Quality of Medicines and Healthcare (EDQM), the US FDA, Medsafe New Zealand, Health Canada and the Medicines Control Council of South Africa.

International Medical Devices Regulators Forum (IMDRF)

National Competent Authorities Report Exchange Program: In March 2015 updated guidance was published on the exchange of reports about serious public health issues between IMDRF members.

Regulated Product Submission: Comprehensive Tables of Contents (ToC) have been established for in vitro diagnostic (IVD) market authorisation and non-IVD market authorisation. Planning for further piloting of the ToCs is underway, with a focus on the development of supporting documents. The pilot plan was publicly released as an IMDRF information document.

Software as a Medical Device (SaMD): Draft guidance was released for consultation on the application of existing, standardised and generally accepted quality management system practices to SaMD.

Medical Device Single Audit Program (MDSAP): An assessment and decision process for the recognition of MDSAP Auditing Organisations has been developed. Two guidance documents are currently under development—guidance on regulatory authority assessment methods of auditing organisation's processes and medical device regulatory authority audit reports. The TGA is actively participating in the MDSAP pilot, including the auditing organisation assessment process**.**

Medical Device Patient Registries: Work commenced on work items for integrating device registries, Unique Device Identification and innovative tools for medical device evaluation.

Adverse event coding for medical devices: Work commenced on the development of common terminology and code related to adverse events involving medical devices.

7.1 Participation in international harmonisation activities

International Generic Drug Regulators Programme (IGDRP)

Continued participation in the pilot IGDRP-EU Decentralised Procedure and EU Centralised Procedure for the evaluation of generic medicine applications.

Incorporated the IGDRP evaluation templates for TGA assessment of Biopharmaceutics Classification System-based biowaivers and Active Substance Master Files/Drug Master Files. The working groups are now reviewing their mandates and workplans for the next direction in work sharing.

As the IGDRP Secretariat, the TGA developed a website for the IGDRP's public face, finalised the Terms of Reference for the next two years of the group and established a new working group to address IT business needs for the IGDRP and its working group.

International Coalition of Medicines Regulatory Authorities (ICMRA)

Participated as a member of the ICMRA Interim Management Committee where, among other things, regulators established a clear strategic framework to clarify the role of the ICMRA and better articulate its value-add across global initiatives.

As the project lead, finalised the draft protocol for sharing information between ICMRA partners to allow for worksharing, particularly in relation to the pre-market authorisation for generic medicines and data requirements for mutual recognition of GMP inspections.

Direct collaboration with other regulators

Generic Medicines

Continued collaboration with Health Canada, the Health Sciences Authority of Singapore and Swissmedic to develop simplified information sharing programmes to facilitate work sharing for assessment of Drug Master Files (DMF) in each country. Finalised DMF quality assessment report template, which is currently being used by all four agencies.

Facilitated communication with selected generic companies for a pilot project to support genuine worksharing between the four agencies, which is based on the EU Decentralised Procedure. Project likely to begin in March 2016 (based on available submissions that meet the criteria).

Continued information sharing with Health Canada in the area of pre-market assessment of generic medicines as business-as-usual through the routine exchange and utilisation of evaluation reports.

Orphan Medicines

Continued to monitor opportunities to enhance collaboration and information sharing regarding assessment of orphan medicines with other regulators.

Collaborative arrangements

Finalised new collaborative arrangements with Medsafe (New Zealand) and the Paul Ehrlich Institut (Germany) that allow for sharing of a broad range of confidential information to support our regulatory functions and underpin future collaborative activities.

Continued work to finalise new collaborative arrangements with Swissmedic, the French Agency for the Safety of Health Products (ANSM) and US FDA to enhance collaboration and information sharing, including the exchange of information such as assessment reports on orphan drugs.

Continued discussions with European regulators to enhance confidence in medical device assessments completed in Europe.

7.2 Collaboration and work-sharing with other regulators	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Exchange of bioequivalence reports[1] to support generic prescription registration	12	17	0
Number of monographs developed with Health Canada to support non-prescription medicines registration[2]	2	0	0
Number of desktop clearances for manufacturers undertaken in place of inspections, taking into consideration regulatory decisions by other comparable regulators.[3]	2144	1941	1481
Work sharing and single inspections under the Medical Devices Single Audit Program (Pilot MDSAP). As it is still in pilot phase, inspections under the MDSAP are yet to commence.[4]	N/A	N/A	N/A
Number of post-market signals for prescription medicines received from international regulators during the reporting period to trigger appropriate early warnings.	0	1	0

[1] We continue to monitor this opportunity for work sharing, particularly regarding some aspects of the biopharmaceutic assessment report in circumstances where the bioequivalence studies submitted to Health Canada and TGA are performed at the same clinical sites and the bioanalysis is done by the same bioanalytical laboratory.
Opportunities for harmonisation efforts in other related areas continue to be explored, including Biopharmaceutic Classification System-based biowaivers.
[2] In the period January – June 2015, we jointly developed monographs for dextromethorphan in oral antitussive preparations, and docusate sodium and/or sennosides in oral laxative preparations
[3] Approximately 95-98% of overseas manufacturer clearances are issued via desktop assessments that take into account overseas regulatory decisions.
[4] We continue to participate in the development of documentation for MDSAP pilot policy and procedures. We intend to incorporate outputs from audits performed by auditing organisations into our business processes to reduce duplication of audits and cost to sponsors.
N/A = not applicable.

8. Decision making

Internal reviews are undertaken when someone affected by a decision requests a review of the decision by the TGA under Section 60 of the *Therapeutic Goods Act 1989.* In some cases, external review of TGA decisions by the Administrative Appeals Tribunal (AAT) is requested.

8. Internal and external review of TGA decisions	Jan – Jun 2015	Jul – Dec 2014	Jan – Jun 2014
Internal review[1]			
We make more than 34,000 regulatory decisions every year. Internal reviews are usually only sought on a small number of these decisions (less than 1%).			
Number of requests for internal review processed during the reporting period	13 (100%)	18 (100%)	25 (100%)
Regulatory decisions subject to internal review, for which the original decision is:			
• initial decision confirmed	9 (69%)	9 (50%)	15 (56%)
• initial decision revoked, or revoked and substituted[2]	4 (31%)	6 (33%)	7 (32%)
• initial decision remitted	0 (0%)	2 (11%)	0 (0%)
• internal review request withdrawn.	0 (0%)	1 (6%)	3 (12%)
External review			
Number of matters referred to the AAT, where the outcome is indicative of an issue about quality of the initial decision.[3]	0 (0%)	1 (25%)	0 (0%)

[1] The data reported are the number and percentage of decisions subject to internal review.

[2] Additional information was provided to the internal review delegate in all four cases where the initial decision was revoked or revoked and substituted. All internal reviews during the reporting period were completed within target (legislated) timeframes.

[3] Three matters referred by sponsors to the AAT were decided during the reporting period. This figure includes substantive regulatory decisions:

- to not include products on the Register
- to remove products from the Register
- to grant or revoke a manufacturing licence or conformity assessment certificate.

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