



Australian Government  
Department of Health  
Therapeutic Goods Administration

# TGA Business Plan 2021 | 2022



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## Message from the Deputy Secretary



The health landscape has changed significantly since 2020, following the declaration of COVID-19 as a major health pandemic. The Australian public has looked to the Therapeutic Goods Administration (TGA) more than ever to assist in making informed choices about the products they use to maintain their health. Our response to these challenges demonstrated our ability to innovate and to improve our business processes. We will build on these process improvements through, for example, the better use of available health administrative data, improved data analytics and the implementation of the TGA digital transformation agenda. We will continue to engage closely with the pharmaceutical and the medical technology sectors, health care professionals and consumer groups. This engagement is essential in the development of flexible but robust regulatory evaluation processes, and expedited access for the Australian health sector, without compromising our regulatory standards. Through our work with supply chain stakeholders, we have implemented new ways of gathering intelligence about potential medicine and device (e.g. personal protective equipment) shortages. The monitoring and management of medicine shortages will continue in 2021-22 with new arrangements for monitoring wholesaler data and working closely with healthcare professionals and consumer organisations to provide public information about shortages.

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

All the while, our people remain our greatest asset. They continue to demonstrate the outstanding commitment they have made during the COVID-19 pandemic to protecting the health and safety of the community in all facets of regulatory activity. We will continue to invest in capability development and new ways of working to build the workforce we need to deliver a world class, efficient, and timely regulatory system for therapeutic goods. We are committed to maintaining a culture where all our employees feel respected and included and focus on our regulatory science capability outlined in the HPRG *Regulatory Science Strategy 2020 – 2025*.

The TGA's role as a regulator has never been so clear. In 2021-22, we will continue to increase our engagement with patients, consumers, and health professionals by strengthening relationships with representative bodies and individuals. We will provide additional information for healthcare professionals to clarify regulatory requirements and application processes for high-risk devices.

Through our commitment to international engagement and supporting Australia's health security, we will continue to provide critical support and play a key role in supporting the safe, effective and timely roll-out of COVID-19 vaccines in South East Asia and the Pacific.

Our Business Plan sets out our product regulation, regulatory reform, international engagement, and regulatory education and compliance agenda for 2021–22. It supplements the *Health Portfolio Budget Statements*, the *Department of Health Corporate Plan*, and is supported by the Australian Government's *Regulator Performance Framework*.

**Adjunct Prof John Skerritt** FTSE FIPAA (Vic)

## Introduction

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

The TGA regulates the supply of:

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

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

## Our vision

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

## Our purpose

The TGA is responsible for protecting the health and safety of the community by regulating therapeutic goods for safety, efficacy or 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.

## Our 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 and the Australian public, and work cooperatively with the industry we regulate
- we communicate meaningfully with stakeholders, including consumers, by 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 for similar decisions to the extent possible.

## Operating environment

Scientific advancements, such as new cancer treatments and personalised medicine, gene therapies, the increasing use of software as a medical device, and 3D printed devices continue to bring opportunities for improved care 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.

Across the globe, regulators are collaborating to respond to the COVID-19 pandemic. The 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 to address any supply issues for existing products. Collaborating with the World Health Organization (WHO), and in leadership roles in the International Coalition of Medicines Regulatory Authorities (ICMRA), and the International Medical Device Regulators Forum (IMDRF) means the TGA can contribute to, and benefit from, a global pool of experts working to make safe and effective therapies and vaccines available.

Our education activities, including those conducted in response to emerging issues, will assist businesses to comply with regulatory requirements. We recognise that a small number of people or businesses will seek to evade the regulatory requirements. Our compliance and enforcement responses will remain proportionate to the risk posed to public health and maintain the integrity of the regulatory framework.

## 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 for all Australians
- an affordable, quality health and aged care system
- better sport outcomes.

We are committed to delivering the Department's Health Protection, Emergency Response and Regulation program through the protection of the health and safety of the Australian community, and the preparedness to respond to national health emergencies and risks through the regulation of therapeutic goods (including medicines, medical devices, and blood, cell, and tissue products). This applies to goods exported, imported, supplied, and manufactured in Australia.

As a regulator, the TGA must measure its performance in accordance with the Government's *Regulator Performance Framework*. Our annual self-assessment against the Framework is validated by the TGA Industry Forum, and is reported externally,

In 2021-22, we will transition to the new *Regulator Performance Guide*. The new Guide outlines three principles of best practice for regulators:

- Continuous improvement and building trust. Regulators adopt a whole-of-system perspective, continuously improving their performance, capability and culture to build trust and confidence in Australia's regulatory settings
- Risk based and data driven. Regulators manage risks proportionately and maintain essential safeguards while minimising regulatory burden, and leveraging data and digital technology to support those they regulate to comply and grow
- Collaboration and engagement. Regulators are transparent and responsive communicators, implementing regulations in a modern and collaborative way

and will replace the externally-validated self-assessment report under the Framework in 2022-23. The Guide is underpinned by the Australian Government's expectations of regulator performance.

Internally, the TGA will continue to focus on its people, aligning our workforce activities with the Department's *People Strategy*. Our Capability and Culture Committee develops initiatives to keep our people front of mind, while internal business planning further articulates specific actions.

The importance of our people is exemplified in our commitment to the capability development of our regulatory scientists. In our *Regulatory Science Strategy 2020-2025*, we will focus on four areas:

1. Maintaining and building skills in regulatory science.
2. Improving domestic and international collaboration with other government agencies, scientific organisations, and regulators.
3. Increasing responsiveness to emerging technologies.
4. Improving communication and engagement with stakeholders about regulatory science.

Further afield, the TGA's *International Engagement Strategy 2021-25* provides the overarching direction for TGA's international engagement. It sets four strategic goals:

1. Build a globally aligned regulatory framework that fosters sovereign decision making.
2. Pre-market global collaboration and information sharing with comparable overseas regulators to reduce regulatory burden.
3. Post-market global surveillance utilising international networks to monitor product safety and quality, and maintain supply chains.
4. Strengthening regional regulatory capabilities for safer therapeutics.

Through these strategic priorities, international regulatory collaboration benefits:

- regional public health by working towards disease elimination
- industry through faster market access and lower costs
- patients through earlier access to medicines and medical devices
- regulators through effective processes, less duplication, and reduced workloads.

## Reporting

In addition to this Business Plan, major performance setting and reporting documents include the *Health Portfolio Budget Statements*, the *Department of Health Annual Report*, the *TGA Annual Performance Statistics Report*, and our supplementary *Half Yearly Performance Snapshot*. As a regulator, The TGA is also required to report in 2021-22 on our self-assessment against six key performance indicators, which are set out in the Government's *Regulator Performance Framework*.

In addition, we publish a range of performance information on the TGA website, including:

- laboratory testing results and summary reports, including up-to-date regular vaccine batch release data
- monitoring, compliance, and investigations outcomes, and advertising compliance reports
- post-market reviews
- an annual stakeholder survey
- publications detailing how we are improving access to therapeutic goods for consumers.

## Funding

The TGA is a cost-recovered entity with fees and charges set in accordance with the Australian Government's *Charging Framework and Cost Recovery Guidelines*. Further information on the breakdown of expenditure can be found in our annual *Cost Recovery Implementation Statement* on our website.

The TGA 2021-22 budget is expected to be approximately \$186 million. The regulatory costs are mostly recovered through annual fees and charges levied on the sponsors and manufacturers of therapeutic goods, except for the cost of the medicines and chemicals scheduling function for which an appropriation is provided by the Government.



The TGA uses an activity-based costing model to calculate the relevant costs for each activity we undertake. In December 2020, we consulted with thirteen industry representative groups, as part of the annual charging review. In addition, we undertook a six-week public consultation on the fees and charges, ending in March 2021. As a result, the Australian Government approved an increase of 1.05% to fees and charges in 2021-22.

In the 2020-21 Federal Budget, measures were announced to support the work of the TGA over four years until June 2025:

- \$12 million to digitise, transform, and modernise the TGA's business systems and infrastructure.
- \$7.7 million to establish a Unique Device Identification (UDI) database for medical devices. Its adoption in the healthcare system will allow the tracking and tracing of medical devices that have been implanted in patients.

In addition, the Department of Foreign Affairs and Trade (DFAT) provides funding to the TGA to deliver three regional support programs to countries in the Indo-Pacific. The TGA provides support through its Indo-Pacific Regulatory Strengthening Program to help build the capabilities of national regulatory authorities in the region. The TGA is also supporting the Pacific Step Up program to undertake testing of essential medicines across a number of Pacific countries. Finally, TGA has recently received funding and is implementing the Australian Expert Technical Assistance Program for Regional COVID-19 Vaccine Access – Regulatory Support and Safety Monitoring program to help deliver timely access and ongoing safety monitoring of COVID-19 vaccines.



## Our priorities for 2021-22

1. **Product regulation and safety** – including COVID-19 medicines, vaccines and medical devices, and digital transformation.
2. **Regulatory reform** – through consulting on and implementing initiatives following policy approval from government.
3. **International engagement** – through activities that promote international information sharing, work sharing, collaboration and regulatory convergence, as well as programs for regulatory strengthening/assistance, and medicines testing in our region.
4. **Regulatory education and compliance** – through education, monitoring, targeted compliance and enforcement activities and appropriate action.

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## Priority 1 - Product regulation and safety

Australia's expertise in regulatory science is recognised around the world. The safety of the Australian community is paramount and must be balanced with the need to support industry through the timely regulation of therapeutic goods.

In 2021-22, our focus will be on:

- prioritising medicines and medical devices associated with COVID-19
- the regulation of other medicines and medical devices
- capability development of our regulatory scientists
- streamlining our business systems and processes through digital transformation
- relocating and transitioning to a new state of the art laboratory and office facility in Fairbairn, ACT.

### Prioritise COVID-19 medicines and medical devices

The TGA remains at the forefront of the Australian Government's response to the COVID-19 pandemic. We will continue to

- prioritise medicines, vaccines and medical devices that are associated with COVID -19 without compromising safety, and work together with our international regulatory counterparts
- support small-to-medium enterprises (SMEs), researchers, and those unfamiliar with therapeutic goods regulation to better understand regulatory requirements
- prioritise the development and approval of therapies that assist with the treatment of COVID-19. This includes advisory support to clinical trial researchers and industry, and contributions to international consortia
- prioritise the regulatory review of diagnostic tests and medical devices for COVID-19, and provide advisory support to researchers and industry (including SMEs) developing hospital ventilators and other medical devices and tests for COVID-19 patients
- monitor COVID-19 vaccines through the TGA vaccine safety monitoring system. The system can rapidly detect, investigate and respond to any emerging safety issues through the review and analysis of adverse events reports, our work with international regulators, and the review of medical literature, media, and other potential sources of new safety information.

### Regulation of medicines and medical devices

Maintaining our high standards of regulation for medicines and medical devices will be delivered by:

- delivering regulatory decisions within target timeframes
- responding to scientific advancements and emerging technologies to support timely access to new therapeutics
- continuing to improve the transparency of our activities.

## Capability development

- The *Regulatory Science Strategy 2020-2025* aims to make sure that we continue to make the best possible regulatory decisions, by ensuring that our regulatory scientists are capable, collaborative, communicative, and responsive to future challenges and emerging technologies.

## Digital transformation

- The four-year digital transformation will deliver simpler, faster, and more secure interactions between industry and government to apply for, track, pay, and manage regulated and subsidised health-related products and services.
- We will continue to modernise the TGA's service experience (eBS/TBS), and the redevelopment of the Australian Register of Therapeutic Goods, as well as making enhancements to support adverse event reporting for COVID-19 and subsequently other vaccines.
- The TGA website will be redeveloped and moved onto the GovCMS platform, while ensuring a consistent user experience across all of the TGA digital channels.
- We will continue to implement a new system for medical device post-market reviews and improving timeliness and the detection of potential safety problems.

## New state of the art laboratories

- After 30 years in Symonston, the TGA will be relocating to new premises in mid-2022. The location will comprise two purpose-built buildings – an office building and a dedicated laboratory building.
- The custom-built laboratories will help maintain the TGA's reputation as a world-class regulator. The laboratories are being constructed specifically to meet TGA's requirements.
- The TGA will plan to ensure the transition to the new premises will have minimal impact on the output of the laboratories and the timeliness of regulatory decisions and safety monitoring actions.

## Priority 2 – Regulatory reform

The TGA continues to implement regulatory reforms with a focus on supporting emerging medical technologies, while delivering efficient, best practice regulatory decisions. We want to simplify pathways and processes for industry and deliver safer products to market.

The following activities will be our focus in 2021-22:

### Prescription medicines

- Implement a program of Good Clinical Practice inspections of Australian clinical trials.
- Update the Pharmaceutical Inspection Cooperation Scheme guidance to reflect current best practice for requirements for medicines manufacturing quality.

### Complementary and OTC medicine and sunscreens

- Develop mandatory requirements for ingredient applications for listed medicines to provide transparency to applicants on the information required by the TGA, and to enable the more efficient screening of applications.

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- Develop new approval pathways for sunscreen ingredients and excipients that lower the regulator burden but assure the safety and performance of sunscreen products.
  - Further enhancement of the listed medicines post-market compliance scheme as part of the TGA's digital transformation project.
  - With recent changes to the regulation of sports supplements, undertake a comprehensive compliance program.

## Medical devices

- Complete the implementation of business processes to enable Australian Conformity Assessment Bodies to provide conformity assessment for medical devices.
- Implement the reclassification of devices to align with the European Union Medical Device Reforms where appropriate.
- Undertake further preparation for the introduction of a Unique Device Identifier system.
- Continue to improve post-market monitoring systems for medical devices, including early detection and action on emerging safety issues, thereby allowing us to notify consumers earlier.
- Continue to implement the Action Plan for Medical Devices. These reforms will improve how devices get on the market, strengthen the monitoring and follow-up of devices already in use, and provide more information to patients about the devices they use.
- Conduct public consultations, and provide advice to Government on the:
  - requirements for medical devices to be used in clinical trials
  - potential inspections of the systems used by sponsors for reporting and tracking adverse events, and
  - enhancements to adverse event reporting, including whether adverse event reporting by healthcare facilities should be mandated.

## Medicines and Chemicals Scheduling

- Ensure that the implementation of changes to the scheduling of nicotine for use in e-cigarettes are adequately supported by related regulatory change, stakeholder interaction and communication once changes come into effect in October 2021.
- Implement a new application form for proposing scheduling changes and release a publicly available searchable Poisons Standard Database.
- Together with major stakeholders, review and communicate improvements to 'Appendix M' to facilitate down-scheduling of appropriate prescription only substances to pharmacist only.

## Medicinal Cannabis

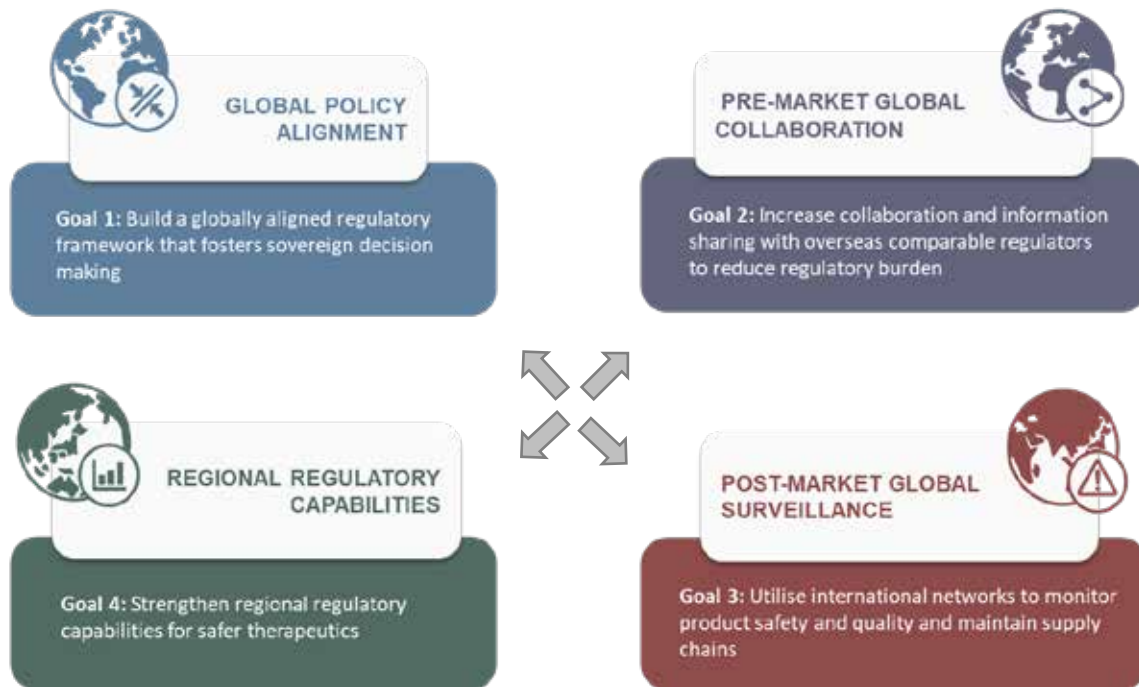
- Progress reforms and improve business processes to the regulation of medicinal cannabis products in Australia, including requirements relating to supply, manufacture, labelling and packaging.



## Priority 3 - International engagement

The *TGA's International Engagement Strategy 2021-2025* describes how working with our international regulatory counterparts will benefit Australians through a more globally aligned regulatory framework. Reduced regulatory burden on industry, a fit for purpose regulatory system that is responsive to the latest medical and scientific developments and enhanced global identification of safety signals leads to improved access to health products and better safeguards for the Australian community.

TGA will achieve this by focussing on the four strategic priorities outlined below.



Activities during 2021-22 include:

- Working closely with participating countries to strengthen their regulatory functions through the Indo-Pacific Regulatory Strengthening Program.
- The Pacific Medicines Testing Program to assist participating Pacific Island Countries with access to Australian laboratory testing for therapeutic goods quality assurance.
- The Australian Expert Technical Assistance Program for Regional COVID-19 Vaccine Access – Regulatory Support and Safety Monitoring program to assist countries in accessing and monitoring the safety of COVID-19 vaccines.
- Work-sharing product evaluations of new prescription medicines, extensions of indications to medicines and generic medicines through the ACCESS Consortium (Australia-Canada-Singapore-Switzerland and the United Kingdom) partners, and collaborative reviews through the US Food and Drug Administration's Project Orbis.

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## Priority 4 - Education and compliance

Education and compliance are central to our role as a regulator and critical to the success of many of our reform activities in 2021-22. The TGA conducts monitoring of the quality, safety, and efficacy of therapeutic goods to support community confidence in these products. We use the data collected from this monitoring to identify trends in non-compliance. This information is used to help prioritise our future compliance review activities and key education activities.

### Industry compliance reforms

- Monitor and enforce compliance, including the import, export, manufacture, supply and advertising of therapeutic goods, imposing sanctions and penalties where necessary. This is achieved through complaints and reports from the community, and advice from other regulators and agencies, including border and law enforcement agencies and state and territory regulators.
- Undertake a review of the Therapeutic Goods Advertising Code, while continuing education and communication activities to facilitate compliance with the Advertising requirements
- Implement the Pharmacovigilance Inspection Program and publish metrics reports to help sponsors understand their obligations and encourage compliance.
- Support stakeholders in completing the transition to updated medicines labelling requirements.
- Provide additional information for healthcare professionals to clarify regulatory requirements and application processes for high-risk devices.
- Continue to develop new ways to provide support and education to small-to-medium enterprises (SME), start-ups, researchers, and those unfamiliar with regulation through SME Assist. Recently live-streaming and podcasts were developed to help these stakeholders better understand their regulatory requirements.
- To support patient safety, manage restrictions to the advertising and supply of autologous cell and tissue therapies that involve significant product processing.

### Public safety education

- Improve understanding of how therapeutic goods regulation is relevant to consumers, health professionals, and industry through the development of regulatory education materials, including tailored content resources, videos, infographics, webinars, podcasts, and other tools.
- Educate consumers about counterfeit therapeutic goods through the publication of safety alerts and other education materials.
- Provide awareness-raising activities to support adverse event reporting by consumers and health professionals, particularly for COVID-19 vaccines.
- Educate consumers on the regulatory changes to nicotine e-cigarettes that take effect from 1 October 2021 through targeted information campaigns and communication activities.
- Continue to undertake and publish the outcomes of listed medicine compliance reviews and educate consumers about the compliance review process.



## Access to information for Industry and Consumers

- Provide exhibition booths at events to assist with providing up-to-date information on regulatory changes, and emerging issues and trends.
- Maintain the TGA website to ensure that it is accessible, easy to navigate, accurate, and meets the needs of industry, health professionals, and the general public, while working towards the development of a new website to be implemented in 2022.
- Build our education capability by partnering to enhance our engagement with consumers, health professionals, and industry stakeholders.
- Inform and educate consumers, health professionals, and stakeholders on regulatory changes in priority areas through targeted digital communication campaigns and activities.
- 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.



## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Regulatory Engagement and Planning Branch	19 August 2021

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