Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Administration

Business Plan 2023–24

Contents

Message from the Deputy Secretary

I am honoured to join the Health Products Regulation Group in the Department of Health and Aged Care and lead the Therapeutic Goods Administration (TGA). As Deputy Secretary, I look forward to contributing the safeguards and health of the Australian community through effective and timely regulation of therapeutic goods, while modernising the TGA's processes to better support Australian's robust therapeutic good sector.

The year ahead provides an ambitious program of work for the TGA. In the 2023-24 Budget, the Australian Government announced new reforms to strengthen the regulation and enforcement of e-cigarettes, including placing new controls on their importation, contents and packaging. The TGA will play a critical role in implementing these reforms, through regulatory changes, compliance activities and development of other controls.

Importantly, the 2023-24 Budget provided $61 million (over four years) for the important work of the TGA, which is a significant financial boost to help us deliver services aimed at protecting public health. This funding will:

- increase our capacity and focus on compliance and enforcement for unregulated products and entities operating outside the regulatory system,
- support more timely management and advice regarding medicine and medical device shortages or supply disruptions,
- develop more consumer and healthcare professional information, responding in more timely ways to enquiries and contributing to broader public health education efforts, and
- offer greater assistance to small and medium enterprises (SMEs), new applicants and developers of emerging therapeutics and devices.

This also relieves cost funding to be directed towards activities supporting more timely product evaluations and approvals.

To enhance our surveillance capability and to respond more quickly to emerging medical device issues, the TGA will work closely with the Australian Commission on Safety and Quality in Health Care, states and territories and healthcare facilities to implement mandatory reporting of medical device adverse events by Australian public, private - hospitals.

Throughout 2023-24, and in partnership with the Department of Foreign Affairs and Trade, our efforts will continue with the national regulatory authorities within the Pacific and South-East Asia regions to promote public health through improved regulatory practice and prevention, detection and treatment of communicable and non-communicable diseases.

Our efforts continue to implement digital transformation to deliver modern tools and digital platforms, including a contemporary online business portal and case management system. This will make it faster and simpler for the therapeutics sector and our staff.

The TGA's activities and priorities will be to enhance our commitment to regular and multi-faceted stakeholder engagement, to continuously drive continuous improvement and to better understand the impacts of our regulatory actions.

Prof Anthony Lawler, FACEM, FRACMA, MBBS, MBA (Health Mgmt), FIFEM, GAICD, BMedSci

Our purpose

The TGA, as part of the Australian Government Department of Health and Aged Care, is responsible for evaluating, assessing, and monitoring products that are defined as therapeutic goods. We help Australians stay safe by regulating therapeutic goods for safety, efficacy, performance, and quality.

We regulate the manufacture, import, export, supply, and advertising of prescription medicines, vaccines, non-prescription medicines, sunscreens and complementary medicines (including vitamins, minerals, herbal and traditional medicines), We also regulate medical devices, blood and blood products, cellular therapies, and biologicals.

Consistent with the *Therapeutic Goods Act 1989 (*the Act*),* 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 vision

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

Our strategic intent

By regulating therapeutic goods in accordance with *the Act* and supporting regulations, we contribute to meeting the Department's aim to protect the health, safety, and wellbeing of all Australians by identifying risks to human health and the environment and managing those risks to prevent harm through education and effective, proportionate compliance activities.

In line with the Government's expectations and the TGA's Statement of Intent, we will maintain a best practice and contemporary regulatory environment, boost productivity through reducing unnecessary or duplicative regulatory costs and work with international partners to share information and identify opportunities to improve the quality of regulation.

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.

We undertake our regulatory functions by applying **three** principles of regulator best practice:

- **Continuous improvement and building trust**

  We will:

  - use qualitative and quantitative analysis to assess and report on performance, and drive evidence-based continuous improvement
  - promote a culture that builds public confidence in our work and trust in our decision-making.

- **Risk based and data driven**

  We will:

  - actively understand, engage with, and effectively mitigate strategic risks to successfully manage our regulatory functions without unnecessarily impeding the operations of regulated entities
  - use data sources that meet relevant data assurance standards for assessing and reporting on the quality of statistical information.

- **Collaboration and engagement**

  We will:

  - seek opportunities to inform, engage and consult with our stakeholders and the Australian community
  - be receptive to feedback and diverse stakeholder views
  - seek to increase transparency in decision-making processes
  - provide up-to-date, clear, and accessible guidance and information to assist regulated entities with compliance.

Our strategic objectives

Using the three principles of best practice as a platform, and through consultation, we arrived at the following strategic objectives:

1 – Improve public health outcomes through best practice regulation

2 – Build trust by actively engaging with our stakeholders

3 – Promote and enforce compliance with regulatory requirements

4 – Innovate and continuously improve

Strategic objective 1 – Improve public health outcomes through best practice regulation

Australia's expertise in regulation is recognised around the world. The safety of the Australian community will be maintained by our high standards of therapeutic goods regulation and our role shaping and responding to world-wide practices. The TGA continues to implement regulatory reforms with a focus on simplifying pathways and processes for consumers, healthcare professionals, and industry while delivering efficient, whilst maintaining best practice regulatory decisions.

Performance Indicators

1.1 Product approvals and regulatory assessments are delivered in accordance with statutory timeframes and non-statutory targets.

1.2 Provide timely access to innovative therapies and emerging technologies that respond to public health needs.

1.3 Propose and support design of regulatory reforms when evidence of value and real benefit is determined, or when risks can be appropriately managed.

Our focus for 2023-24

a. Strengthen regulation and enforcement for vaping products, including new controls on their importation, contents, and packaging.

b. Establish a medicine repurposing function to identify potential new uses for older medicines through research and evidence.

c. Continue the design and implementation of reforms to improve recall actions for all therapeutic goods.

d. Prioritise evaluations, post-market safety and performance monitoring of new products in consideration of national health emergencies and other public health issues.

e. Report and manage medicine and medical device shortages to support continued patient access to important therapeutic goods.

f. Implement regulatory changes and guidance to facilitate domestic manufacture, import, prescribing and supply of psilocybin and MDMA to patients by authorised psychiatrists.

g. Increase laboratory testing of TGA registered and listed products that are at higher risk of non-compliance with regulatory requirements.

h. Continue implementation of the Action Plan for Medical Devices to 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.

i. Progress the development and international alignment of the Unique Device Identification system to improve product safety and surveillance of products in the Australian supply chain.

j. Assist and support sponsors to navigate the regulatory and reimbursement processes and expand the regulatory approvals for the uses of therapeutic goods.

k. Review and reform clinical trials regulation to provide clear guidance, expand formal technical advice relating to clinical trial design, provide greater access to scientific advice about regulatory submissions, and increase oversight of high-risk therapeutic goods address safety concerns.

l. Continue engagement, both domestically and internationally, to build flexible and robust regulatory systems and processes, improve work sharing and harmonisation with international regulators resulting in faster and safer access to products for communicable diseases, and minimising supply of products that are of poor quality or present health risks.

m. Work with National Regulatory Authorities within the Pacific and South-East Asia regions to strengthen regulatory systems.

n. Monitor and refine regulatory frameworks to support new and emerging technologies, such as digitally enabled models of testing and treatment tailored to patients, involving software, medicine dosage and genomic sequencing and analysis, point of care manufacturing, hybrid models of access such as cloud based and offshore to ensure they are effective and keeping pace with new advances.

o. Implement enhancements to medical device adverse event reporting, including the development of processes for mandatory reporting of adverse events by healthcare facilities, and pilot of a new medical device vigilance program.

p. Increase transparency and provide greater access to adverse event information through an enhanced Database of Adverse Event Notifications (DAEN).

Strategic objective 2 – Build trust by actively engaging with our stakeholders

The TGA aims to be open and responsive to feedback about our practices and regulatory decisions. We engage regularly with our stakeholders and offer a range of mechanisms for the public, health practitioners and regulated entities to engage with us. Ongoing collaboration and engagement with experts and industry bodies has enabled the TGA to build confidence and trust in our decision-making and the globally aligned regulatory framework in which we operate. It also ensures we are responsive to risk and the latest medical and scientific developments.

Performance Indicators

2.1 Be responsive to enquiries and clear about our regulatory decisions.

2.2 Communicate effectively so that we empower consumers, health practitioners and industry to be informed about their regulatory obligations.

2.3 Engage and collaborate with stakeholders impacted by our regulatory activities.

2.4 Collaborate with domestic and international health system stakeholders to address regulatory issues and understand the impact of changing policies, practices, and services.

Our focus for 2023-24

a. Engagement with peak industry associations, state and territory health departments, professional bodies and consumer advocacy groups on regulatory policy changes and proposed improvements to regulatory practice.

b. Use a variety of communication channels, such as the TGA consultation hub, to ensure transparency of our decision-making processes.

c. Continue investment in the TGA website to improve consistency, trust, authority, and currency of information.

d. Build on our partnerships with international regulators through alliances such as Project Orbis, the Pharmaceutical Inspection Cooperation Scheme, the International Coalition of Medicines Regulatory Authorities, the International Medical Devices Regulators' Forum, and the ACCESS Consortium to strengthen working arrangements, harmonise regulatory practices, and collaborate on regulatory policies.

e. Undertake public awareness and education activities to inform consumers, health professionals, and industry about the safe and effective use of therapeutic goods so they can take appropriate action.

f. Implement 'TGA Learn' to help enterprises, researchers, start-ups and those unfamiliar with therapeutic goods regulation understand their regulatory and legislative obligations by delivering self-paced online education, structured online learning events, targeted in-person educational events, and strategic education partnerships.

g. Provide advice to developers of emerging technologies (e.g., cell and gene therapy) and devices (e.g., software apps and 3D printed devices), who are unfamiliar with regulatory requirements.

h. Enhance our engagement channels for stakeholder enquiries to better support timely responses and the provision of accurate and consistent information.

Strategic objective 3 – Promote and enforce compliance with regulatory requirements

We will promote and monitor the quality, safety, efficacy, and performance of therapeutic goods to support community confidence in these products. We aim to encourage compliance, promote leading best practice, establish trust with the regulated community and assist businesses and individuals to comply with the law. Information collected from allegations received, risk and intelligence assessments and our monitoring activities will be used to identify trends in non-compliance, prioritise our activities and allocate resources proportionate to risk.

Performance Indicators

3.1 Data and intelligence are used to identify risks of non-compliance and inform compliance strategy.

3.2 Serious non-compliance is addressed.

3.3 Product safety, quality, efficacy, and performance issues are identified and assessed proportionally with the risk being managed.

Our focus for 2023-24

a. Improve compliance with the import, manufacture, advertising, supply, and advertising requirements of the Act by undertaking education activities to help individuals and businesses understand and comply with the law.

b. Continue to deliver risk based, intelligence informed, responsive compliance and enforcement activities to ensure compliance with the import, manufacture, advertising, and supply requirements of the Act as informed by our compliance priorities.

c. Collaborate and continue to build relationships with co-regulators and other local and international health and law enforcement agencies.

d. Improve the effectiveness of our compliance activities by monitoring, reviewing, and reporting on our education, compliance, and enforcement activities and build our data analytics and operational intelligence capabilities.

e. Implement the agreed recommendations from the Australian National Audit Office (ANAO) Performance Audit on the TGA's regulatory compliance activities.

Strategic objective 4 – Innovate and continuously improve

We will aim to continuously improve our performance and make regulatory decisions in the context of impacts on the whole health system. This will include building staff capability and sustaining a culture that identifies and implements improved practices.

Performance Indicators

4.1 Continuously improve services, processes, and systems to ensure they are fit for purpose.

4.2 Continue to foster an impartial, capable, flexible, and innovative workforce.

Our focus for 2023-24

a. Deliver modern digital tools and platforms including a contemporary portal and foundational case management system to enable organisations to start preparing and submitting applications and requests online, see the status of requests/applications and benefit from pre-population.

b. Enhance the Special Access Scheme and Authorised Prescriber Online system to uplift performance, usability, and accessibility, while reducing burden on health professionals.

c. Improve the technology, systems and business processes of TGA Laboratories through the implementation of an integrated and unified laboratory software solution.

d. Drive a user-centred, evidence-based TGA website experience focused on continuous improvement to maintain a modern digital service.

e. Improve the management of medicine, vaccine, and medical device safety by increasing transparency and streamline sharing of adverse event data through improvements to the Database of Adverse Event Notifications (DAEN-medicines) and implementation of new data exchange methods that enable receipt and sharing of adverse event information with state and territory health departments and health care professionals.

f. Restore staff capacity to evaluation functions that were diverted to COVID-19 activities, to improve the quality and timeliness of submissions and reduce evaluation timeframes. Areas of focus include medical devices, In vitro diagnostics (IVDs), biologicals and new ingredients for sunscreens and complementary medicines.

Reporting

Reporting on our performance against this Business Plan will primarily include the Department's Portfolio Budget Statements and Annual Report, and the TGA Performance Report.

The TGA Performance Report will be published following the cessation of the 2023-24 financial year, consisting of both qualitative and quantitative performance data to more clearly outline how we performed as a regulator against this business plan.

In addition, we will continue to 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 and nicotine vaping products testing results
- monitoring, compliance, and investigations outcomes, and advertising compliance reports
- post-market reviews
- annual stakeholder survey
- publications detailing how we are improving access to therapeutic goods for consumers.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Regulatory Engagement Branch	1 July 2023
V1.1	Revision	Office of Deputy Secretary	26 July 2023

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