Australian Government

Department of Health

Therapeutic Goods Administration

Regulator Performance Framework
Self-assessment report
July 2019 to June 2020

Contents

About the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is part of the Department of Health (Health) and is responsible for assessing whether therapeutic goods available for supply in Australia are safe and fit for their intended purpose. Approved therapeutic goods can be lawfully manufactured and supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices.

Products for which therapeutic claims are made are entered on the Australian Register of Therapeutic Goods (ARTG).

Some examples of goods the TGA regulates the supply of include:

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

We also play a regulatory role in overseeing the manufacturing process and advertising of therapeutic goods in Australia.

More information about how therapeutic goods are regulated can be found on our website at www.tga.gov.au.

Overview for 2019-20

Balancing the demands of regulatory reform, while maintaining our core business of providing high quality regulation of therapeutic goods in Australia, continues to be both a challenge and a priority.

Following the declaration of COVID-19 as a major health pandemic, the role of the regulator has emerged as critical and has necessarily influenced our future priorities. As a key partner in government-industry collaboration, the TGA continues to engage with stakeholders across the therapeutic goods sector while also supporting health professionals, consumers and patients. Our response to the COVID-19 pandemic included working with stakeholders to accelerate approvals for certain therapeutic goods including COVID-19 tests, ventilators and personal protective equipment to maximise access for the Australian health sector without compromising our regulatory standards. This was supported through focused, clear and consistent messaging endorsed by the Australian Chief Medical Officer, and the Australian Health Protection Principal Committee, to educate health professionals and the Australian public, with a strong compliance and enforcement approach. This work is ongoing, and will remain a priority for the TGA into the future.

TGA staff were diverted from established business priorities to assist in the response to the COVID-19 pandemic. TGA fielded an increase of 250% in general enquiries in April 2020 alone, with medicine shortage and medical device enquiries experiencing increases of 300% and over 200% respectively in the March to June 2020 period. Other examples of the diversion of resources included:

- granting 49 approvals through April and May 2020 to supply an overseas registered product to address medicine shortages (compared with an average of ten per month in the 2019 calendar year);
- fielding a 180% increase in over the counter enquiries for hand sanitiser products during March to June 2020; and
- receiving a 51% increase in advertising complaints over the 2019-20 year, with COVID-19 a significant contributor to this.

Implementing the Australian Government's reforms provides a number of opportunities for improving therapeutic goods regulation and reducing regulatory burden for industry.

Key program milestones achieved in the 2019-20 financial year included the implementation of regulatory options to address prescription opioid misuse, the launching of a database of listed medicine compliance review results, the inclusion of the names of excipient ingredients in public summaries of medicines and biologicals on the Australian Register of Therapeutic Goods (ARTG), and the active work of the Medicine Shortage Working Party to assist industry to manage medicine shortages during the COVID-19 pandemic to meet the new requirement of mandatory shortage reporting.

We look forward to enhancing our interactions with stakeholders in the future through major projects announced in the 2020 Federal Budget and funded through TGA reserves (and some industry cost recovery). These projects include:

- Digital Transformation, enabling us to digitise, transform and modernise the TGA's business systems and infrastructure. This will enable simpler and more secure interactions between the TGA and industry to apply for, track, pay for, and manage listings on the ARTG as well as facilitate adverse event reporting by enabling sponsors to use an electronic database to submit a wider range of reports via automatic data transfer; and
- a Unique Device Identification (UDI) database for medical devices, which will allow tracking and tracing of implanted medical devices. Patients will be notified quickly if there are issues with a device, and it will strengthen the TGA's post-market medical device adverse event monitoring system. The TGA will consult with industry ahead of its implementation.

Regulator Performance Framework

The Government is committed to reducing the cost of unnecessary or inefficient regulation imposed on business, community organisations and individuals. The Regulator Performance Framework (RPF)[1] establishes a common set of performance measures for the comprehensive assessment of regulator performance and their engagement with stakeholders. The way regulators administer regulations can have a major effect on the burden imposed, and therefore the framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives.

The RPF comprises six outcomes-based Key Performance Indicators (KPIs) and associated measures. The KPIs articulate the Government's overarching 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.

Under the RPF, regulators are required to undertake an annual self-assessment of regulatory performance against the six KPIs.

The metrics used to assess performance are a mix of qualitative and quantitative measurements that have been agreed through a ministerially approved stakeholder consultation mechanism, and approved by the Minister.

[1] Further information on the Regulator Performance Framework is available at www.pmc.gov.au/resource-centre/regulation/regulator-performance-framework

External Validation

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

The TIF 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		**Activities**
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

Using the above performance ratings, 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, publication of materials on our website, and social media promotion. Our online presence significantly increased through the COVID-19 pandemic, with tailored information available through our COVID-19 landing page; as well as increased stakeholder engagement through regular virtual meetings. We also continued to publish the outcomes of consultations on the TGA website.

Our commitment to the TGA Customer Service Standards is ongoing. Notwithstanding the very significant increase in customer contact during COVID-19, we have improved our response times year on year. In response to a significant increase in stakeholder engagement following the COVID-19 outbreak, we expanded the operations of the Regulatory Assistance Section (RAS), and the Product Billing and Industry Assistance Section to seven days a week. This maintained the TGA's service delivery all stakeholders, including sponsors and members of the public.

We have engaged with stakeholders at all levels, providing information and assistance for the ongoing operation of regulated entities. The COVID-19 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 mixed or remote option, and forums and meetings moved to virtual environments where possible.

The TGA has worked closely with medicine and medical device sponsors, 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 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 have expanded our social media profile with the addition of new platforms and increased our social media activity. Often this activity was linked to new information being published 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.

We have utilised risk-based models in areas such as advertising, recalls and product testing, to minimise impact on regulated entities. We continued to monitor potential non-compliance, and considered emerging trends and compliance history when undertaking intervention.

Our ongoing collaboration with international regulators, as well as various state and territory bodies, has streamlined our compliance and monitoring activities in areas such as breast implants, manufacturing inspections, and medicine shortages.

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. While much of the feedback was positive, all suggestions are noted and taken into consideration.

In 2020-21, we will seek feedback to improve the effectiveness of our consultations. While processing times for some non-COVID-19 related applications were longer than the comparable period in previous years due to the diversion of resources to COVID-19 activities, these were 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.

We will continue to collaborate with our international colleagues, and use comparable overseas regulator (COR) pathways, worksharing and Project Orbis to minimise regulatory burden on industry.

We will continue to publish performance and activity reports, as well as regularly revise and update guidance material, to ensure transparency to our stakeholders and the Australian public.

2019-20 Performance Reporting

KPI 1 Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2019-20)**
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 2019-20, we participated in formal stakeholder forums that included industry events, regulatory workshops for stakeholders and bilateral meetings with industry groups. Highlights included: • Chairing 15 meetings of the Medicine Shortage Working Party, including representatives from Medicines Australia and the Generic and Biosimilar Medicines Association in addition to peak health professional groups to develop coordinated solutions to medicine shortage issues related to the COVID-19 pandemic. • Chairing nine meetings of medicines sponsors under the authorisation granted by the Australian Competition and Consumer Commission (ACCC) to Medicines Australia and the Generic and Biosimilar Medicines Association, to discuss the need for coordination to address COVID-19 pandemic-related supply issues of specific medicines. • Meetings of the TGA Consultative Committee and TGA Industry Forum where stakeholders discussed regulatory activities and priorities. • Bi-monthly Medicines Australia Regulatory Affairs Working Group meetings, in addition to regular targeted consultation with the Generic and Biosimilar Medicines Association. • Hosting four meetings of the Regulatory and Technical Consultative Forum for Medical Devices to discuss issues of a regulatory and technical nature with industry. • Continuing regular advisory committee meetings throughout 2019-20. This included the Advisory Committee on Medical Devices (seven meetings), the Advisory Committee on Medicines (six meetings), and the Advisory Committee on Complementary Medicines (three meetings). These meetings provided independent advice to the Minister for Health and the TGA on issues relating to the safety, quality and efficacy of medicines supplied in Australia; and the Advisory Committee on Vaccines (two meetings) provided advice relating to safe use in national immunisation programs.

KPI 1 Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2019-20)**
	• Convening meetings of the Advisory Committee on Biologicals (three meetings), Advisory Committee on Medicines Scheduling (four meetings) and Advisory Committee on Chemical Scheduling (two meetings) and joint meetings of both scheduling advisory committees (three meetings). • Hosting the second Industry Forum on Good Manufacturing Practice (GMP), which was the TGA's largest face-to-face event, with 465 delegates in attendance. • Chairing and participating in meetings of the TGA Industry Working Group on Good Manufacturing Practice (TIWGG) and TIWGG Technical Working Groups. • Working with the Medicinal Cannabis Industry Association to develop the new GMP guidance on medicinal cannabis from licensing to GMP expectations. • Attending six meetings with Australian Red Cross Lifeblood covering business activities, regulatory and operational issues. • Participating in quarterly meetings of the Eye and Tissue Committee, as well as hosting forums at the annual meetings for the Biotherapeutics Association of Australasia (Tissue banks) and Eye Bank Association of Australia and New Zealand (Eye banks). • The Association of Regulatory and Clinical Scientists (ARCS Australia); Complementary Medicines Australia; Medical Technology Association of Australia; Medicines Australia, AusBiotech, Cell Therapy Society and the 2020 eMedication Management Conference. Attending these annual conferences allowed us to develop an understanding of current and future issues and priorities of the industry. The Therapeutic Goods Advertising Consultative Committee (TGACC) held four meetings in 2019-20. The TGACC also provided input to the development of a range of educational materials to assist advertisers. TGACC members provided valuable input to an independent review of the reforms to the therapeutic goods advertising framework and a review of the advertising complaints framework.

KPI 1 Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2019-20)**
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.	The COVID-19 pandemic has disrupted normal application assessment processes due to the higher than average number of medical device (including in-vitro diagnostic) and disinfectant applications received. Processing times for some non-COVID-19-related therapeutic goods applications were longer than the comparable period in previous years, but were still within legislative timeframes. In response to the COVID-19 pandemic, we worked 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 TGA implemented expedited assessment processes for those applications related to the COVID-19 pandemic. Emergency Exemptions for certain medical devices from the normal requirements of assessment and inclusion on the ARTG under section 41GS of the *Therapeutic Goods Act 1989* (the Act) were enacted by the Secretary. The *Therapeutic Goods (Excluded Goods - Hand Sanitisers) Determination 2020* was established in March 2020 to facilitate the urgent supply of hand sanitisers in Australia. Our expert working group on ventilators assisted our assessment of ventilators manufactured under the ventilator exemption. We worked closely with medicine sponsors, health professional groups, industry and wholesaler peak bodies, and our government departments to ensure a coordinated approach to managing medicine supply during the pandemic. In response to concerns from state and territory health departments and hospitals about supply of medicines for intensive care of COVID-19 patients, we worked to develop rapid estimates of medicines availability. The supply of some crucial OTC medicines, such as paediatric paracetamol preparations and TGA approved hand sanitisers, was adversely affected due to impacts on overseas manufacturers, and shortages of ingredients and packaging materials. Consequently, resources were directed to expediting applications for affected products that sought to change the approved details for their products.

KPI 1 Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2019-20)**
	To enable GMP inspections during the COVID-19 pandemic we introduced a remote inspection process for the domestic sector in March 2020. Regulatory exemptions were made to address the difficulties in obtaining supplies of radiopharmaceuticals from licensed manufacturers in a timely manner during the COVID-19 pandemic. The transition period for Faecal Microbiota Transplant (FMT) manufacturers to comply with new requirements was extended for six months, due to the impacts of COVID-19 pandemic. Four-year exemptions to FMT manufacturers and related IVD providers were granted, to allow them to validate their donor screening assays to comply with the IVD framework. We published 25 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: • Sports supplements • PIC/S guide to GMP for medicinal products version 14 • Faecal Microbiota Transplant standards • Serialisation and 2D barcodes on medicines. • Reforms to the generic medicines market authorisation process • Increased online access to ingredient information • Review of the regulation of certain self-testing IVDs • Scope of Software Based Products.
KPI 1.3 Regulators implement continuous improvement strategies to reduce the costs of compliance for those they regulate.	We approved 26 prescription medicine registrations via expedited pathways, and made a further ten provisional determinations and ten priority determinations for prescription medicines. The TGA made five conformity assessment (priority applicant) designations and approved four medical device conformity assessments through the priority review pathway. Twelve additional pharmaceutical companies transitioned to using the Electronic Data Interchange (EDI), which enables submission of adverse event reports directly into the TGA's database.

KPI 1 Regulators do not unnecessarily impede the efficient operation of regulated entities	
Measures/Metrics	**Evidence (Performance in 2019-20)**
	Regular webinars on topics including TGA's role in digital health and regulation of software, to keep industry and consumers informed of regulatory requirements for emerging technologies. Cybersecurity guidance was published in October 2019 to support industry and consumers. The reduction of administrative requirements for sponsors when using overseas medicine reference products, and the use of international templates to support work sharing, were implemented in December 2019. Amendments to the *Therapeutic Goods Act 1989* to allow for the provision of early scientific advice on aspects of medicine applications was passed by Parliament in June 2020. We continued to comply with the best practice regulation requirements. During 2019-20, the TGA sought advice from the Office of Best Practice Regulation (OBPR) on 37 occasions as to whether a Regulatory Impact Statement (RIS) would be required for proposed reforms. The OBPR determined six RIS or RIS-like processes were required. Where the OBPR confirmed a RIS was not required, prior to introducing the reforms, the TGA engaged with potentially affected parties to explore opportunities for the best outcome. As a WHO Essential Regulatory Laboratory, the TGA ensures the availability of calibrated influenza reagents for the use of influenza vaccine manufacturers worldwide. The request procedure was moved to an online portal in August 2019, allowing for a smoother and more efficient process for clients. The TGA completed the development and implementation of a new online e-form to facilitate the more efficient notification and processing of industry recall notifications.
Self-assessed rating:	Met

External validators acknowledged the range of opportunities we provided to stakeholders to raise current and emerging issues directly with us, and our consistent efforts to avoid unnecessary impediments to efficiently regulate therapeutic products. Feedback also commended our response to the COVID-10 pandemic and close collaboration with industry in managing the public health emergency.

Overall, validators' comments were positive. Some feedback however, noted a lack of understanding of the operational environment of their sector in relation to the implementation of Medicines and Medical Devices Review (MMDR) reforms. Stakeholders suggested future consideration be given to earlier consultation about policy changes, and better alignment and coordination in the way in which MMDR reforms are implemented. Validators indicated that improvements could also be made to the transparency of timeframes and risk proportionality for lower-risk products,

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 will endeavour to minimise the impact of staff changes on the continuity of established work programs, noting the significant investment of time and resources made by our stakeholders increase the transparency of evaluation timeframes. We will continue to seek feedback to improve the effectiveness of our consultations informally (through meetings and forums) and formally (through stakeholder surveys).

COVID-19 disrupted many of our business processes, including our ability to consult with industry and stakeholders. Our response to the pandemic, while posing challenges, did reduce red tape in several areas, including the streamlined entry of essential therapeutic goods to the market. We will review these process changes, and in conjunction with stakeholder feedback, advise government as to whether some should remain permanent procedures and processes.

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	**Evidence (Performance in 2019-20)**
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 reflect current best practice, as well as to comply with Australian Government requirements and international standards for web content accessibility. In response to stakeholder feedback, a new tool for presenting Australian Regulatory Guidelines was developed. The new format for the Australian Regulatory Guidelines for Prescription Medicines was launched in September 2019. We have also significantly increased the publication of new and updated regulatory guidance material. In this reporting period, 144 new guidance documents were published and 151 existing guidance documents were updated (compared with 62 and 50 respectively in the previous year). Key documents published included: • Medical device cyber security guidance for industry • Advertising guidance for businesses involved with medicinal cannabis products • Advertising guidance for businesses involved with stem cells and other human cell or tissue (HCT) products • Medicinal cannabis manufacture • Export of human substances – Applying for a permit under the *Customs (Prohibited Exports) Regulations 1958* • TGA Instructions for disinfectant testing, and • Ventilator for COVID-19 use in Australia. Other new guidelines published included information about: • Regulatory requirements relating to COVID-19 pandemic products • Regulation of disinfectants • Medical devices, including cyber security, IVD companion diagnostics, researcher considerations, labelling obligations, ventilators for COVID-19 pandemic use • Advertising of disease education activities, stem cells and other human cell or tissue products, medicinal cannabis products, social media advertising • Comparable overseas bodies for complementary medicines • Medicinal cannabis manufacture, advertising, microbiological quality, and • Faecal Microbiota Transplant product regulation.

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	Evidence (Performance in 2019-20)
	New and updated guidelines outlining industry responsibilities regarding a number of regulatory changes also came into effect. This included updated exemption status for: • Domestic GMP inspections during COVID-19 pandemic • TGA expectations for overseas manufacturing sites hosting remote inspections during the COVID-19 pandemic • Information to assist overseas manufactures who may undergo a remote GMP inspection during the COVID-19 pandemic • PIC/S Guide to GMP for medicinal products version 13 • Evidence of GMP for prescription medicines • GMP Clearance code tables guidance • GMP requirements for medicinal cannabis manufacture. In 2019-20, the TGA added Instagram and LinkedIn to our social media presence. From 1 July 2019 to 30 June 2020, we created 471 posts on Facebook, achieving almost 10,000 followers, our social channels included COVID-19 specific posts, such as: • Information for those looking to supply or manufacture therapeutic products for the first time • Minimum technical requirements for manufacturing ventilators • Advice about surgical masks and gowns • Safety information on restrictions on prescribing hydroxychloroquine • Regulatory requirements for manufacturing hand sanitiser, and • Warnings about advertising medical devices or medicines that provide false and misleading claims about preventing or curing COVID-19. Since March, LinkedIn has become a successful avenue for reaching a targeted health professional and regulatory affairs audience gaining about 5,000 highly engaged followers in this period. SME Assist published five videos on the TGA website targeted at small and medium enterprises (SMEs), start-ups, researchers and those unfamiliar with therapeutic goods regulation, to help them understand regulatory requirements. In February 2020, we livestreamed our SME Assist 'Meeting Your Obligations' workshop for the first time from the University of New South Wales.

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	Evidence (Performance in 2019-20)
	SME Assist also held two webinars for new sponsors, 'Introduction to TBS' and 'Supplying and advertising certain therapeutic goods for COVID-19'. Other educational activities included a webinar for sponsors supplying and advertising therapeutic goods related to the COVID-19 pandemic, and the information for advertisers to support the end of the statutory requirement for the pre-approval of certain medicine advertisements. We also aimed our information at consumers; for example, our social media campaign 'How to spot a dodgy ad' included a post cautioning consumers about social media influencers promoting goods for the prevention or cure of COVID-19. In response to the COVID-19 pandemic, the TGA published relevant information as it has become available and in a format that provided targeted search and sorting functions. 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. The TGA funded seven projects to the total of $1.5 million during 2019-20. By June 2020, the TGA-funded projects had delivered: • updates to six of the Faculty of Pain Medicine Better Pain Management eLearning opioid modules • four tailored digital modules for pharmacists • new Opioid Cautionary Advisory Labels on dispensed opioid medications • a webinar series hosted by the Australian College of Rural & Remote Medicine • updates to the Clinical e-Audit, Pharmacy Practice review, and the National Prescribing Curriculum modules • prescription covers for dispensed prescriptions to community pharmacies; and • the development of a National Opioid Analgesic Stewardship program and associated Clinical Care Standards. We also undertook a five week, targeted education series for sponsors aimed to address common labelling deficiencies observed during the transition from TGO 69 to TGO 91.

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	Evidence (Performance in 2019-20)
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 Consultative Forum, and continued preparations for the reform of the Regulation of Software, including Software as a Medical Device (SaMD). This reform was due to commence in August 2020 but was delayed to 25 February 2021. In preparation for the reform, the TGA engaged with stakeholders, through a workshop on in October 2019, a further 15 stakeholder meetings in early 2020, and phone calls and email contact. Stakeholder feedback continues to inform the reform approach.
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 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. In response to more recent requests from industry and other external stakeholders to provide better access to recall data, the TGA completed an enhancement of SARA's (System for Australian Recall Action) search facility. Users are now able to download search results of summary recall data in editable, MS Excel format, in addition to the existing PDF reports. In addition, detailed TGA web statements are now published for certain recall actions like Hazard Alerts for implantable medical devices, consumer level recalls and any other recalls that may have wider implications for public health and safety. During the period, there were nine new or updated web statements and these were typically published within one to three business days following approval of the recall action. This timeframe allowed sponsors to commence required actions early. Eleven new medicines and extension applications were evaluated as priority applications. The time for approval for each of the pathways was well within legislated or operational timelines. For major applications: • 38 new chemical entities/new biological entities/biosimilars approved in a median 196 working days (for standard pathway; legislated 255 working days)

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	Evidence (Performance in 2019-20)
	• 53 extensions of indications approved in a median 185 working days (for standard pathway; legislated 255 working days) • 11 medicines and indications approved via the priority evaluations pathway in a median 122 working days (operational target of 150 working days). Industry alerted TGA to delays in supply chains triggered by the COVID-19 pandemic, delaying the supply of medicines in compliant packaging. To ensure supply of essential medicines, we initiated a pathway to obtain exemptions from labelling requirements with short (five day) turnaround times. 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 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. To facilitate the urgent and continued supply of hand sanitisers as a result of the COVID-19 pandemic, the TGA introduced a temporary exemption for specified hand sanitiser manufacturing, advertising, labelling, and presentation requirements. The TGA has also prioritised all hand sanitiser related enquiries and expedited applications to include hand sanitisers in the ARTG.
KPI 2.4 Regulators' advice is consistent and supports predictable outcomes.	We reviewed the Australian Regulatory Guidelines for Complementary Medicines to ensure consistency with changes from the recent reforms to the regulatory framework for listed medicines and registered complementary medicines. New guidance was published in May 2020. In August 2020 we added new sections to the guidelines to clarify the market exclusivity process for applications for new substances in listed medicines, and to clarify what happens when two applicants submit an application for the same substance. These additions ensure applicants have a more transparent understanding of the application process and potential application outcomes. Fifteen internal reviews of regulatory decisions were finalised in this period, with 80% 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.

KPI 2 - Communication with regulated entities is clear, targeted and effective	
Measures/Metrics	Evidence (Performance in 2019-20)
	During this period, we were party to two matters before the Administrative Appeals Tribunal. One matter was dismissed and one was resolved. Neither of the outcomes were related to issues relating to quality of TGA decisions.
Self-assessed rating:	**Met**

External validators acknowledged our clear, targeted and effective communication via face-to-face meetings, consultations, and webinars, and recognised our professional and timely responses to email enquiries. Stakeholders expressed satisfaction with the level and quality of access to TGA staff and their collaborative approach while appreciating the additional guidance provided around COVID-19 products. Feedback noted that some of our communication had been too slow, noting that improvement is required to minimise the impact on industry in relation to new or changed policies.

Identified opportunities for improvement

We will listen to feedback from industry and stakeholders on our current methods and frequency of communication, in particular to ensure that clear guidance is provided prior to any regulatory or policy changes. There was positive feedback from our recently expanded social media channels, and although this is a relatively new communication tool for the TGA, it is one we will look to expand in the future. We remain committed to direct communication with industry where possible, educating them on their regulatory responsibilities, and improving our awareness of the issues they are facing. We will continue to embrace alternative digital tools to ensure this communication is effective and timely.

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed	
Measures/Metrics	**Evidence (Performance in 2019-20)**
KPI 3.1 Regulators apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions.	A new framework for the management of advertising complaints was introduced in 2018 with a risk-based approach to the categorisation of complaints. Each case was categorised based on the risk to public health with corresponding actions escalating as appropriate. Examples of the range of actions taken proportionate to the matter included: • 684 Regulatory Obligations letters sent (with guidance) to the advertisers identified in the low risk cases, and a number of warning and cease and desist letters were also sent for medium risk cases. • 187 infringement notices issued during the year and court proceedings were commenced against two companies and their directors for unlawful advertisements of therapeutic goods that pose serious risks to public health and safety. Five matters were referred to the Commonwealth Department of Public Prosecution. • 3,299 compliance investigations in relation to the supply, manufacture, import or export of therapeutic goods were finalised, and 753,897 units of non-compliant goods were destroyed during this time. In 2019-20, work commenced to further enhance the advertising compliance approach, with a greater focus on intelligence and risk. This work will assist us to concentrate on the advertising matters that represent the greatest risk to public health and safety. In March 2020, the TGA COVID-19 Enforcement Taskforce was established to focus on compliance activity specific to therapeutic goods regulation. The taskforce focussed on education and non-punitive preventative measures through to enforcement action, such as the issue of infringement notices, where necessary and proportionate.
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	During the year we supported an independent review of the effectiveness of the advertising reforms introduced in 2018. During 2020-21, a number of enhancements will be made to the management of advertising compliance as a result of the review. Following misleading and unfounded health claims about COVID-19 treatments and the increase in supply of unapproved goods related to COVID-19, the TGA prioritised a number of new and amended practices in rapid response to the pandemic. This included new and targeted education measures on the regulatory requirements, complemented by new approaches to compliance and enforcement.

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed	
Measures/Metrics	Evidence (Performance in 2019-20)
evolving regulatory threats, without diminishing regulatory certainty or impact.	The TGA streamlined enforcement action and issued a number of infringement notices for alleged breaches of the *Therapeutic Goods Act 1989*, including for the use of inappropriate COVID-19 claims in advertising and/or the supply or promotion of unapproved therapeutic goods in relation to COVID-19. The TGA has also initiated civil proceedings in relation to several COVID-19-related matters involving high-risk goods. Our Regulatory Compliance and Risk Committee meets six times a year. It operates as a community of practice for identification and consideration of improvements to compliance frameworks, and facilitates data and information sharing across the compliance streams. The committee also prepares the annual compliance plan. The Enforcement Committee also meets regularly to ensure a consistent and appropriate approach to higher level enforcement actions. The Compliance and Enforcement hub on the TGA website contains information about our compliance activities, educational resources, and provides an avenue for reporting alleged non-compliant activity.
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. We evaluate the level of risk to determine the classification and level to which a recall is undertaken. We consider the significance of the hazard, the channels by which the goods have been distributed, and the level to which distribution has taken place. The levels include consumer level, retail level, hospital level or wholesale level. 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 690 recalls issued for medicines, medical devices and biologicals undertaken during the reporting period: • 95 were Class I (i.e. can or have resulted in serious injury or death to patients or users), • 507 were Class II (i.e. potential to cause illness, injury or result in mistreatment) and • 88 were Class III (i.e. issues may not pose a significant hazard to health, but action potentially required).

KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed	
Measures/Metrics	Evidence (Performance in 2019-20)
	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*'. 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 and unacceptable with further granularity provided by applying a high, medium or low risk rating. These ratings are applied when setting the date for reinspection. The compliance outcomes from inspections overall have shown an increase in satisfactory compliance with less marginal compliance inspection results. The TGA uses the compliance history of manufacturing sites and the products supplied by manufacturing sites together with any risks assessments requested from sponsors to inform regulatory actions.
Self-assessed rating:	**Met**

While external validators noted our evolving recognition of products with lower risk profiles, they highlighted concerns about the approaches we have taken in relation to evaluating, and drafting guidance for some lower-risk products. There was also comment that under this KPI TGA should include its approach to all facets of risk, not just compliance and monitoring programs. Other feedback noted the regulatory reforms implemented by the TGA continued to ensure that regulatory actions were proportionate to the risk, citing the use of data from overseas approvals for Australian applications as a good example.

Identified opportunities for improvement

We 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 also look at ways in which we can report on our approach to risk in other areas where this remains relevant to industry.

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

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	
Measures/Metrics	**Evidence (Performance in 2019-20)**
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 continually identify ways to improve our processes to minimise the number of formal requests for information made to regulated entities. We are increasing content on our website, removing the need for regulator information requests. 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 other regulators, such as our international 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. For medical devices, the Medical Device Single Audit Program (MDSAP) is a joint venture with the 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 (ARTG). More than 90 per cent of ARTG entries requiring supporting evidence utilise documents from comparable overseas regulators. This reduced duplication of assessments, and documentation which can 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. In 2019-20, the TGA collaborated with Health Canada, the Health Sciences Authority of Singapore and Swissmedic in the evaluation of six new medicines. Of the six, two were generic medicines and four were new active substances.

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	
Measures/Metrics	Evidence (Performance in 2019-20)
	The TGA has also been leading the development of an efficacy evaluation template for complementary healthcare products in collaboration with the ACSS Consortium.
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 data held by our Manufacturing Quality Branch to identify medicine sponsors who may have been at risk of COVID-related shortages, to facilitate targeted discussions with sponsors regarding contingency and alternative 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. We met regularly with state and territory health departments during the first half of 2020 to share information about the supply of hospital medicines in the context of the COVID-19 pandemic. The TGA met weekly in April and May with major global regulators about medicines supply chain impacts of the COVID-19 pandemic. The TGA has also co-chaired the International Coalition of Medicines Regulatory Authorities' COVID-19 Vaccine Pharmacovigilance Network. This network of 15 regulators and the WHO facilitates sharing of knowledge, experience and communications on pharmacovigilance activities and the emerging benefit-risk profile of COVID-19 vaccine(s), in preparation for their deployment. The TGA participates in international information meetings with regulatory partners to share inspection planning information for Active Pharmaceutical Ingredient manufacturing sites. Foreign manufacturing sites of shared interest are identified and opportunities for joint inspections are explored to limit multiple inspections of the same manufacturing sites. In addition, the TGA is currently chairing a pilot programme for sharing inspection planning information for sterile finished dosage form manufacturers. The TGA continues to be a member of the International Medical Device Regulators Forum. We have undertaken regular meetings with international regulators, states and territories, and expert working groups on breast implants and ventilators.

KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated	
Measures/Metrics	Evidence (Performance in 2019-20)
	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 2019-20, almost 3,800 applications were approved via these 'Mutual Recognition Agreement' and 'Compliance Verification' pathways. We continue to work with the Food Standards Australia New Zealand (FSANZ), Customs, the Australian Government Department of Agriculture, the Australian Federal Police and relevant state and territory agencies as appropriate when it is necessary to decide whether products are regulated as food or as therapeutic goods (food-medicine interface), or regarding 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 at a time earlier than the normal inspection calendar. We have also developed a desktop assessment program which may preclude a physical inspection. With COVID-19 travel constraints, all international inspections were postponed for the remainder of the financial year, with remote inspections of international manufacturers recommencing in July 2020, and remote assessment of international Medical Device Single Audit Program (third party) auditing organisations commencing in May 2020. The domestic GMP inspections program continued to be delivered either via a remote domestic inspection or a hybrid inspection with remote and onsite components. During the period we conducted a total of 214 inspections (163 domestic and 51 overseas) of regulated entities. We also conducted 36 on-site audits (21 domestic and 15 international) of medical device manufacturers.
Self-assessed rating:	Met

External validators commended our efforts in providing regular updates on post-market compliance activities, and in international harmonisation initiatives. Stakeholders strongly endorsed our approaches to collaboration with other government agencies and international regulators, in streamlining our compliance and monitoring activities, and cited the Australia, Canada, Singapore and Switzerland (ACSS) consortium work-sharing initiative, as a positive example of this. Our efforts to keep stakeholders informed of our harmonisation work with the International Medical Device Regulators Forum, was also praised.

Identified opportunities for improvement

We will continue to collaborate with relevant state and territory bodies and international colleagues to streamline our compliance and monitoring activities. We will particularly focus on work sharing and harmonisation activities with international regulators, including in relation to risk assessments. 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 2019-20)**
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. 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. New resources added over the reporting period include guidance on 'Researcher considerations' and new interactive decision tools such as 'What do I require to have a listed medicine in the ARTG?'. We have developed a new approach to presenting Australian Regulatory Guidelines information, that allows users to search and filter content according to topic. This new tool is already in use for prescription medicines (www.tga.gov.au/collection/argpm) Rather than a single large document, Guidelines are collections of individual pieces of related content that can be easily added to and kept current. A collaborative approach for drafting guidance on new Regulations for personalised medical devices has resulted in a document that is fit for purpose for regulated entities and users of these devices.
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 some time delays for implementing new medical device reforms and provide some relief from TGA charges. After Government agreement, these requests were implemented, including a 50% reduction in annual charges in 2020-21 for medical devices Class IIa, IIb, III and AIMD which were listed on the Prostheses List. We utilise a number of different mediums for communicating with regulated entities including email, website information, Facebook and offering a first contact point through the Regulatory Assistance Service, which manages our central enquiry lines. We have implemented a new enquiry management system within RAS to improve the stakeholder experience.

KPI 5 - Regulators are open and transparent in their dealings with regulated entities	
Measures/Metrics	Evidence (Performance in 2019-20)
	We maintained business continuity during the January 2020 bushfires by temporarily relocating RAS staff from Symonston to our Woden premises and ensuring phone and email enquiry lines remained open with minimal interruption to customer service. This reporting period saw a 39% increase in our direct communication with stakeholders, with RAS managing 33,632 phone and email enquiries. This was largely due to an increase in enquiries relating to the COVID-19 pandemic. We drew on additional staffing and opened the service to industry and the public on weekends. Despite this significant increase in enquiries, approximately 98% were compliant with TGA Customer Service Standards. On 12 June 2020 we implemented an upgraded enquiry management system for RAS. We also saw a significant increase to our specialised enquiry lines in 2020 due to the COVID-19 pandemic. The Medical Devices inquiry line received over 3,800 calls and more than 7,200 emails between March and June 2020 and expanded their service to take calls seven days a week. Similarly, requests to the TGA Business Services Helpdesk increased exponentially between March and June 2020 as new organisations sought to supply goods such as personal protective equipment, ventilators and sanitiser. The Medicine Shortages team observed a 387% increase in emails from the previous reporting period. 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). • Therapeutic Goods Advertising Compliance Annual Report (September). • Department of Health Annual Report (October). • Annual Stakeholder Survey (December). • Annual Regulator Performance Framework Self-Assessment Report (December). • Database of TGA Laboratory Testing Results
Self-assessed rating:	**Met**

External validators commended our transparency and collaboration with industry, and noted a consistent level of engagement. Feedback also noted our collaborative, pragmatic approach in responding to issues raised, however encouraged us to be more proactive in providing updates and briefings on upcoming changes.

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. We will also work to ensure our advice is timely and effective, and commit to improving the communication of information flowing from international regulators and initiatives. Streamlining audit requirements to ensure consistency with comparable overseas bodies, such as the Medical Device Single Audit Program, will also be a focus.

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 on how to improve our information and messages.

We will also to continue to uphold our Customer Service Standards. The COVID-19 pandemic put additional pressure on the management of telephone and email enquiries, which will assist in future planning for crisis communication.

KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks	
Measures/Metrics	**Evidence (Performance in 2019-20)**
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. 3,286 people responded to the 2020 stakeholder survey. Stakeholders working in the medical products industry made up just under half of the responses. The results showed 83% of respondents agreed or strongly agreed the TGA "can be trusted to perform its role ethically and with integrity". Just over one in five respondents advised they had been involved in a TGA consultation in the last 12 months. The majority of respondents (72%) who had ever contacted the TGA were satisfied or very satisfied with their experience communicating with the TGA. SME Assist uses a variety of methods to engage with target audiences and continues to evolve to meet stakeholder needs. To further promote trust and improve the effectiveness of the regulatory framework we collaborated with consumers and consumer groups to draft *'Five questions to ask before you get a medical implant'* and *'Breast implants: things to consider before having the procedure'*. In March 2020 the TGA also established the Opioid Regulatory Communication Committee. The Committee's purpose is to support a coordinated and consistent approach for the delivery of key messages and education material to affected stakeholders in relation to the implementation of the reforms to the regulation of prescription opioid medicines. 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 also coordinates the Medicine Shortages Working Party meetings to discuss how medicine shortages should be best managed. The COVID-19 Intelligence Coordination Group facilitates intelligence sharing between agencies and departments with intelligence, compliance and enforcement responsibilities relevant to COVID-19.

KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks	
Measures/Metrics	Evidence (Performance in 2019-20)
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.	By seeking out practical solutions, such as desktop audits, the TGA has identified and implemented a number of reforms to improve how we do our business. This has resulted in the removal of a number of onsite audits that are resource intensive for manufacturers. In addition to the 37 reform proposals that were considered by the Office of Best Practice Regulation (see KPI 1.3), approximately 12 reform proposals were considered minor in nature as they did not substantially alter the existing regulatory arrangements for businesses, community organisations or individuals. This includes a proposal to make the fee structure for site inspections clearer - by making a minor amendment the regulations, provided TGA with the authority to waive GMP reinspection fees. Each year we conduct meetings with industry bodies as part of our ongoing business improvements, with the aim of reducing compliance costs.
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. As an example, to enhance and improve the regulation of products used for and by people with disabilities TGA has sought feedback from the devices industry, health professional and consumer groups, and has also engaged with a range of Commonwealth departments and agencies including the National Disability Insurance Agency, and state government departments in health, disability and aged care sectors. For medical devices, we work collaboratively with state and territory governments on the procurement of medical devices as well as working with many Australian Government policy departments to improve the operation of the regulatory framework and administrative processes such as with: • the Australian Competition and Consumer Commission – on button batteries; • the Department of Defence – on test kits and ventilators; • the Department of Agriculture – on biosecurity matters; • the Australian Digital Health Agency – on mobile apps; • the Department of Industry, Science, Energy and Resources – COVID-19 related medical devices;

KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks	
Measures/Metrics	Evidence (Performance in 2019-20)
	• Australian Border Force - on medical devices imported to Australia; and • The Australian Commission on Safety and Quality in Health Care - on the safe introduction of Neuraxial devices compliant with latest standards into Australia.
Self-assessed rating:	**Met**

External validators acknowledged our consistent receptiveness to suggestions for improvement, and their implementation wherever possible. The acceptance of overseas regulatory approvals was highlighted as a good example of this. Feedback however, also suggested we continue to implement reforms that streamline and simplify regulation processes of low-risk products, and to implement well-considered approaches to bulk reforms and guidance, in order to minimise the impact on business.

Identified opportunities for improvement

We will improve our use of appropriate research when considering business improvement strategies and ensure that opportunities are provided, for example, through surveys and consultations, to elicit a broad range of views. We will also examine the effectiveness of our stakeholder engagement practices, to optimise information sharing and reduce compliance burdens.

We are committed to provide ongoing support and education to stakeholders during a transition period, for example the changes to the regulation of Faecal Microbiota Transplant products and MMDR reforms. In addition to responding to direct feedback from industry, we address the issues and comments raised through formal feedback, such as the annual stakeholder survey.

Glossary	
Acronym	**Description**
AAT	Administrative Appeals Tribunal
ACSS	Australia-Canada-Singapore-Switzerland Consortium
AEFI	Adverse Events Following Immunisation
AEMS	Adverse Event Management System
ANVISA	National Health Surveillance Agency Brazil
ARCBS	Australian Red Cross Blood Service
ARGATG	Australian Regulatory Guidelines for Advertising Therapeutic Goods
ARTG	Australian Register of Therapeutic Goods
AusPARs	Australian Public Assessment Reports
CMI	Consumer Medicine Information
CORs	Comparable Overseas Regulators
eCTD	electronic Common Technical Documents
EDI	Electronic Data Interchange
EMA	European Medicines Agency
EOI	Extension of Indications
GMP	Good Manufacturing Practice
HTML	Hypertext Markup Language
IMDRF	International Medical Device Regulators Forum

Glossary	
Acronym	Description
IVDs	In Vitro Diagnostic Devices
KPIs	Key Performance Indicators
NCE	New Chemical Entity
NeeS	Non eCTD electronic Submissions
NCCIWG	Nationally Coordinated Codeine Implementation Working Group
MDSAP	Medical Devices Single Audit Program
MMDR	Review of Medicines and Medical Device Regulation
OBPR	Office of Best Practice Regulation
ODC	Office of Drug Control
PDF	Portable Document Format
PI	Product Information
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PLAC	Prostheses List Advisory Committee
PVIP	Pharmacovigilance Inspection Program
RAWG	Regulatory Affairs Working Group
RCRC	Regulatory Compliance and Risk Committee
RegTech	Regulatory and Technical Consultative Forum
RIS	Regulation Impact Statement

Glossary	
Acronym	Description
SARA	System for Australian Recall Actions
SAS	Special Access Scheme
SLA	Service Level Agreement
SMEs	Small to Medium Enterprises
TGA	Therapeutic Goods Administration
TGACC	Therapeutic Goods Advertising Consultative Committee
TGO	Therapeutic Goods Order
TIF	TGA Industry Forum
TIWGG	TGA-Industry Working Group on GMP
USFDA	United States Food and Drug Administration

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605

https://www.tga.gov.au