Australian Government
Department of Health
Therapeutic Goods Administration

TGA Key Performance Indicators

Our indicators and reporting measures

Version 1.2, March 2014

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	06/09/2013
V1.1	Minor changes to formatting for web-friendly version	TGA	26/09/2013
V1.2	Minor amendment to formatting	TGA	6/3/2014

TGA key performance indicators

As a part of the Department of Health, the TGA safeguards and enhances the health of the Australian community through the effective and timely administration of the *Therapeutic Goods Act 1989*, through which the Australian Government aims to:

- regulate therapeutic goods for safety, effectiveness and quality
- implement the TGA Reform Blueprint, and
- establish the Australia New Zealand Therapeutic Products Agency.

We are guided by the *TGA Strategic Statement 2012-2015* in delivering these outcomes. We intend to report to stakeholders at six monthly intervals on our progress in delivery against a set of agreed Key Performance Indicators (KPIs). The KPIs have been endorsed by the Australian Therapeutic Goods Advisory Council following consultation with the TGA-Industry Consultative Committee. Eight KPIs address:

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

We will commence implementation of reporting against them during the 2013/14 financial year. Since some of the reporting measures require development of data collection systems, we will start reporting on a subset of the KPIs for the period ending December 2013, with reporting against the full set of KPIs by June 2014. The first year of KPI reporting will represent the baseline for future benchmarking of reporting. Wherever possible, target outcomes will be identified in the report as a source of additional benchmarking.

Other business performance indicators

The KPIs are high-level indicators for the TGA's overall performance against our broad strategic intent. Within that matrix of KPIs is a requirement for measuring whether 'business operations are consistent and meet agreed service and timeliness standards'. Measures of specific business activities will continue to be documented in our *Half-yearly performance reports*.

These reports are provided to members of the TGA-Industry Consultative Committee to enable us to report on specific parameters of relevance to industry stakeholders and to enable stakeholders to provide performance feedback. They provide detailed quantitative information about our performance on the timeliness of business activities as well as information for industry about the volumes of work performed by the TGA.

Examples of data provided in half yearly performance reports include:

- processing times for applications for registration of prescription and over-the-counter medicines
- number of applications received for listed medicines
- number of notifications of clinical trials received
- processing times for recalls for medical devices, and
- number of inclusions on the Australian Register of Therapeutic Goods.

The information provided in these reports will also inform some of the measures and reports against the proposed KPIs. They are also a useful business planning tool for the TGA. We will continue to produce these detailed reports in parallel with high-level KPI reporting.

TGA key performance indicators and reporting measures

KPI 1. Stakeholder communication, education and satisfaction

Purpose of this indicator

This indicator assesses whether we are clearly communicating TGA's role and our risk management approach to regulation and decision making. It also seeks to ensure that the regulatory framework reflects the broadest possible analysis and that a wide range of views have been taken into account by TGA in developing reform proposals.

How we will report against this indicator

Improved community, health professional and industry understanding of TGA's regulatory role

Overall performance in improving stakeholder engagement and understanding:

- Number of visitors to TGA's web pages and pages viewed
- Number of TGA participations in key stakeholder forums
- Market research on the level of understanding of TGA's regulatory role, with a goal of continual improvement, and an emphasis on community involvement.

Stakeholder engagement and satisfaction with TGA consultative processes

- Number of consultations completed during the reporting period. The number of submissions received for each consultation will also be reported, in order to provide context for related measures
- Percent of submissions and TGA responses published on the TGA website within target timeframes
- Number of subscribers to TGA information channels including the consultation email list
- Summary of quantitative survey results measuring stakeholder satisfaction with our consultative processes, obtained from twice-yearly online surveys. (As surveys and processes need to be developed, reporting against this measure will commence for the period ending 30 Jun 2014).

Performance against TGA customer service standards

Measures used to report against this performance indicator include quantitative data about the performance of the Public Contact Team, measured against TGA's customer service standards[1]:

- Adherence to quantitative standards of service commitments made under the TGA customer service standards, including percentage of email and voice mail messages responded to target timeframes
- Number of complaints received, and median time taken to process complaints to resolution.

[1] TGA's customer service standards set out our commitment to the standards of service you can expect in your dealings with us. We will:

- be helpful and treat you with courtesy
- acknowledge your letters and emails within 5 working days and ensure that our responses to you are timely, relevant and easy to understand
- where a full response cannot be provided within 5 working days, we will advise you when a response can be expected and keep you informed on progress if the issue is complex
- provide a courteous, efficient telephone service
- aim to respond to voice mail messages within two working days
- identify ourselves to you on the telephone and in our letters and emails we will include a name and contact details
- provide you with background and reasons for adverse decisions
- provide information and guidelines in plain language
- respect your right to privacy and confidentiality.

KPI 2. Premarket business operations

Purpose of this indicator

This indicator provides evidence about whether TGA is enabling timely access to therapeutic goods for the Australian public. More detailed information about application volumes and processing times is available in TGA's half-yearly performance reports.

How we will report against this indicator

These reports will be implemented for the period ending 30 June 2014.

- Percentage of applications processed in target timeframes:
  - prescription medicines: applications lodged under the prescription medicines registration process ('Category 1' applications) and quality-related evaluations ('Category 3' applications) processed in legislated timeframes
  - over-the counter medicines: 'new' and 'change' applications
  - complementary medicines: applications for registered complementary medicines and new substances
  - medical devices (in vitro diagnostic devices; IVD): application audits
  - medical devices (non-IVD): application audits and conformity assessments.

KPI 3. Postmarket business operations

Purpose of this indicator

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. More detailed information about sector-specific postmarket activity is available in TGA's half-yearly performance reports.

How we will report against this indicator

These reports will be implemented for the period ending 30 June 2014.

- Time taken to complete initial review, or where applicable, percent of TGA actions that took place within target timeframes
  - Class I and II medicines, biologicals and devices recalls, when they are indicative of a safety concern
  - non-compliance of listed medicines, where a safety issue has been identified through targeted or random review
  - safety signals identified through adverse event reporting and other surveillance activities by sector
- Public information on inappropriate unlisted therapeutic goods and other non-compliance complaints, including inappropriate claims by sector
- Percentage of priority laboratory testing, identified as a result of safety issues, completed within target timeframes
- Percentage of medical device incidents triaged and investigated in 30 days
- Activities undertaken by the TGA relating to regulatory compliance
  - cancellations of listed medicines following compliance review
  - decisions in relation to complaints about advertising of therapeutic goods
  - investigations of alleged offences, according to action taken
  - cases of deliberate non-compliance referred to the Commonwealth Director of Public Prosecutions for criminal prosecution.

KPI 4. Organisational health

Purpose of this indicator

This indicator demonstrates whether TGA is able to attract, develop and retain a professional workforce that can respond appropriately to both current and emerging regulatory needs.

How we will report against this indicator

- Number of positions that remain unfilled 90 days after the position is advertised
- Number of corporate training days per total number of full-time equivalent positions
- Percent of medical staff that attended at least one professional development activity in the last 12 months
- Evidence of internal communication activities to inform TGA staff on regulatory and corporate developments
- Outcomes of annual staff survey:
  - percentage of staff that would recommend the TGA as a good place to work
  - percentage of staff that agree that the work they do is important for public health.

KPI 5. Financial performance

Purpose of this indicator

This indicator demonstrates that we are maintaining sound financial performance. The TGA is required by the Australian Government to fully recover its operating costs for all activities that fall within the scope of the *Therapeutic Goods Act 1989* (the Act), including the TGA's public health responsibilities.

How we will report against this indicator

Summary of actual year-to-date income and operating expenses relative to budget projections.

KPI 6. Statutory obligations

Purpose of this indicator

This indicator provides evidence about whether we are meeting our public sector obligations.

How we will report against this indicator

Audits – financial statements and performance audits

- Outcome of financial audit report for previous year (Any category 'A', 'B' and 'C' findings addressed within target timeframes).
- Outcome of performance audit reports for previous year
- Percentage of management responses completed prior to publication of formal audit report

Compliance with other requirements and policies

- Percentage of requests under freedom of information legislation processed within statutory timeframes
- Percentage of relevant contracts paid within 30 days, as required for compliance with on-time payment policy for small business
- Progress towards implementation of the Australian Government Digital Transition Policy, measured through percentage of applications and submissions received by the TGA that are available in an electronic form
- Percentage of compliant regulation impact statements and cost-recovery impact statements completed by the TGA.

KPI 7. International cooperation

Purpose of this indicator

This indicator aims to assess whether enhanced international regulatory cooperation through better exchange of information, work sharing and capacity building has taken place, in order to improve TGA efficiency and regulatory outcomes through a reduction in duplication of effort in pre- and postmarket evaluation of therapeutic goods.

How we will report against this indicator

- Information on participation in international harmonisation initiatives that can be demonstrated to have ensured the international regulatory framework meets acceptable Australian standards of safety, quality and efficacy.
- The use of information from (or in collaboration with) other regulators. These reports will be implemented for the period ending 30 June 2014.
  - Number of bioequivalence reports and monographs exchanged to support generic prescription and OTC medicines registration, respectively
  - Number of desktop clearances for manufacturers undertaken in place of inspections, based on information from other comparable regulators
  - Work sharing and single inspections under the Medical Devices Single Audit Program – summary of activities
  - Number of postmarket signals received from international regulators to trigger appropriate early warnings.

KPI 8. Decision making

Purpose of this indicator

This indicator provides evidence about whether TGA is regulating consistently with close reference to the Act and Regulations.

How we will report against this indicator

This is best measured by reporting on possible issues with individual regulatory decisions made at the TGA, which are usually identified through legislative review processes.

- Percentage of substantive regulatory decisions subject to internal review, for which the original decision is revoked and substituted, without review of additional information. This includes 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
- Number of matters referred by sponsors to the Administrative Appeals Tribunal, where the outcome is indicative of an issue about quality of the initial decision.

Therapeutic Goods Administration

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