Australian Government
Department of Health
Therapeutic Goods Administration

TGA key performance indicators and reporting measures

Regulator Performance Framework

Version 1.0, May 2015

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. The 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>.

Introduction

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) 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 new Framework will apply from 1 July 2015—with the first assessment period being the 2015–16 financial year. Further information on the Framework is available at: Cutting Red Tape: Regulator Performance Framework.

Assessing our achievement of the KPIs

In consultation with the TGA Industry Consultative Committee (TICC) and the Australian Therapeutic Goods Advisory Council, we have developed a series of qualitative and quantitative outputs and evidence to assess our achievement of the six KPIs and associated measures.

The first report assessing our achievement of the KPIs will be available following completion of the first assessment period (2015-16 financial year), and then annually thereafter. These annual reports will replace the previous TGA KPI reports published twice yearly.

These reports will focus on our performance as a regulator and our engagement with stakeholders. We will, however, continue to produce other reports with more detailed information about our regulatory and corporate activities, including:

- The half-yearly performance reports
- The TGA annual business plan

These are available on the TGA website and can be read in conjunction with the reports that will be produced against the Framework KPIs.

Our role and our stakeholders

We are a partner in the National Medicines Policy with a major role in ensuring the quality, safety and efficacy of medicines. We are committed to working with our partners under the policy towards better health outcomes for the Australian population. Consumers and health professionals are key stakeholders, as well as the members of the therapeutic goods industry.

In addition to this, our overarching mission is to:

> *…safeguard and enhance the health of the Australian community through the effective and timely administration of the* Therapeutic Goods Act 1989*.*

As part of the Department of Health we work collaboratively with a number of other areas of the department towards achieving our collective vision of better health and wellbeing for all Australians.

While the purpose of the Framework is to encourage regulators to minimise the impact of carrying out their regulatory objectives, with a particular focus on the regulated industry, we have a broader remit, as outlined above. Therefore, we have developed outputs and activity-based evidence as required by the Framework, as well as additional outputs to demonstrate that we are fulfilling our public health and safety obligations.

Measures of good regulatory performance	Output/evidence
KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities.	
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.	a. Number of TGA participations in industry formal stakeholder forums, including meetings and working groups and feedback received on TGA presentations. This metric will include information on how the TGA has addressed feedback and survey information received from industry, at workshops and after GMP inspections b. 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.
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.	a. Evidence of continued compliance with our practice of engagement with industry before a regulatory impact statement (RIS) is finalised, to minimise the potential for unintended impacts on regulated entities and product supply.
3. Regulators implement continuous improvement strategies to reduce the costs of compliance for those they regulate.	a. Progress towards implementation of the Australian Government Digital Transition Policy b. Progress of the strategies being implemented under the business improvement programme and other specific projects aimed at reducing compliance costs for industry.

Measures of good regulatory performance	Output/evidence
KPI 2 – Communication with regulated entities is clear, targeted and effective.	
1. Regulators provide guidance and information that is up to date, clear, accessible and concise through media appropriate to the target audience.	a. Percentage of pages on the TGA website that comply with Australian Government accessibility requirements b. Improvements made to guidance documents, forms, and information on the TGA website c. 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.
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.	a. Details of formal consultations completed during the reporting period, including evidence that the TGA has closely considered submissions from stakeholders b. Evidence of discussions with affected stakeholders before TGA processes are changed.
3. Regulators' decisions and advice are provided in a timely manner, clearly articulating expectations and the underlying reasons for decisions.	a. 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 b. Percentage of pre-market applications and post-market activities processed in target timeframes c. Publication of information for health professionals, consumers and industry when medicines are registered and/or new information arises on therapeutic goods, for example through Australian Public Assessment Reports (AusPARs), recall notices, safety alerts and expert advisory committee meeting statements.
4. Regulators' advice is consistent and supports predictable outcomes.[1]	a. Percentage of substantive regulatory decisions[2] subject to internal review, for which the original decision is revoked and substituted, without consideration of additional information b. Outcomes of matters referred by sponsors to the AAT, including where TGA decisions are upheld, and where the outcome is indicative of an issue about the quality of the decision.

[1]The best evidence for this measure is reporting on possible issues with individual regulatory decisions made at the TGA, which are usually identified through legislative review processes.

[2]Substantive regulatory decisions include decisions:

- to not include products on the Australian Register of Therapeutic Goods (the Register)
- to remove products from the Register
- to grant or revoke a manufacturing licence or conformity assessment certificate.

Measures of good regulatory performance	Output/evidence
KPI 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed	
1. Regulators apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions.	a. Outcomes of completed investigations and alleged offences b. Publication of evidence of compliance activities to support the continued availability of safe, effective and high quality therapeutic goods for the Australian public.
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.	a. Information for consumers, health professionals and industry on the TGA's risk framework published on the TGA website, and regularly kept up-to-date b. 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.
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.	a. Information on activities undertaken to ensure that a risk-based approach is taken to monitoring and compliance activities, such as: – scheduling of inspections based on compliance record – the use of information from international regulators on regulated activities – proportionate complementary medicines compliance activities.

Measures of good regulatory performance	Output/evidence
KPI 4 – Compliance and monitoring approaches are streamlined and coordinated.	
1. Regulators' information requests are tailored and only made when necessary to secure regulatory objectives, and only then in a way that minimises impact.	a. Information on activities undertaken to minimise the need for, or number of, requests for information to sponsors under the relevant legislation.
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.	a. 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) b. Information on cooperative activities carried out with international regulators to minimise information collection from industry (such as joint inspections and desktop GMP clearances).
3. Regulators utilise existing information to limit the reliance on requests from regulated entities and share the information among other regulators, where possible.	a. 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 b. Collaborative work undertaken with health professionals. For example, interactions on significant medicine shortages, recall actions or safety issues.
4. Regulators base monitoring and inspection approaches on risk and, where possible, take into account the circumstance and operational needs of the regulated entity.	a. Refer to KPI 3.3 – (Information on activities undertaken to ensure that a risk-based approach is taken to monitoring and compliance activities).

Measures of good regulatory performance	Output/evidence
KPI 5 – Regulators are open and transparent in their dealings with regulated entities.	
1. Regulators' risk-based frameworks are publicly available in a format which is clear, understandable and accessible.	a. Refer to KPI 3.2 – (Information on the TGA's risk framework published on the TGA website). b. Information on the TGA's regulatory compliance framework published on the TGA website, with evidence of systems for regular review and updates.
2. Regulators are open and responsive to requests from regulated entities regarding the operation of the regulatory framework, and approaches implemented by regulators.	a. 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 b. Refer to KPI 1.1 – (Information on interactions with industry).
3. Regulators' performance measurement results are published in a timely manner to ensure accountability to the public.	a. Information on ongoing reporting activities including applicable timeframes: – Half Yearly Performance Reports published twice yearly – Measures in Portfolio Budget Statements – Regulatory Performance Framework KPI report – Agreed reporting on the TGA's reform program plans and achievements.

Measures of good regulatory performance	Output/evidence
KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks.	
1. Regulators establish cooperative and collaborative relationships with stakeholders to promote trust and improve the efficiency and effectiveness of the regulatory framework.	a. Market research conducted on an annual basis to measure consumer, health professional and industry trust in—and engagement with—the regulatory framework b. Percentage of stakeholders satisfied or very satisfied with TGA consultative processes
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.	a. Refer to KPI 2.1 – (Evidence of continuous compliance with our practice of engagement with industry before a RIS is finalised) b. Progress of business improvements and other projects aimed at reducing compliance costs.
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.	a. Information on cooperation and collaboration with policy areas of our Department b. Information on interactions with other Australian government departments, regulators and statutory authorities.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Engagement, Education and Planning Branch	May 2015

Therapeutic Goods Administration

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