



Australian Government

Department of Health
Therapeutic Goods Administration



Therapeutic Goods Administration

Business Plan

2020-21

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Introduction

The Therapeutic Goods Administration (TGA) is part of the Health Products Regulation Group (HPRG) within the Australian Government Department of Health and is committed to delivering a world class, efficient and timely regulatory system for therapeutic goods using a best practice, risk-based approach. The TGA Business Plan sets out our product regulation, regulatory reform, international engagement and regulatory compliance agenda for 2020–21 and the steps we will take to achieve our vision. It also supplements the *Health Portfolio Budget Statements* and the *Department of Health Corporate Plan* and is supported by the Australian Government's *Regulator Performance Framework*.

The TGA Business Plan provides details on our key deliverables in relation to the regulation of therapeutic goods, and should be read in concert with our performance reporting.

Our vision is for **better health and wellbeing for all Australians through regulatory excellence**. This links directly with the Department of Health vision; **Better health and wellbeing for all Australians, now and for future generations**.

We protect the health and safety of the community by regulating therapeutic goods. We strive for regulatory excellence through our:

- purpose – who we are and what we do
- principles – how we will conduct ourselves
- priorities – what we will focus on
- people – focussing on our staff development and wellbeing
- stakeholders – through transparency, meaningful engagement and education.



Purpose

The TGA is responsible for protecting the health and safety of the community by regulating therapeutic goods for safety, efficacy, performance and quality. Consistent with the *Therapeutic Goods Act 1989*, we:

- apply scientific and clinical expertise to assess whether the benefits of a therapeutic good outweigh any risks to health and safety
- assess the suitability of therapeutic goods for supply, import and export from Australia
- regulate manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality
- assess the quality and compliance of therapeutic goods on the market, including through laboratory testing where appropriate
- implement a range of regulatory actions that are proportionate to the potential risk arising from non-compliance or emerging safety concerns.

We achieve this by applying risk-based processes for both pre-market assessment and post-market monitoring, as well as promoting regulatory compliance through clear and transparent decision-making, providing education and guidance, and using innovative technologies and ideas to streamline business functions.

The TGA does not regulate veterinary medicines, health professionals, health insurance, food standards, and cosmetic and chemical standards. These are regulated by other federal, state or territory bodies.

Strategic framework

By regulating therapeutic goods in accordance with the *Therapeutic Goods Act 1989* and supporting regulations, we contribute to the department's strategic priorities:

- better health and ageing outcomes and reduced inequality
- affordable, accessible, efficient, and high quality health and aged care system.

Our commitment to achieving the department's strategic priorities is articulated through:

- **Regulation that protects the health and safety of the community, while minimising unnecessary compliance burden.** We protect the health and safety of the Australian community through effective, timely and risk proportionate regulation of therapeutic goods (including medicines, medical devices, blood, cell and tissue products). This applies to goods exported, imported, supplied and manufactured in Australia.

In 2020–21 we will continue to implement regulatory reforms, with a focus on supporting emerging medical technologies, while delivering efficient, best practice regulatory outcomes. We want to simplify pathways and processes for industry, and deliver more safe products to market. We will also support small-to-medium enterprises, researchers and those unfamiliar with therapeutic goods regulation to better understand regulatory requirements.

Principles

As an Australian Government regulator we adhere to the following principles:

- we are committed to maintaining the trust and confidence of the Australian public
- we are accountable to the government of the day and the Australian public and work cooperatively with the industry we regulate
- we communicate meaningfully with stakeholders including consumers, providing transparency across our regulatory practice
- we assess evidence in making decisions and recognise the value of taking a risk-based approach to regulatory, compliance and enforcement activity
- we perform our functions consistently to ensure predictable outcomes in like decisions.

Environment

The health landscape is intricate and dynamic. In response to this changing environment, we continue to innovate to improve our business processes through the better use of available health administrative data and improved data analytics.

The increasing amount of data describing therapeutic goods, generated at multiple points in the supply chain, is creating a complex but valuable information source. Regulators have a role in helping ensure the integrity of the data and creation of appropriate electronic systems. We plan to lay the foundations for developing new systems for the unique identification of medical devices and enabling, at this stage on an opt in-basis to set some foundations for a traceability system for medicines.

Scientific advancements such as new cancer treatments and personalised medicine, gene therapies, increasing use of software as a medical device and new technologies including patient matched device manufacture (including 3D printed devices), continue to bring opportunities for Australians. They also require a regulatory framework that is contemporary, adaptable and supports innovation. Our challenge is to capitalise on advancements in technology while ensuring that regulation is appropriate to manage risk.

In 2020-21 we will continue to increase our engagement with patients, consumers and health professionals by strengthening relationships with representative peak bodies. We will continue to assist the Australian public in making informed choices, through opportunities to make more information about therapeutic goods publically available and consumer-focused. We are currently realising this through expanding our social media presence, and during 2020-21 will engage consumers more in co-design of communication and education initiatives around critical issues.

We will provide additional information for healthcare professionals to clarify regulatory requirements and application processes for high risk devices. To remain competitive globally, and to reduce duplication in the regulatory review of products, we will also continue to collaborate with international regulatory counterparts on information and work sharing activities (including joint product reviews) and assess opportunities to align regulatory requirements that support global access to safe, effective therapeutic goods.

The implications of COVID-19

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. The TGA was (and is) a key partner in the government-industry collaboration, providing close engagement with the pharmaceuticals and medtech sector and developing accelerated approval processes for new medical devices including COVID tests, ventilators and personal protective equipment to maximise access for the Australian health sector without compromising our regulatory standards.

For example, this allowed rapid approval of different design variations for ventilators on the production line, allowing Australia to get earlier access to those ventilators which may have otherwise gone to other countries; and access COVID-19 test kits via emergency exemption status for use by Public Health Laboratories.

In less than two months, more than 3,000 new medical devices were included in the Australian Register of Therapeutic Goods. We took a flexible and nimble approach to allow expedited approvals and exemptions to allow the rapid manufacture, importation and access to these devices. In addition, a number of emergency exemptions were implemented for certain devices to maximise access for the National Medical Stockpile and Australian Public Health Laboratories.

Approvals for supply were granted based on specified conditions and safeguards including post market reviews to ensure the areas of greatest risk could be identified quickly, and that these medical devices demonstrated their ongoing safety and performance. We will continue the focus on post market reviews of COVID-19 related medical devices, particularly face masks, into 2020-21.

The pandemic has also led to a large volume of complaints and reports alleging unlawful import, supply and advertising of therapeutic goods in relation to COVID-19. The TGA has commenced a targeted compliance strategy which will continue into 2020-21.

We also saw high sales of particular medications, which led to some community pharmacists and retail stores to rapidly run low on local stock. We worked with the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, and the National Pharmaceutical Services Association to place limits on dispensing and sales of prescription and over-the-counter medicines at community pharmacies. Our work in monitoring and managing medicine shortages will continue in 2020-21, and focus on those medicines that are required to manage COVID-19 complications that require treatment in Intensive Care Units.

The rapid publication of targeted information for consumers and healthcare facilities to assist them with sourcing and safety using products was an important feature. The TGA will continue to provide guidance about regulatory requirements, and provide close support to new manufacturers and sponsors during the COVID-19 response.

Priorities

In 2020–21 our key priorities are implemented through four activity streams:

Product regulation and safety – through our core regulatory activity and business process improvements.

Regulatory reform – including activities associated with the final year of implementation of recommendations from the Review of Medicines and Medical Devices Regulation and the Action Plan for Medical Devices.

International engagement – through activities that promote international information sharing, work sharing and regulatory convergence, as well as programs for regulatory strengthening and medicines testing in our region.

Regulatory education and compliance – through education, monitoring, targeted compliance and enforcement activities and appropriate action.

Our priorities are derived from:

- the *Therapeutic Goods Act 1989* and related regulations
- *Health Portfolio Budget Statements*
- the *Department of Health Corporate Plan*
- the Key Performance Indicators (KPIs) outlined in the Regulator Performance Framework
- the Government Response to the Review of Medicines and Medical Devices Regulation (MMDR)
- Review of Therapeutic Goods Advertising Framework

In addition, we will respond proactively to emerging public health issues and government policies that affect regulation. We will also be open to innovations in therapeutic goods, which may require updates to regulation and attraction of particular skills. The TGA will continue to explore opportunities for international work sharing and alignment.

Reporting

In order to provide transparency to the Australian public, industry and healthcare professionals, and to address reporting requirements under the Government's Regulator Performance Framework, we publish a number of statistical and performance reports and other information on both the TGA and main Department of Health websites.

We respond to the performance commitments outlined in the *Health Portfolio Budget Statements*, and report against the performance indicators in the *Department of Health Annual Report*. We report in detail on our performance through the *TGA Annual Performance Statistics Report*, which provides data for each financial year (1 July to 30 June). In addition, we also publish a *Half Yearly Performance Snapshot* which provides a subset of data covering 1 July to 31 December each year.

We provide transparency and are held accountable to our stakeholders by reporting against the six KPIs under the *Regulator Performance Framework*. These outcomes-based KPIs articulate the overarching expectations of regulators' performance:

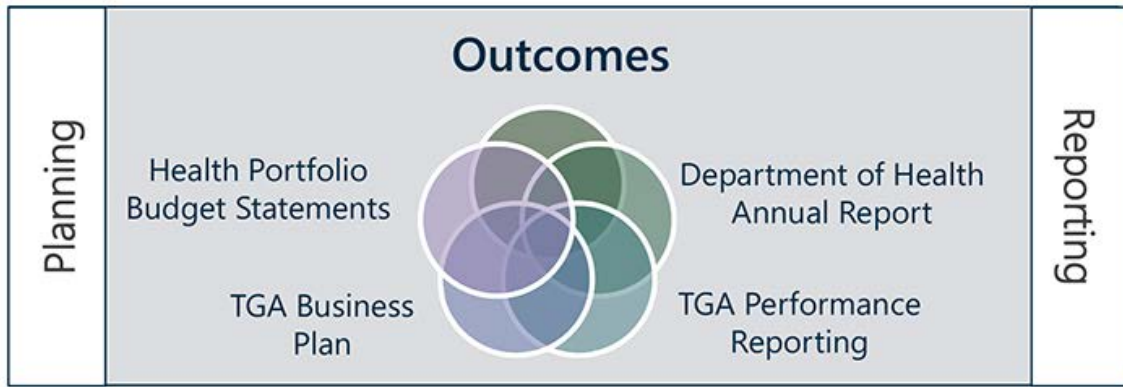
1. Regulators do not unnecessarily impede the efficient operation of regulated entities
2. Communication with regulated entities will be clear, targeted and effective
3. Actions undertaken by regulators are proportionate to the regulatory risk being managed
4. Compliance and monitoring approaches are streamlined and coordinated
5. Regulators are open and transparent in their dealings with regulated entities
6. Regulators actively contribute to the continuous improvement of regulatory frameworks.

We publish an annual Self-Assessment Report that measures our performance against the Framework. The report is externally validated by the TGA Industry Forum, which comprises ten peak industry associations. The Forum assesses our performance against our own self-rating against each of the KPIs and provides feedback, which assists us to identify opportunities for future process improvements.

In addition, we publish the following performance information on the TGA website:

- laboratory testing results and summary reports
- monitoring, compliance and investigations outcomes
- post-market reviews
- annual stakeholder survey
- publications detailing how we are improving access to therapeutic goods for consumers.

The following diagram illustrates the relationship between our planning and reporting activities on an annual cycle. This framework allows us to set out what we plan to do at the beginning of the financial year and then report on what we have achieved by the end of the period.



Funding

The TGA 2020-21 budget is approximately \$170 million and we operate overwhelmingly on a industry cost recovery basis, although a significant number of activities that the TGA performs are conducted to benefit broader public health rather than directly benefiting identifiable entities among the regulated industry. Many of these are required by legislation, or have been specifically required by Government. The regulatory costs are recovered through annual fees and charges levied on sponsors and manufacturers of therapeutic goods. We use an activity based costing model to calculate the relevant costs for each activity we undertake.

Annual Cost Recovery Implementation Statements (CRIS) provide information on how we implement cost recovery activities associated with the registration and listing of medicines and inclusion of medical devices, including in vitro diagnostic devices (IVDs), and biologicals on the Australian Register of Therapeutic Goods (ARTG) and their ongoing monitoring and surveillance. The CRIS (available on our website) is prepared and updated at least annually as required under the Australian Government Cost Recovery Guidelines.

Consistent with its approach to consultation in relation to fees and charges, the TGA met with industry representative groups in a series of meetings in December 2019 to discuss the TGA's financial outlook for 2020-21 and the proposed changes to fees and charges for 2020-21. This was followed by the release of a consultation paper for a six-week public consultation period.

After consideration of the submissions and meetings, the Government approved the indexation based increase of 1.95% to most fees and charges, while annual charges for many class II and III and AIMD medical devices were reduced by 50% for 2020-21. The indexation increase is not only consistent with the long-standing practice industry is familiar with, but also ensures that TGA's provision of services are kept up with the current standard. The change to income is significantly lower than the amount that would be required to cover the known costs increase for 2020-21, so will require efficiency gains through business process improvement.

Product regulation

We assess therapeutic goods available for supply in Australia to ensure they are safe for Australian consumers 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.

Some examples of goods that the TGA regulates include:

- medicines prescribed by a doctor, dentist or other approved prescribing health care professional
- medicines available from supermarkets, the general pharmacy or from behind the pharmacy counter
- complementary medicines, including vitamins, herbal and traditional medicines
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- In Vitro Diagnostic tests used to test for various diseases or conditions, such as blood tests
- vaccines, blood and blood components, and biologicals (cells and tissues).

We conduct pre-market assessment, post-market monitoring and enforcement of standards as appropriate, licensing of Australian manufacturers, and verifying overseas manufacturers' compliance to local and adopted international standards.

We continuously look for opportunities to reduce regulatory burden on stakeholders by strengthening our relationships and understanding their business without compromising the health and safety of Australians. The TGA promotes the safe use of therapeutic goods, and looks for opportunities to improve publicly available information.

The TGA is also undertaking a Digital Transformation project to streamline our business systems and modernise IT infrastructure. This will benefit industry through facilitating simpler, faster interactions with the TGA while reducing our administrative effort, therefore increasing our ability to provide timely information and decisions. It will also allow for greater transparency in the regulation of medicines and medical devices, which should improve consumer confidence and benefit health care professionals.

The following section outlines the work we will be doing as part of our ongoing regulatory reform and core business activities.

Regulatory reform

The reforms forecast for delivery in 2020–21 will support better health outcomes for Australians and, where possible, reduce regulatory burden.

We are also committed to an ongoing program of business improvement focussed on transparency of regulatory decision-making processes, increased efficiencies in our business processes and a strategic approach to the use of information technology to support regulatory operations.

Overviews of our 2020-21 major regulatory reform activities are provided in the following table. Work related to the COVID-19 pandemic is also included in this section.

Major regulatory reform activities for 2020-21	
Outcome	Activities
Prescription medicines regulatory evaluation	<ul style="list-style-type: none"> Continue to provide advisory support to clinical trial researchers and industry (including SMEs) developing or repurposing therapies and developing vaccines for COVID-19 patients Continue to prioritise regulatory review of potential therapies and vaccines for COVID-19 Contribute to global decision making through ICMRA on clinical trial design and data requirements for therapies and vaccines for COVID-19 Continue to expand and evolve work-sharing product evaluations of new prescription medicines, extensions of indications to medicines and generic medicines with Australia-Canada-Singapore-Switzerland consortium (ACSS) partners and joint evaluations of new oncology medicines with the USA and Canada through Project Orbis Support greater utilisation of comparable overseas regulator reports for registration of medicines and new indications, to bring products to market faster Enhance business processes and IT systems to support prescription medicines review and safety monitoring, including greater use of electronic submissions Monitor and review designation process and eligibility criteria for orphan drugs Continue to improve alignment between regulatory evaluation and reimbursement evaluation (Pharmaceutical Benefits Scheme) for new prescription medicines Support the adoption of the revised Consumer Medicine Information template by industry Implement new business processes for the provision of early scientific advice on bioequivalence data for new generic medicines

Major regulatory reform activities for 2020-21

Outcome	Activities
	<ul style="list-style-type: none"> • Implement a program of Good Clinical Practice inspections of Australian clinical trials • Implement enhanced transparency measures for prescription medicines that are under evaluation • Increase staff technical capacity and resources to support advanced cellular and biological therapies • Reform mechanisms to enable advice on regulatory applications from external advisors at an early stage • Complete reshaping of Product Information documents to ensure the most important information for prescribers is prominent • Implement a new therapeutic goods order with requirements for machine-readable codes used to serialise medicines so that they can be better identified throughout the supply chain • Update the Pharmaceutical Inspection Cooperation Scheme guidance to reflect current best practice for requirements for medicines manufacturing quality
Complementary and OTC medicine and sunscreens	<ul style="list-style-type: none"> • Implement a mechanism to make it clear which sports supplements, are considered therapeutic goods • Enhance the listed medicines post-market compliance scheme, including a risk-based enforcement model • Update guidance material for evidence requirements for listed (including complementary) medicines • Improve regulatory guidance for listed medicines and registered complementary medicines • Implement a data protection scheme for assessed listed medicines • Develop mandatory requirements for ingredient applications for listed medicines • Develop new approval pathways for sunscreen ingredients and excipients, which lower regulator burden but assure safety and performance of sunscreen products • Support adoption of the revised Consumer Medicine Information template for certain over-the counter medicines
Medicines and Chemicals Scheduling	<ul style="list-style-type: none"> • Consult on, and decision made on whether to proceed with reforms to scheduling of nicotine for use in e-cigarettes • Implement business process changes, including a new application form and portal for public submissions on proposed scheduling changes

Major regulatory reform activities for 2020-21

Outcome	Activities
Biologicals	<ul style="list-style-type: none"> • Manage appropriate restrictions to the advertising and supply of autologous cell and tissue therapies that involve significant processing to support patient safety • Implement policies and regulatory changes for the regulation of faecal microbial transplant products
Medical device reforms	<ul style="list-style-type: none"> • Continue to provide advisory support to researchers and industry (including SMEs) developing hospital ventilators and other medical devices and tests for COVID-19 patients • Continue to prioritise regulatory review of diagnostic tests and medical devices for COVID-19 • Complete the implementation of regulations and business processes to enable Australian notified bodies to provide conformity assessment for medical devices • Implement reforms to regulatory frameworks • alignment of device classification with the European Union scheme • new regulatory framework for personalised (including 3D printed) medical devices • medical device software, including appropriate carve-outs from TGA regulatory oversight • undertake further preparation for potential introduction of a Unique Device Identifier system
Medical device safety reforms	<ul style="list-style-type: none"> • Establish a comprehensive testing system for face masks and other personal protective equipment PPE and undertake a full review of all face mask inclusions in the ARTG • Continue to consult and implement the Action Plan for Medical Devices. These reforms will improve how devices get on the market; strengthen monitoring and follow-up of devices already in use; and provide more information to patients about the devices they use. Conduct public consultations on, and provide advice to government on: <ul style="list-style-type: none"> – clarifying requirements for medical devices to be used in clinical trials – potential inspections of the systems used by sponsors for reporting and tracking adverse events – enhancements to adverse event reporting, including whether adverse event reporting by healthcare facilities should be mandated. • Continue to improve post-market monitoring systems for medical devices including early detection and action on

Major regulatory reform activities for 2020-21

Outcome	Activities
	<p>emerging safety issues, allowing us to notify consumers earlier</p> <ul style="list-style-type: none"> • Complete implementation of new IT systems for medical device postmarket reviews, improving timeliness and extent of detection of potential safety problems
Prescription medicines safety	<ul style="list-style-type: none"> • Continue to implement regulatory options to address prescription opioid misuse, including tightening indications, registering smaller pack sizes and enhancing safety information in the Product Information and Consumer Medicine Information leaflet • Continue to implement a major education and communication campaign on the opioid reforms in partnership with healthcare professional and consumer organisations, with strategies based on extensive consumer and healthcare professional research surveys • Undertake and publicly report the results of safety reviews on priority issues, including use of antidepressants in adolescents and misuse of gabapentoids
Better reporting and management of medicine shortages	<ul style="list-style-type: none"> • Work with external stakeholders to improve identification, communication and management of medicine shortages and build consumer and health professional understanding of the how medicine shortages are managed and how medicines can be accessed during a shortage
Advertising reforms	<ul style="list-style-type: none"> • Implement the Government's response to the Review of Therapeutic Goods Advertising Framework • Undertake a full review of the Therapeutic Goods Advertising Code • Implement improvements to the handling of advertising complaints including a shift from individual complaints handling to a more strategic compliance management approach, identification of compliance priority areas for focussed compliance and enforcement action in accordance with public health risks • Address regulatory compliance and enforcement priorities and advertising compliance breaches related to COVID-19 as a priority given risks to individual and public health; resolve the backlog of (other) advertising complaints that have arisen during the pandemic

Core regulatory activities

Product regulation activities for 2020-21	
Outcome	Activities
Pre-market evaluation, assessment and approval of medicines, medical devices, biologicals and other therapeutic goods	<p>Evaluation and assessment</p> <ul style="list-style-type: none"> Evaluate and process applications within legislated or target timeframes for market authorisation of prescription, over-the-counter, assessed listed and registered complementary medicines; listed medicine ingredients; biologicals, blood components and medical devices (including IVDs) that are imported into, exported from, manufactured and/or supplied in Australia Undertake orphan, priority and provisional designations for medicines and priority designations for medical devices based on legislated criteria Regulate medical devices and medicines through their lifecycle through efficient and accountable regulatory practices Track and ensure completion of conditions of registration for prescription medicines Provide access to unapproved therapeutic goods for use in Australia where no alternative treatment is available through the Special Access Scheme, the Authorised Prescriber scheme, and the Clinical Trial Notification and exemptions schemes <p>Risk management</p> <ul style="list-style-type: none"> Evaluate risk management plans for high-risk medicines and biologicals to ensure that safety concerns are identified, characterised and managed e.g. through additional pharmacovigilance or education Monitor sponsor implementation of post-market risk management activities, to ensure that safety concerns are managed appropriately and effectively Assess, process and publish sponsor notifications of medicines shortages to provide reliable and timely information about shortages and alternative medicines to assist consumers and health professionals Monitor sponsor compliance with medicine shortage reporting obligations Monitor medicinal cannabis sponsor compliance with Therapeutic Goods Order No.93 declarations on composition and impurities

Product regulation activities for 2020-21

Outcome	Activities
	Transparency <ul style="list-style-type: none"> Continue publication of Australian Public Assessment Reports (AusPARs) and announcements of the registration of new prescription medicines
Ongoing monitoring of the safety, efficacy, performance and quality of medicines, medical devices, biologicals and other therapeutic goods	Safety <ul style="list-style-type: none"> Continue to investigate and monitor safety issues in a timely manner, using a risk-based framework Continue to evaluate Periodic Safety Update Reports to identify the impact of new and emerging safety information on the overall risks and benefits of a product to ensure that positive benefit vs risk balance is maintained following supply Undertake assessment of updates to Risk Management Plans as new information emerges to ensure the risk management strategy for the product remains appropriate Conduct enforcement activities jointly with other Commonwealth, state and territory agencies, targeting registered and unregistered therapeutic goods non-compliance Undertake risk-based inspections of medicine sponsors to verify compliance with pharmacovigilance legislation and guidelines, and address any deficiencies that may pose a risk to public health Utilise and further explore large health datasets such as the Medicare Benefits Schedule and the Pharmaceutical Benefits Scheme in detection of potential safety issues Remove products from the market that pose an unacceptable risk to consumers Ongoing evaluation of the prescription opioid reforms to ensure harms associated with these medicines are reduced and that they continue to be utilised in accordance with the quality use of medicines principles Ongoing review of the Therapeutic Goods (Permissible Ingredients) Determination to reflect evaluation undertaken on the safety and quality of ingredients available for use in listed medicines Maintain the Poisons Standard, the national regulatory framework for the access of substances, and continue to provide advice across industry, government and consumer sectors

Product regulation activities for 2020-21

Outcome	Activities
	<p>Manufacturing quality</p> <ul style="list-style-type: none"> Regulate manufacturers of therapeutic goods through risk-based inspection and desk-top assessment programs to confirm the quality of therapeutic goods supplied in Australia from domestic and international manufacturers meet specified standards and manufacturing principles Undertake risk-based testing to monitor medicines, medical devices and biologicals supplied in Australia for compliance with standards and essential principles Continue to provide public updates of the results of laboratory compliance testing <p>Education and compliance</p> <ul style="list-style-type: none"> Monitor and enforce compliance, including the quality, supply and advertising of therapeutic goods, utilising sanctions and penalties where necessary Continue education and awareness raising activities to support adverse event reporting by consumers and health professionals Educate consumers about counterfeit therapeutic goods through publishing safety alerts and other education material Continue to provide guidance and education to small-to-medium enterprises, start-ups, researchers and new industry stakeholders through SME Assist Manage our digital submission and monitoring systems for prescription and over-the-counter medicines Continue to publish listed medicine compliance review outcomes and educate consumers about the compliance review process Publish annual Pharmacovigilance Inspection Program metrics reports to help sponsors understand their obligations and encourage compliance Support stakeholders in completing the transition to updated medicines labelling requirements
Business activities to support regulatory outcomes and a cost recovered framework	<p>Governance and support functions</p> <ul style="list-style-type: none"> Ensure that fees and charges appropriately reflect the regulatory effort involved and our cost recovery obligations, including through a charging review across all TGA activities

Product regulation activities for 2020-21

Outcome

Activities

- Implement agreed recommendations of the Australian National Audit Office's Application of Cost Recovery Principles Audit
- Continue to support governance arrangements for our statutory advisory committees, manage specialist expert advisory groups, and source specialist advice when necessary to strengthen regulatory decision making processes
- Provide timely, accurate and appropriate information to support parliamentary, media, Freedom of Information, reporting and secretariat services
- Continue to assess the performance of legislative instruments that are scheduled to sunset to ensure that instruments are achieving their objectives
- Ongoing stakeholder engagement through stakeholder surveys, public consultations, market research, and formal and informal forums
- Streamline the management of general email and phone enquiries from external stakeholders) following implementation of a new enquiry management system

Regulatory guidance

- Continue to develop and publish new and updated guidance material and navigation tools that assist external stakeholders to understand and meet their regulatory obligations

Education

- Develop and disseminate regulatory education materials, including tailored content resources, videos, infographics webinars and other tools, that improve the understanding of how therapeutic goods regulation is relevant to consumers, health professionals and industry
- Continue to provide the SME Assist service, helping small to medium enterprises, start-ups, researchers and those unfamiliar with therapeutic goods regulation to better understand regulatory requirements, and increase access to information through webinars and live-streamed events
- Improve the TGA website, ensuring it is accessible, easy to navigate, accurate, and meets the needs of industry, health professionals and the general public

Product regulation activities for 2020-21

Outcome	Activities
	<ul style="list-style-type: none"> • Build our education capability by partnering to enhance our engagement with consumer, health professional and industry stakeholders • Manage the TGA's social media accounts, including Facebook, Twitter, LinkedIn, Instagram and YouTube to maximise audience reach and ensure messages are distributed in channels used by consumers, health professionals and other stakeholders • Implement the Consumer Engagement Strategy to embed principles and techniques for engaging with consumers early and often throughout the regulatory process on changes, decisions or information that affects them
Monitor and enforce compliance of therapeutic goods	<ul style="list-style-type: none"> • Prevent low level non-compliance through education and guidance using proactive communication strategies • Monitor the market for signals of potential non-compliance, through complaints, referrals and intelligence activities, and carry out investigations against a risk based compliance framework • Monitor compliance with Therapeutic Goods advertising requirements, including assurance reviews, random sampling and use of trend analysis to identify requirements for educational materials and activities • Develop compliance plans to address compliance priorities identified during the year through monitoring, data analysis and intelligence activities • Continue to collaborate with state, territory, federal and international partners on matters of compliance and intelligence • Investigate and prosecute serious criminal and civil offending against the <i>Therapeutic Goods Act 1989</i> with a view to appropriate deterrence outcomes

International engagement



TGA's international activities promote synergies between regulators worldwide, leading to collaboration, strategic alignment and resource savings in order to deliver faster access to safe and effective therapeutic products.

Across the globe, regulators are collaborating to respond to the COVID-19 pandemic. TGA's engagement in this work is vital if Australia is to be aware of the full range of new and repurposed treatments, diagnostics and vaccines that are becoming available, as well as address any supply issues for existing products. Collaborating with the WHO, and in leadership roles in the International Coalition of Medicines Regulatory Authorities (ICMRA), the International Medical Device Regulators Forum (IMDRF) and other groups means the TGA can contribute to, and benefit from, a global pool of experts working to make available safe and effective therapies and vaccines.

The TGA leverages international relationships to enable industry, health care providers, and consumers to take advantage of technological advances producing the next generation of more effective and often more complex medicines and devices. In partnership with our international counterparts, we are aligning approaches to regulation and improving the use of reliance mechanisms and work-sharing activities. Benefits arise from the sharing of regulatory best practice, including when we are able to assist less advanced regulators to strengthen their capabilities. In particular, the COVID-19 pandemic has placed considerable pressure on regulators across the world and delayed reforms and other processes that enable regulators to identify and adopt best practice.

In 2020-21 the TGA will continue to collaborate internationally for the benefit of:

- patients – through earlier access to safe and effective vaccines, medicines and medical devices, and ongoing assurance that products remain safe
- regional public health – by working towards disease elimination with regulatory counterparts
- industry – through faster market access, reduced duplication of effort, and lower costs
- regulators in our region, and more broadly – through the sharing of best practice and expertise.

International Coalition of Medicines Regulatory Authorities (ICMRA)

Throughout 2020-21 the TGA will continue to participate in ICMRA meetings to share information and expedite, where possible, the development and evaluation of potential vaccines and treatments for COVID-19. The ICMRA comprises 29 regulatory authorities, with the WHO as an Observer. The TGA is currently Vice-Chair and part of the ICMRA Executive Committee.

International Medical Device Regulators Forum (IMDRF)

The TGA will also continue its close engagement with the IMDRF. This group comprises medical device regulators from around the world working to implement a globally harmonised approach to the regulation of medical devices, including standards, adverse event terminology, and a unique device identification system. Australia is a member of the IMDRF Management Committee.

Increased collaboration with the USFDA Oncology Center of Excellence (OCE)

The TGA will continue to work with the US Food and Drug Administration (USFDA) Oncology Center of Excellence (OCE) on two projects. The first involves the TGA and OCE, along with other international regulators, collaborating on the review of new oncology drugs. The second project aims to evaluate the global experience with accelerated regulatory approval pathways for oncology drugs. Partnering with the OCE on these projects will increase the timeliness of access to some new oncology drugs for Australians, as well as identify potential areas for improvement in the application of provisional registration pathways.

Australia plays a significant role in the region in supporting regulatory counterparts to strengthen their practices and access quality assured medicines. These activities are through two international development assistance programs:

Indo-Pacific Regulatory Strengthening Program

The TGA is partnering with the Department of Foreign Affairs and Trade (DFAT) to deliver the Indo-Pacific Regulatory Strengthening Program (RSP). The TGA is leading the technical engagement for the RSP and works closely with the national regulatory authorities of Cambodia, Indonesia, Lao PDR, Myanmar, Thailand, Papua New Guinea and Vietnam to strengthen their regulatory capabilities. The RSP aims to increase participating countries' access to quality assured therapeutic goods.

Pacific Medicines Testing Program

The TGA and DFAT are piloting a program to provide Pacific Island Countries access to Australian laboratory testing for medicines quality assurance. The program is focused on testing medicines used to treat non-communicable diseases (such as heart disease and diabetes), as well as some antibiotics. Pacific Island Countries are able to send medicines to the TGA for testing when there is a problem or a complaint. There are 12 countries participating: Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Nauru, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu.



International engagement activities for 2020-21

Outcome	Activities
Improved public health and safety	<ul style="list-style-type: none"> Continue to work closely with participating countries to strengthen their regulatory functions through the Indo-Pacific Regulatory Strengthening Program to ensure greater access to high quality, safe and effective therapeutic goods Continue the Pacific Medicines Testing Program Participate in international regulator forums when considering vaccines, medical devices, complementary or prescription medicines or the implementation of pharmacovigilance activities to ensure emerging regulatory policy is aligned with international best practice Support bilateral and multilateral agreements that underpin our international engagement
Improved regulatory systems	<ul style="list-style-type: none"> Establish new relationships with countries in our region to assist in increasing their regulatory capacity Work with comparable overseas regulators to increase efficiencies in regulatory systems and processes. For example, to accelerate regulatory alignment, fast track approval processes for certain medicines and medical devices, and explore how risk assessments and determinations by comparable overseas regulators can be used more extensively Enhance pharmacovigilance activities; increase engagement with overseas counterparts to identify sources of supply to both identify and alleviate medicine shortages; undertake quality system audits of manufacturing facilities; strengthen intelligence with respect to provisionally approved medicines; and facilitating the exchange of information about medical device adverse events
Advanced work sharing, information sharing and regulatory convergence	<ul style="list-style-type: none"> Participate in programs to develop enhanced collaboration frameworks with comparable overseas counterparts and promote the use of aligned regulatory systems and processes to reduce unnecessary duplication of effort across regulators Support the development of standards that ensure the safety and quality of products by working with standard setting bodies, including the International Organization for Standardization and Standards Australia.

For further information about our work with international agencies and overseas regulators are available on the International page on the TGA website..

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>