Australian Government
Department of Health
Therapeutic Goods Administration

Regulator Performance Framework

Self-assessment Report July 2020 - June 2021

Version 1.0, December 2021

TGA Health Safety Regulation

Contents

About the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA), as part of the Australian Government Department of Health, is responsible for enabling therapeutic goods available for supply in Australia to be safe and fit for their intended purpose. These include goods Australians rely on every day, such as analgesics, disinfectants and sunscreens, through to goods used to treat and prevent serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

The TGA regulates the supply of:

- medicines prescribed by a health care professional
- medicines available from behind the pharmacy counter or in the general pharmacy
- medicines available from retail outlets
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- complementary medicines, including vitamins, herbal and traditional medicines
- products used to test for various diseases or conditions (in vitro diagnostic devices), such as blood tests, and
- vaccines, blood products, and other biologics.

The TGA also regulates the manufacturing and advertising of these products.

Overview for 2020-21

The health landscape has changed significantly since 2020, following the declaration of COVID-19 as a health pandemic. Balancing the impacts of COVID-19, and the demands of implementing regulatory reforms with our core business of providing high quality regulation of therapeutic goods in Australia, continues to be both a challenge and a priority.

Our response to these challenges demonstrated our ability to innovate and to improve our business processes. We continued to engage closely with the pharmaceutical and medical technology sectors, health care professionals and consumer groups. Our engagement both domestically and internationally has been essential in the development of flexible but robust regulatory evaluation processes, and expedited access for the Australian health sector, without compromising our regulatory standards.

Through our work with supply chain stakeholders, we have implemented new ways of gathering intelligence about potential medicine and device (e.g. personal protective equipment) shortages. Approvals were accelerated for certain therapeutic goods including COVID-19 vaccines and tests, ventilators, hand sanitisers and personal protective equipment to maximise access for the Australian health sector and community without compromising our regulatory standards. This work is ongoing and will remain a priority for the TGA for the duration of the pandemic.

TGA staff continued to balance established business priorities with the ongoing response to the COVID-19 pandemic. The substantial increase in enquiries fielded by the TGA in 2019-20 remained high in 2020-21. Enquiries about medical devices increased by 66% on last year's enquiries, which itself experienced a peak increase of over 200% in March to June 2020.

Other examples of where resources were diverted to manage COVID priorities include:

- the priority review of COVID-19 vaccine and treatment candidates and device applications
- an over 5-fold increase in the laboratory testing of medical devices, predominantly due to the testing of face masks and respirators
- performing priority assessments to approve 49 overseas manufacturers to support the quality and timely supply of COVID-19 vaccines and treatments, and
- additional meetings and closer collaboration with international regulatory counterparts to share information, including about emerging safety signals of COVID-19 vaccines, tests, and treatments.

We implemented a number of further reforms to improve therapeutic goods regulation and reduce regulatory burden for industry Program milestones achieved in the 2020-21 financial year included:

- the clarification of the requirements for software-based medical devices, including the publication of a classification tool
- the enhancement of the TGA Business Services Portal to enable the electronic lodgement of Product Information and Consumer Medicine Information documents
- the implementation of a data protection scheme for assessed listed medicines which provides incentives for innovation in the Australian complementary medicines industry
- the implementation of recommendations made by the Medicine Shortage Working Party to assist industry to manage medicine shortages.

We will also continue to progress digital transformation to streamline our business systems and modernise our IT infrastructure. This will facilitate simpler, faster interactions with the TGA. It will also allow for greater transparency in the regulation of medicines and medical devices.

Regulator Performance Framework

The Government is committed to reducing the impact of inefficient regulation imposed on business, community organisations and individuals. The Regulator Performance Framework establishes a common set of performance measures for the assessment of regulator performance and their engagement with stakeholders. The Framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives.

The Framework comprises six outcomes-based Key Performance Indicators (KPIs) and associated measures. The KPIs articulate the Government's expectations of regulator performance, namely that:

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 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.

Regulators are required to undertake an annual self assessment of regulatory performance against the six KPIs.

This is the final year regulators, including the TGA, are required to report under the Framework. From the 2021-22 financial year, regulators will measure and report performance under the Government's new Regulator Performance Guide. The Guide sets out the Government's expectations for regulator performance and reporting, including three new principles under which our performance must be measured:

1. Continuous improvement and building trust
2. Risk based and data driven
3. Collaboration and engagement.

The Guide aims to increase regulator transparency and accountability, while moving to an outcomes-focussed regulatory culture.

We will consult peak stakeholders in the development of new performance measures and reports.

The results of this self-assessment are required to be validated by the TGA Industry Forum (as the approved stakeholder consultation mechanism.

The Forum comprises industry peak bodies. They provide assessment of our performance during the reporting period and all feedback is considered in detail.

Certification by the Accountable Authority

The self-assessment is required to be certified by the Secretary of the Department of Health as the Accountable Authority under the *Public Governance, Performance and Accountability Act 2013* and the *Therapeutic Goods Act 1989*.

Rating scale

Met	Substantially met	Not met
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

Summary of self-assessment results

Regulator Performance Framework KPIs	Ratings for 2020-21
KPI 1. Regulators do not unnecessarily impede the efficient operation of regulated entities.	MET
KPI 2. Communication with regulated entities is clear, targeted and effective.	MET
KPI 3. Actions undertaken by regulators are proportionate to the regulatory risk being managed.	MET
KPI 4. Compliance and monitoring approaches are streamlined and coordinated.	MET
KPI 5. Regulators are open and transparent in their dealings with regulated entities.	MET
KPI 6. Regulators actively contribute to the continuous improvement of regulatory frameworks.	MET

Overall assessment

Targets have been met for all measures under the six KPIs. We have continued to report on our performance and activities through various publications available on the Health and TGA websites. We raised awareness of our regulatory framework with stakeholders through meetings, workshops, webinars, and social media promotion. Our online presence has increased significantly since the COVID-19 pandemic, with tailored information 'hubs' available through our COVID-19 landing page, as well as stakeholder engagement through regular virtual meetings, and an expanded range of social media platforms. We also continued to publish the outcomes of consultations on the TGA website.

We remain committed to the TGA Customer Service Standards. Notwithstanding the sustained increase in customer contact since COVID-19, we have maintained satisfactory response times.

We engaged with, and supported, stakeholders at all levels, providing information and assistance for the ongoing operation of regulated entities. The pandemic presented some challenges with planned consultations and industry engagement, however both industry and the TGA were able to adapt, with modifications such as GMP site inspections moved to a hybrid or remote option, and forums and meetings moved to virtual environments.

The TGA worked closely with medicine and medical device sponsors and manufacturers, health professional groups, industry and wholesaler peak bodies, and other government departments

to ensure a coordinated and proactive approach to managing therapeutic goods supply during the COVID-19 pandemic. We prioritised and expedited the assessment of vaccine, medicine, medical device, hand sanitiser and disinfectant applications associated with the detection, prevention and treatment of COVID-19, ensuring Australia has products available to support the pandemic response. At the same time, we met all statutory timeframes for review of other (non-COVID) products.

We expanded our social media profile through strategies including targeted paid campaigns and leveraging stakeholder channels. Often this activity was linked to the publication of new information on our website, which has been essential to industry and the public during the COVID-19 pandemic. This has further enhanced our commitment to open and transparent information and communication.

By utilising risk-based models in areas such as advertising, recalls and product testing, we minimised the impact on regulated entities; whilst continuing to monitor potential non-compliance, emerging trends and compliance history when undertaking intervention.

Our ongoing collaboration with international regulators, as well as various state and territory bodies, streamlined our compliance, monitoring and pharmacovigilance activities in areas such as manufacturing inspections, medicine shortages and the global deployment of COVID-19 vaccines.

We supported our stakeholders by working collaboratively with industry through business improvements and the implementation of reforms.

Opportunities for improvement

Our external validators were asked to suggest opportunities for improvement against each of the KPIs and the self-assessment process overall. In addition to a range of positive feedback, our external validators have provided a number of suggestions which have been noted and will be taken into consideration.

The TGA website continues to be a focus for improvement. In June 2021, the TGA Website Redevelopment Project was launched, as part of the broader Transformation Program, to deliver a modern digital front door for the TGA, with clear pathways to information and services.

We will continue to review our engagement with industry, including through consultations, to improve timeliness and transparency.

While processing times for some non-COVID-19 related medical device applications were slightly longer than the comparable period in previous years due to the diversion of resources to COVID-19 activities, these were all still completed within legislative timeframes. We are continuing to examine learnings from our COVID-19 response and transfer these, wherever possible, into our regular business while staying committed to direct communication with industry and other stakeholders, educating them on their regulatory responsibilities, and improving our awareness of the issues they are facing in the future.

We will apply a proportionate, risk-based approach to our monitoring and compliance activities. We commit to ongoing collaboration with law enforcement in our states and territories as well as at a national and international level, and to remain transparent by publishing our regulatory compliance activities on our website.

Displaying global leadership to drive collaboration with our international colleagues has helped build a globally aligned regulatory framework while maintaining sovereign decision making. We continued to use comparable overseas regulator pathways, work-sharing and Project Orbis to minimise regulatory burden on industry and utilise international networks to monitor product safety and quality and maintain supply chains. Our focus also remained on strengthening

regional regulatory capabilities for safer and effective therapeutics throughout the Indo-Pacific region.

Publishing performance and activity reports, as well as regularly update guidance material, has assisted in ensuring transparency to our stakeholders and the Australian public. We commit to engaging with industry to design a suite of metrics which reflect performance against the new Regulator Performance Guide.

2020-21 Performance Reporting

KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2020-21)**
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.	Ongoing engagement with industry provided opportunities for us to identify and respond to emerging risks and introduce change to stakeholders in a manner that did not impede their functions. In addition, it allowed stakeholders to provide input on policy development. In 2020-21, we participated in a wide range of formal stakeholder forums that included industry events and regulatory workshops for stakeholders, while hosting or co-chairing over 60 meetings with industry groups and advisory committees. Our work with Medicines Australia, the Generic and Biosimilar Medicines Association and other peak health professional groups to develop coordinated solutions to COVID-19 related medicine shortages, was an example of our engagement with, and understanding of current issues affecting the medicines sector.
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.	In response to the COVID-19 pandemic, we continued to work closely with industry and government taskforces and other working groups to share information, reduce duplication and respond quickly to supply and supply chain issues as they emerged. The *Therapeutic Goods (Excluded Goods - Hand Sanitisers) Determination 2020*, made in March 2020, continued to facilitate the on-going supply of hand sanitisers in Australia. The TGA continued to monitor the supply of critical ICU medicines using the Dynamic Model for Medicine Availability, developed from discussions with the Medicine Shortages Working Party. It led to the successful management of critical medicine shortages including the recent enoxaparin shortage in May 2021. COVID-19 continued to disrupt normal application assessment processes due to the higher than average number of medical device (including in-vitro diagnostic) and disinfectant applications received. To enable GMP inspections during the COVID-19 pandemic we continued the onsite/remote/hybrid inspection process established in early 2020 for domestic inspections and, in August 2020, implemented a remote overseas inspections process.

KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	We published 38 public consultations on the TGA website, giving regulated entities the opportunity to provide input on any potential for unintended impacts that had not been considered prior to proposed implementation. Significant consultations undertaken included: • compounded medicines and good manufacturing practice • refinements to regulation of personalised medical devices • the Therapeutic Goods Advertising Code • required Advisory Statements for Medicine Labels • building a more robust medicine supply • the Standard for vaporiser nicotine (TGO 110) • repurposing of prescription medicines • medicinal cannabis manufacturing, labelling and packing requirements • options relating to the Unique Device Identification System • adverse event reporting for medical devices • proposed amendments to the Poisons Standard • consultation on permissible ingredients annual changes. In response to significant decreases in income in parts of the medical devices industry (as a result of its suspension during the height of the COVID-19 pandemic), TGA annual charges in 2020-21 were reduced by 50% for higher risk medical devices that were particularly affected by the hold on elective surgery. We collaborated with international regulators and global industry parties and learned about the challenges which hindered manufacturers' abilities to rapidly increase capacity for COVID-19 therapeutics and vaccines. In response, we identified priority regulatory mechanisms and flexible approaches that industry viewed as being critical to meet the manufacturing demands for COVID-19 products.
KPI 1.3 Regulators implement continuous improvement strategies to reduce the costs of compliance for those they regulate.	Twelve additional companies transitioned to using the Electronic Data Interchange (EDI), which enables submission of adverse event reports directly into the TGA's database. A file-upload capability was also introduced to streamline reporting of adverse events for COVID-19 vaccines from consumers and state and territory health departments. This has supported more timely information sharing with sponsors to allow them to meet their post-market obligations. We continued to comply with the best practice regulation requirements. During 2020-21, the TGA sought advice from the Office of Best Practice

KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	Regulation (OBPR) on 35 occasions to determine whether a Regulatory Impact Statement (RIS) would be required for proposed reforms. To help make the medicines application process more efficient, the TGA no longer allocates proprietary ingredient numbers (PI numbers) to ingredient mixtures that contain an active ingredient.
Self-assessed rating:	**Met**

The response from our external validators to the self-assessed rating of 'met' was mixed with half of the respondents agreeing and half somewhat agreeing. The external validators acknowledged the TGA's continued engagement with industry, and while noting the significant impact COVID-19 had on usual operations, were generally satisfied with TGA's flexibility and responsiveness.

External validators commented that early and timely engagement with industry, including formal consultations, will facilitate greater understanding of issues impacting regulated entities while improving alignment with major reforms. The TGA's existing communication channels could be better utilised to forward plan activities to mutual benefit.

Identified opportunities for improvement

The TGA undertakes a significant level of ongoing formal and informal consultation with industry and stakeholders. These consultations provide insight into the current and emerging issues experienced by regulated entities, as well as providing transparency for industry as to the processes and constraints of the TGA as a regulator.

We acknowledge that COVID-19 disrupted many of our business processes, including the way we consulted with industry and stakeholders, and that this resulted in some inconsistencies in the way we work across the TGA.

We will continue our focus on business and process improvement, including learnings from procedures put in place to respond to the COVID-19 pandemic and stakeholder feedback. We will advise government (where required) as to any business process changes. We will continue to seek feedback to improve the effectiveness of our consultations informally (through meetings and forums) and formally (through stakeholder surveys).

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	**Evidence (Performance in 2020-21)**
KPI 2.1 Regulators provide guidance and information that is up to date, clear, accessible and concise through media appropriate to the target audience.	The TGA continually develops, reviews and updates regulatory guidance to comply with Australian Government requirements and international standards for web content accessibility. This material includes extensive information conveying requirements and outcomes relating to therapeutic goods associated with the COVID-19 pandemic. In this reporting period, 86 new guidance documents were published, and 187 guidance documents were updated. Documents included: • a PIC/S guide to GMP for medicinal products version 14 • guidance for sponsors to assist with meeting mandatory reporting requirements for medicine shortages and discontinuations • guidance for software-based medical devices and personalised medical devices • an application and submission user guide for listed and assessed listed medicines • the revised Australian Regulatory Guidelines for Sunscreens • the management of GMP compliance signals • the GMP approach to overseas manufacturers of medicines and biologicals during the COVID-19 pandemic • changes to the regulation of sports supplements in Australia • decision tools including 'Is my sports supplement a therapeutic good?' and a guidance tool for access to unapproved therapeutic goods • the Standard for unregistered nicotine vaping products • suites of information about nicotine e-cigarettes and medicinal cannabis tailored to different audiences • determinations for Australian conformity assessment bodies. In addition, we published key information about: • complying with advertising requirements • changes to requirements for reporting medicine shortages • in-vitro devices for self-testing • medical device reforms, including the Unique Device Identification system • changes to the regulation of personalised medical devices.

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	New and updated information outlining industry responsibilities came into effect, which included: • TGA expectations for overseas manufacturing sites hosting remote inspections during the COVID-19 pandemic • GMP Clearance code tables guidance - manufacturing steps • GMP clearance questionnaire, and • information for Australian manufacturers of medicinal cannabis products. In 2020-21, the TGA expanded our social media profile using targeted paid campaigns and leveraging stakeholder channels. In this period, we achieved the following activity on our channels: • Facebook: 287 posts; 31% increase in followers to 11,102 • Twitter: 438 tweets; 32% increase in followers to 6,826 • Instagram: 247 posts; 240% increase in followers to 595 • LinkedIn: 332 posts; 35% increase in followers to 13,789. During this period, we conducted 10 paid campaigns across our social media platforms. Topics included: • changes to nicotine vaping products regulation • reporting side effects to medicines and medical devices • medicine shortages • medical device software and implants • how to access medicinal cannabis • changes to sport supplements regulation • general information about Consumer Medicine Information, and • face mask regulation. The average number of people reached for the paid campaigns was two million users, with a total combined reach of all campaigns at over 20 million users. Our social media campaign 'How to spot a dodgy ad' included a post to caution consumers about social media influencers promoting goods for the prevention or cure of COVID-19. SME Assist provided a range of guidance products targeted at small and medium enterprises (SMEs), start-ups, researchers and those unfamiliar with therapeutic goods regulation, to help them understand regulatory requirements.

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	These included: • hosting the 'Personalised medical devices' webinar with 171 live participants • attending the BridgeTech Symposium • producing a series of podcasts on 'Navigating therapeutic goods regulation' • hosting a 'Meeting Your Obligations' workshop via webinar and the 'Advertising therapeutic goods' webinar for MTPConnect • Delivering presentations to Flinders University and the BioMelbourne Network. The TGA also worked with a range of external stakeholders on communication and education activities relating to the implementation of the prescription opioids regulatory reforms. These included education activities for healthcare professionals such as webinars, video series, as well as: • the Faculty of Pain Medicine Better Pain Management eLearning opioid module • five modules for pharmacists developed by the Pharmaceutical Society of Australia, and the Society of Hospital Pharmacists of Australia • NPS MedicineWise undertaking funded GP visits, and • opioid analgesic tapering information sheets published on the TGA website developed in partnership with pain specialists and healthcare professional stakeholders.
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.	We engage in extensive formal consultation prior to changing policies, practice and service standards, and where regulation is being amended, to ensure industry is consulted prior to implementing change. In addition to the consultations mentioned at KPI 1, throughout the reporting period, we held regular meetings with the Complementary and OTC Medicines Regulatory and Technical Forum (ComTech). Through ComTech we presented: • proposed changes to guidance on the quality of listed probiotic medicines • proposed draft versions of updates to the Guidelines on the evidence required to support indications for listed medicines, the publication of which is expected in late 2021, and • guidance on the data protection scheme for assessed listed medicines. A number of medical devices reforms continued to be implemented, including introduction of a new framework for personalised medical devices and new requirements for software-based medical devices. We continued to

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	engage with a significant number of impacted stakeholders, including the dental industry and software developers, to provide support and resources to ensure awareness of regulatory obligations, and opportunities to discuss further refinements after regulatory changes were implemented. As part of the TGA's digital transformation program, we consulted sponsor peak bodies and their members to inform the implementation of enhancements to the medicine shortage electronic reporting system. Engagement with sponsors allowed us to finalise amendments to the selections for 'reasons for shortage' in the online form and enabled the sharing of information and discussion of improvement ideas from the perspective of the sponsor, leading to enhancements to the medicine shortage reporting system. Improvements were made to: • streamline the notification process • allow sponsors better access to information to help them assess and manage their shortage notifications, including a new downloadable .csv file of all current shortages on the Medicine shortage reports database on the TGA website, and • provide sponsors with better information to help them with meet shortage reporting requirements. We revised the Medicine Shortages sponsor web page on the TGA website and published three medicine shortages guidance documents.
KPI 2.3 Regulators' decisions and advice are provided in a timely manner, clearly articulating expectations and the underlying reasons for decisions.	As detailed in the TGA's Annual Performance Statistics Report, during the reporting period 100% of prescription medicine applications and 100% of device applications were completed within legislated timeframes. To support the response to the pandemic and assist with the urgent demand for products such as COVID-19 tests, disinfectants, hand sanitiser, gloves and face masks, the TGA prioritised applications and undertook an expedited assessment process for all therapeutic goods associated with the detection, prevention and treatment of COVID-19. Web statements are published with information on recalls that have wider implications for public health and safety. These include recalls of implantable medical devices and consumer level recalls of medicines and medical devices. During the period, there were 11 new or updated web statements, usually published within one to three business days following approval of the recall action. For major applications: • 45 new chemical entities/new biological entities/biosimilars approved in a median 193 working days • 49 extensions of indications approved in a median 191 working days • 11 medicines and indications approved via the priority evaluations pathway in a median 141 working days

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	• Industry alerted TGA to delays in manufacturing and supply chains triggered by the COVID-19 pandemic, delaying the supply of medicines in compliant packaging. To ensure supply of essential prescription medicines, as well as over the counter and complementary medicines, we initiated a temporary expedited pathway to obtain exemptions from labelling Order requirements with short (five day) turnaround times.
KPI 2.4 Regulators' advice is consistent and supports predictable outcomes.	Thirteen internal reviews of regulatory decisions were finalised in this period, with 77% remaining unchanged from the original decision or changed because additional (new) information was provided with the internal review request. All internal reviews were completed within legislated timeframes, except one which resulted in a "deemed decision" due to the expiry of the decision-making timeframe. During this period, we were party to two matters before the Administrative Appeals Tribunal. One matter was withdrawn, and one remained underway at the end of the reporting period. Neither matter raised any concerns about the consistency of TGA advice, nor the predictability of outcomes.
Self-assessed rating:	**Met**

Feedback from our external validators was generally positive, citing the TGA's active willingness to communicate with regulated entities and the public, as well as to seek feedback, through a range of mechanisms.

External validators suggested improvements could be made to better qualify stakeholder satisfaction with TGA's communication efforts, to more accurately gauge whether these were clear, targeted and effective. It was acknowledged that the TGA was amenable to working with industry on appropriate metrics. Feedback also indicated the need for more consistency in notifying industry of changes to milestone dates and other outcomes, and the provision of adequate notice for upcoming changes to policies and practices.

Identified opportunities for improvement

We strive to balance the amount and type of our consultations by mixing targeted and general methods, while using established industry forums to streamline these activities. Feedback from industry and stakeholders on our consultation methods and frequency of communication continues to inform our approach. Consultations with stakeholders resulted in improvements including enhancements to the medicine shortage electronic reporting system. Positive feedback last year resulted in a further expansion in our social media platforms, and an increase in followers, broadening the scope and reach of our communications.

We remain committed to direct communication with industry wherever possible, providing education to stakeholders about their regulatory responsibilities, and to improve our awareness of the issues they are facing. We will continue to embrace alternative digital tools, such as prompt web statements to ensure this communication is timely.

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed	
Measures/Metrics	**Evidence (Performance in 2020-21)**
KPI 3.1 Regulators apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions.	The TGA made improvements to the way that allegations of non-compliance were addressed by adopting a risk-based and intelligence-led approach. Allegations of non-compliance received were assessed through a first and second pass risk assessment. Intelligence assessments were also used to determine compliance priority areas and inform the effective allocation of compliance and enforcement resources. An Enforcement Committee provided advice on proportionate and consistent use of enforcement powers. The TGA maintained focussed work on compliance activity related to the COVID-19 pandemic. This included education and preventative measures through to enforcement action, such as the issue of infringement notices, where necessary and proportionate. The Pharmacovigilance Inspection Program assists medicine and vaccine sponsors to meet their pharmacovigilance obligations. Sponsors are selected for inspection on the basis of risk. The inspections assess sponsor compliance with pharmacovigilance regulations and guidelines, providing education and taking enforcement action where necessary and appropriate. There are approximately 12,000 medicines listed on the ARTG at any one time and over 1000 are newly listed each year. The TGA selects some of those in the ARTG for post-market compliance review each year. During review, if a medicine is found to not comply with requirements, proportionate enforcement action is taken by the TGA according to the risk posed by the medicine to the consumer.
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.	The TGA uses intelligence and a risk-based approach to strategically target listed medicines or sponsors for compliance review. Priority is given to signals related to listed medicines that may result in: an immediate or potential health risk to consumers; could significantly mislead the Australian public, particularly where there is a health impact; involve a new or emerging issue of concern; are likely to become widespread if we do not intervene; are the subject of public or media scrutiny and concern; are of national or international significance or could lead to a loss of stakeholder confidence in the Government's regulatory scheme or in therapeutic goods. Priority may also be given to medicines of recidivist sponsors. This can include behaviours such as 'relisting' of a medicine that was recently cancelled from the ARTG or continuing with conduct that they have been informed previously was non-compliant and conduct that relates to issues covered by amply available educational materials. We use signals from a variety of sources to select medicines for targeted review that include: reports from the public, media, healthcare

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	professionals or other external sources; information from other regulators; screening the ARTG for recently listed medicines; information from previous compliance reviews, such as medicine characteristics, the nature of the compliance deficiencies identified and the identities of the sponsors; and complaints or referrals, if appropriate. In 2020-21, for the first time, we published our annual compliance priorities on the TGA website. Since November 2020, the TGA has been identifying emerging risks using a combination of intelligence, industry consultation, and other considerations including: • reports that collectively suggest an emerging trend • low risk but frequent breaches linked to the same manufacturer • advertising that targets particular conditions, especially those affecting vulnerable communities • multiple reports of the same breach indicating many people may be impacted • breaches linked to a public health concern or in relation to activity contradicting a public health campaign, and • the introduction of significant regulatory changes or the emergence of new markets in therapeutic goods. On the basis of this risk-based approach, TGA compliance activities for 2020-21 included the issuing of 421 warnings to advertisers, the removal of 569 online advertisements, the referral of 68 advertisers to other regulators, the issuing of a directions notice, and 127 infringement notices issued for alleged breaches of therapeutic goods advertising legislation. Civil action in the Federal Court proceeded against three advertisers. Meanwhile, 4,049 compliance investigations in relation to the supply, manufacture, import or export of therapeutic goods were finalised, and over one million units of non-compliant goods were destroyed during this time. A number of criminal proceedings also progressed throughout 2020-21. Following a pharmacovigilance inspection, inspectors develop a Corrective and Preventative Action (CAPA) plan to ensure the timely addressing of the deficiencies by the sponsors of medicines. The implementation of a CAPA Plan is monitored until the inspection closure. In instances when TGA Pharmacovigilance Inspectors identified critical deficiencies, linked to a serious violation of pharmacovigilance legislation, further enforcement actions are considered. Five infringement notices were issued in 2020-21, and an enforceable undertaking entered into with one sponsor.

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed	
Measures/Metrics	**Evidence (Performance in 2020-21)**
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.	The risk-based model that underpins compliance and enforcement activity enables us to focus investigative resources on the matters that represent the greatest risk to public health and safety, and tailor our actions accordingly. The compliance record of an entity is a significant factor in assessing risk. Under the model, the most serious sanctions (such as court action) are reserved for the most egregious cases of non-compliance. The TGA uses the compliance history of manufacturing sites as well as assessing information that may signal GMP non-compliance, together with any risk assessments requested from sponsors, to inform regulatory actions. We also employ a risk-based approach to the frequency of facility GMP and QMS inspections. Manufacturer performance at inspection is categorised as good, satisfactory, marginal or unacceptable with further granularity provided by applying a high, medium or low risk rating. These ratings are applied when setting the date for reinspection. We evaluate the level of risk to determine the classification and level to which a recall is undertaken. Recall actions vary depending on the deficiency of the therapeutic good and the risk the deficiency poses to public health and safety. Out of the 779 recalls issued for medicines, medical devices and biologicals undertaken during the reporting period: • 90 were Class I (i.e. can or have resulted in serious injury or death to patients or users). • 595 were Class II (i.e. potential to cause illness, injury or result in mistreatment). • 94 were Class III (i.e. issues may not pose a significant hazard to health, but action potentially required). We use a risk-based approach to the selection and prioritisation of products for testing within the TGA, with an aim of investigating the potential risk of non-compliance, and to monitor continuing compliance if required. The development of the testing plan is governed by a risk management framework based on '*ISO 31000:2009 - Risk management - principles and guidelines*'. The TGA applies a risk-based approach to scheduling pharmacovigilance inspections. This considers risk factors relating to the sponsor, their products, their pharmacovigilance system and their compliance history.
Self-assessed rating:	**Met**

Feedback from external validators largely supported the TGA's risk-based approach to regulation, noting our successful compliance investigations into the supply of non-ARTG listed products. It was suggested that the TGA improve consistency to risk approaches across all regulatory activities, not only compliance, to produce more appropriate outcomes, particularly for the assessment of lower-risk products.

Identified opportunities for improvement

We will continue to apply a proportionate, risk-based approach to our monitoring and compliance activities. We also remain transparent by publishing our regulatory compliance activities on our website. We will consider further ways we can make advertising compliance outcomes more transparent through the use of, for example, case studies and other information.

We commit to ongoing collaboration with law enforcement in our states and territories as well as at a national and international level.

TGA has been identifying emerging risks using a combination of intelligence, industry consultation, and other considerations including compliance histories, to determine the most appropriate mitigation actions. We will continue to use this combination as part of our risk-based model for compliance and enforcement.

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	
Measures/Metrics	**Evidence (Performance in 2020-21)**
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.	We produce clear, user-focussed guidance for the website to assist stakeholders undertake regulatory activities, and thereby reduce the number of requests made by the TGA for further information. We encourage sponsors to attend pre-submission meetings before submitting applications. This has allowed us to provide tailored advice and clarify the regulatory requirements.
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.	Whenever possible, we complement information from sponsors with information already gathered by our international regulatory counterparts. Six joint- or concurrent-GMP inspections were conducted during this period, and there were nine occasions where the TGA observed an international regulator on inspection to facilitate information sharing. We undertake desktop GMP clearances for overseas manufacturers, with consideration of decisions made by comparable regulators, and share manufacturing inspection schedules with our international counterparts. The Medical Device Single Audit Program is a joint venture with regulators in the USA, Canada, Brazil and Japan. MDSAP allows for recognised Auditing Organisations to conduct a single program of regulatory audits of a medical device manufacturer. Medical device regulation also allows a range of international assessments and approvals from comparable overseas regulators to be used to support applications for inclusion of medical devices in the Australian Register of Therapeutic Goods. More than 90 per cent of medical device ARTG entries

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	requiring supporting evidence utilise documents from comparable overseas regulators. This reduced duplication of assessments, and documentation which could be used included assessment and approvals from European notified bodies, and regulators in the USA, Canada or Japan. TGA is also increasing the use of assessment reports as the basis for abridgement of the assessment of an application for a TGA conformity assessment certificate. Project Orbis is a collaboration between the US FDA and the TGA, Health Canada, Singapore's Health Sciences Authority, Swissmedic, the UK's MHRA and Brazil's ANVISA for concurrent submission and review of oncology drugs. Eleven submissions were approved in 2020-21 following collaborative review through Project Orbis. This included 3 new chemical entity applications and 8 extension of indications applications. Throughout 2020-21, the TGA continued its collaboration with the ACCESS Consortium members Health Canada, the Health Sciences Authority of Singapore, Swissmedic, with the UK's MHRA joining the Consortium in October 2020. ACCESS enhances the efficiency of regulatory systems whilst maintaining independent decision making. Through information and work sharing, ACCESS evaluated one new medicine. For complementary medicines, ACCESS developed joint guidance for the safety evaluation of ingredients, shared information, and conducted numerous joint safety assessments and peer reviews of products. A joint efficacy evaluation template and guidance for complementary products was also developed. The TGA has published a list of recognised comparable overseas bodies for complementary medicines with the goal of reducing duplicating evaluations and to shorten evaluation timeframes. The Pharmacovigilance Inspection Program considers whether an inspection has recently been conducted by a comparable overseas regulator when scheduling a pharmacovigilance inspection, and targets information collection where appropriate.
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	Wherever possible we share information with our international counterparts, and with state and territory health departments. Early in the COVID-19 pandemic, the TGA used manufacturing site to identify medicine sponsors who may have been at risk of COVID-related shortages. This helped facilitate discussions with sponsors on measures to ensure continuity of supply of medicines in Australia. The TGA uses medicine shortage notification data provided by sponsors to assess impacts of a shortage on supply across multiple brands of a molecule, or multiple medicines in a class, to determine the need for broader management actions.

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	We met regularly with state and territory health departments throughout the year to share information about the supply of hospital medicines in the context of the COVID-19 pandemic. The TGA continued to meet with major global regulators about medicine supply chain impacts of the COVID-19 pandemic and to share shortage prevention and mitigation strategies. The TGA drove the establishment of the International Coalition of Medicines Regulatory Authorities' COVID-19 Vaccine Pharmacovigilance Network. This network of over 22 regulators and the World Health Organization facilitated sharing of knowledge, experience and communications on pharmacovigilance methods and the emerging safety signals for COVID-19 vaccines. Since August 2020, the network met 17 times to identify emerging adverse events of significant interest and recommend mitigation strategies at a globally aligned level. The TGA participates in international information meetings with regulatory partners to share inspection planning information for Active Pharmaceutical Ingredient manufacturing sites to limit multiple inspections of the same manufacturing sites. The TGA's GMP Clearance framework leverages off GMP inspections performed by overseas regulatory authorities to avoid the need for us to conduct an on-site inspection for the same manufacturer. In 2020-21, over 3,800 applications were approved via these pathways. We continue to work with the Food Standards Australia New Zealand, Customs, the Department of Agriculture, Water and Environment, the Australian Federal Police and relevant state and territory agencies to decide whether products are regulated as food or as therapeutic goods or on suspected illegal importation of products.
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.	Our processes have been developed to ensure as little impact on regulated entities during the monitoring and inspection process. The inspection timeline is based on a risk approach unless it has been identified there may be issues with a specific facility that requires attention. We have also developed a desktop assessment program which may preclude a physical inspection. Remote inspections of international manufacturers commenced in August 2020, and remote assessment of international Medical Device Single Audit Program auditing organisations commenced in May 2020. Domestic GMP inspections continued to be delivered either via a remote inspection or a hybrid inspection with remote and onsite components. During the period we conducted 264 inspections of regulated entities and 24 audits of medical device manufacturers. In addition, we conducted 2 remote inspections of investigator sites participating in clinical trials of COVID-19 vaccines.

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	The Pharmacovigilance Inspection Program continued to be delivered remotely over this reporting period. A listed medicine's sponsor profile is used to determine the likelihood and risks of the entity being non-compliant.
Self-assessed rating:	**Met**

The response from our external validators to the self-assessed rating of 'met' was mixed with half of the respondents agreeing and half somewhat agreeing. External validators commended the TGA's continued collaboration with overseas regulators, including the ACCESS Consortium, to reduce duplication and subsequent burden on industry. Validators also praised the TGA's desktop assessment program and GMP inspections, highlighting our ability to adapt our processes, keep communication channels open and maintain timeframes.

It was suggested that the TGA review its approach to requests made of sponsors to provide evidence to substantiate claims, where doing so may contravene copyright laws and result in compliance breaches.

Identified opportunities for improvement

We will continue to adapt our compliance and monitoring activities in light of the challenges of the COVID-19 pandemic, including in GMP inspection reliance and how inspections were prioritised and performed.

The use of information from international regulators continues to provide an opportunity to reduce the impact of our monitoring activities on the regulated community. We will continue to focus work-sharing initiatives, such as with the ACCESS Consortium, which will focus on the evaluation of applications for new active substances, generics and biosimilars.

We will continue to consult with stakeholders to identify areas for improvement.

KPI 5 - Regulators are open and transparent in their dealings with regulated entities	
Measures/Metrics	**Evidence (Performance in 2020-21)**
KPI 5.1 Regulators' risk-based frameworks are publicly available in a format which is clear, understandable and accessible.	We continue to ensure all published guidance material is of a high quality, is user focussed, accessible, and adheres to the Digital Transformation Agency standards. Our risk-based frameworks are described on the TGA website and detail how the TGA applies risk management to its regulatory activities. Information includes how we manage pre- and post-market product risks, and compliance risk, including programmed laboratory testing of therapeutic goods. In February 2021 we published an updated version of The TGA's risk management framework. This document outlines the approach adopted by the TGA to identify and manage risks associated with therapeutic

KPI 5 - Regulators are open and transparent in their dealings with regulated entities	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	goods. The new version is written in plain language and with users in mind. We have targeted information available on our website to help SMEs, start-ups, researchers, and those unfamiliar with therapeutic goods regulation, understand the TGA's risk-based approach to evaluation and post-market monitoring. The SME Assist web resources, including interactive decision tools, are designed to assist industry stakeholders to navigate regulatory requirements and meet their compliance obligations. Our approach to presenting Australian Regulatory Guidelines information allows users to search and filter content according to topic. Rather than a single large document, Guidelines are collections of individual pieces of related content that can be easily added to and kept current. In May 2021, we released guidance on the management of GMP compliance signals associated with the manufacture of medicines and biological products at Australian and overseas manufacturing sites. The guidance provides transparency on the processes we use to review signals and implement regulatory actions.
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.	Due to COVID-19, we received requests to allow extra time to implement medical device reforms and to provide some relief from TGA charges. These requests were accommodated, including a 50% reduction in annual charges in 2020-21 for medical devices Class IIa, IIb, III and active implantable medical devices on the Prostheses List. We utilised a number of different media for communicating with regulated entities including email, website information, social media and through the Regulatory Assistance Service (which managed 35,500 phone and email enquiries, 5% higher than 2019-20). We recognise that the timeliness of responses to enquiries to the TGA is essential. Approximately 96% of enquiries were compliant with TGA Customer Service Standards. Formal and informal stakeholder interactions are detailed in KPI 1.1.
KPI 5.3 Regulators' performance measurement results are published in a timely manner to ensure accountability to the public.	We publish a number of reports annually detailing our performance and activities. These reports meet the Australian Government reporting requirements and provide transparency of our activities. The following reports are available on the Health and TGA websites: • Annual Health Portfolio Budget Statements (May) • July to June Annual Performance Statistics Report (October). • July to December Half Yearly Performance Snapshot (March).

KPI 5 - Regulators are open and transparent in their dealings with regulated entities	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	• Therapeutic Goods Advertising Compliance Annual Report (September). • Department of Health Annual Report (October). • Good Manufacturing Practice Annual Report (November) • Recalls Annual Report (November) • Annual Stakeholder Survey (December). • Annual Regulator Performance Framework Self-Assessment Report (December). • Database of TGA Laboratory Testing Results
Self-assessed rating:	**Met**

Our external validators were satisfied overall with our performance for this indicator but encouraged us to consider metrics which better demonstrate our transparency. Improving consistency of proactive communications between different evaluation streams with sponsors in relation to changes in milestone dates for example, would result in increased process efficiency.

Identified opportunities for improvement

We will continue to publish performance and activity reports, as well as regularly revise and update guidance material, to enable transparency to our stakeholders. The introduction of the Regulator Performance Guide will provide a significant opportunity for the TGA to engage and consult with regulated entities, with a view to further increasing the transparency and communication of our regulatory activities.

Our increased social media presence provides a more interactive platform to provide information to industry. As this form of communication evolves, we will work with industry to improve our information and messages.

While the COVID-19 pandemic continued to put additional pressure on the management of telephone and email enquiries, we will continue to uphold our Customer Service Standards and develop processes to enhance enquiry management.

KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks	
Measures/Metrics	**Evidence (Performance in 2020-21)**
KPI 6.1 Regulators establish cooperative and collaborative relationships with stakeholders to promote trust and improve the efficiency and effectiveness of the regulatory framework.	We undertake an annual stakeholder survey to measure the TGA's performance. 2,420 responses were analysed for the 2020 Stakeholder Survey. The results showed 73% of respondents agreed or strongly agreed the TGA "can be trusted to perform its role ethically and with integrity". Two thirds of respondents (67%) who had ever contacted the TGA were satisfied or very satisfied with their experience communicating with the TGA. Due to the COVID-19 pandemic, SME Assist's face-to-face activities were replaced with alternative delivery mechanisms. Activities included: • live-streamed workshops • increased use of webinars • introduction of podcasts • participating in external events using a variety of platforms such as Blackboard • interacting with stakeholders through a range of platforms including zoom. The TGA established the Opioid Regulatory Communication Committee on 29 April 2020 with representatives from key peak health professional and consumer bodies to advise the TGA on its communication and education strategies about the opioid regulatory reforms. The Committee met 10 times. The TGA coordinates the Medicinal Cannabis Access Working Group meetings, consisting of representatives from each of the state and territory health departments to promote collaboration on issues relating to patient access to medicinal cannabis. The Therapeutic Goods Advertising Consultative Committee provides a forum for engagement on issues and policy relating to therapeutic goods advertising and assists with reviewing and shaping TGA reporting activities with respect to advertising compliance. It also provides input on the development of education and compliance priorities. The TGA continued to coordinate the Medicine Shortages Working Party meetings to discuss how medicine shortages should be best managed. The COVID-19 Intelligence Coordination Group facilitated intelligence sharing between agencies and departments with intelligence, compliance and enforcement responsibilities relevant to COVID-19. To assist industry and other regulators understand the changing nature of TGA's role, emerging regulatory challenges, and our response to

KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks	
Measures/Metrics	**Evidence (Performance in 2020-21)**
	COVID-19, a new International Engagement Strategy 2021-2025 was published.
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.	Each year we conduct meetings with industry bodies as part of our ongoing business improvements, with the aim of reducing compliance costs. The TGA has commenced a four-year digital transformation which will deliver simpler, faster, and more secure interactions between industry and government to apply for, track, pay, and manage regulated and subsidised health-related products and services. We will continue to modernise the TGA's service experience, for example through TGA Business Services and eBS, the redevelopment of the ARTG (including to enhance its searchability), redesigning evaluation processes, making enhancements to support adverse event reporting for COVID-19 and subsequently other vaccines, and redesigning the TGA website. In addition to the 35 reform proposals that were considered by the Office of Best Practice Regulation (see KPI 1.3), approximately five reform proposals were considered minor in nature as they did not substantially alter the existing regulatory arrangements for businesses, community organisations or individuals.
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.	We work collaboratively with policy areas across the Department of Health to inform and improve operations in areas related to our regulatory framework. We work closely with other Government Departments, regulators and statutory authorities to ensure effective and consistent regulatory functions. To work towards Australian ratification of the Minamata Convention on Mercury, which requires parties to take steps to prohibit or restrict the import, export, manufacture or supply of therapeutic goods that are mercury or mercury-added products, the TGA has worked closely with The Department of Agriculture, Water and the Environment and sponsors and manufacturers of affected therapeutic goods, in preparing the Regulatory Impact Statement for required legislation amendments.
Self-assessed rating:	**Met**

Feedback from external validators was positive and cited our international collaborations with ACCESS and Project Orbis as examples of efforts to continually improve regulatory frameworks. External validators were also positive about the expected benefits from the TGA's Digital Transformation Program. It was suggested, however, that performance measures could be improved by increasing data-based metrics for this indicator.

Identified opportunities for improvement

In addition to responding to direct feedback from industry, we will address the issues and comments raised through formal feedback, such as the annual stakeholder survey. Feedback mechanisms provide an important opportunity to reflect and improve regulatory processes and interaction with stakeholders.

The TGA has commenced work on implementation of the Regulator Performance Guide which will shape how we communicate regulatory frameworks and activities with our stakeholders.

Therapeutic Goods Administration

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