Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Therapeutic Goods Administration
Business Plan
2026-2027

Acknowledgement of Country

The Therapeutic Goods Administration proudly acknowledges the Traditional Owners and Custodians of Country throughout Australia and pays respect to those who have preserved and cared for the lands on which we live, work, and benefit from each day.

We recognise the inherent strengths and knowledge Aboriginal and Torres Strait Islander peoples provide to the health and aged care system and thank them for their existing and ongoing contributions to the wider community. We extend this gratitude to all health and aged care workers who contribute to improving health and wellbeing outcomes with, and for, First Nations peoples and communities.

We also recognise and respect Aboriginal and Torres Strait Islander people's continuing connections and relationships to the lands, waters, culture, and community, and pay respect to all Elders past and present.

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Message from the Deputy Secretary

I am pleased to present the *2026-27 Business Plan* for the Therapeutic Goods Administration (TGA). Our mission is to safeguard Australians' health and wellbeing through the best practice regulation of medicines, medical devices, blood and blood products, and biologicals. We maintain a dynamic regulatory framework that balances safety with facilitating access to new and innovative treatments as soon as possible. This document outlines our operational direction and priorities for the coming year and introduces new performance indicators for additional transparency.

The TGA operates in an increasingly complex regulatory environment. Our approach and regulations must respond to changes to how and where therapeutic products are manufactured, including at the point of care. Other key elements drive this complexity, including emerging technologies, the increasing use of artificial intelligence (AI) and the rapid flow of information, particularly online. Advancements in AI and automation present new possibilities for therapeutic goods, including in their development and how we regulate, which needs to be balanced with appropriate safeguards. We are strengthening our data governance to support our AI readiness and engaging with AI's potential as an additional tool for efficient evaluations and post-market safety surveillance.

While enabling ready access to important health knowledge, the current online environment can also facilitate and promote the spread of mis- and disinformation. We are focused on ensuring Australians have access to clear and accurate information and that stakeholders comply with their regulatory obligations. For example, we continue to see online promotion and importation of unapproved peptide products that pose significant risks to Australians' health and safety. Peptides are one of 13 priority focus areas identified in our Compliance Principles for 2026-27. We will continue to use education to empower the public, and our digital capability to raise awareness of risks and improve compliance. Where necessary we will also work with our enforcement partners to take swift and proportionate action to remove unsafe products from circulation.

The TGA will continue to play a pivotal role in national efforts to deter and disrupt the unlawful importation, manufacturing, advertising and supply of illicit vaping goods. We support a coordinated and multi-jurisdictional approach, including as a member of the Australian Border Force-led National Disruption Group. We remain focused on

strengthening our response to the illicit trade of vaping goods through strong enforcement and effective regulation.

Our program of regulatory reform remains a priority. Significant reforms and refinements to Australia's medical device regulatory framework continues to strengthen medical device lifecycle oversight and post-market monitoring. We will focus on reforms to the regulation of sunscreens to maintain consumer confidence in their quality, safety and efficacy, including our testing capabilities. Reforms to prescription medicines regulatory processes will improve efficiency and consistency as well as adapt business processes to meet high-volume demands in an increasingly complex environment. We will also examine options to reform the regulation of unapproved medicinal cannabis products. These options will focus on patient safety, strengthened sponsor responsibility and ensuring regulation remains proportionate to risk.

Our digital transformation will continue to modernise regulatory services. Over the year ahead, we will focus on replacing the current TGA business services portal (known as TBS) and onboarding TGA services to the Health Business Services Portal (HBSP). We will continue to transform manufacturing evidence management services and improve case management capabilities for staff. This work has been complex and required significant foundation building. We are now making strong progress in delivering secure, reusable, and scalable digital foundations to support business transformation across the TGA.

The TGA will continue to contribute to key international initiatives. This includes advancing regulatory harmonisation through the International Medical Device Regulators Forum (IMDRF) and strengthening regulatory cooperation through the International Pharmaceutical Regulators Programme (IPRP). We will expand regional capacity-building efforts through the Indo-Pacific Regulatory Strengthening Program (RSP) and improve efficiency through international work-sharing initiatives, including the Access Consortium, Project Orbis and the Medical Device Single Audit Program (MDSAP).

I am proud of the role the TGA plays in the global therapeutic goods regulatory community. My election as Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) reflects the TGA's strong international reputation and influence. In 2027 the TGA will assume the Chair of the Access Consortium and continue its efforts to achieve full membership of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This is in addition to our 2025 designation as a World Health Organization Listed Authority (WLA) for medicines.

Our efforts will position the TGA to respond confidently to emerging risks and future regulatory demands, while continuing to strengthen the way we operate. I thank our stakeholders and partners for their ongoing commitment, expertise and collaboration as we work together to support a robust, responsive and trusted regulatory framework for therapeutic goods.

Professor Anthony Lawler

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

Our Purpose

The TGA was established to administer the *Therapeutic Goods Act 1989* (the Act) by maintaining a national regulatory system for the safety, quality, efficacy, performance and timely availability of therapeutic goods. Our work supports the health, safety and wellbeing of all Australians and contributes significantly to the Health Protection, Emergency Response and Regulation program of the Australian Government Department of Health, Disability and Ageing (the department).

What we do

We regulate the advertising, manufacture, import, export and supply of a wide range of therapeutic goods, including:

- prescription, complementary and over-the-counter medicines
- vaccines
- blood and blood products
- cellular therapies
- biologicals
- sunscreens
- medical devices
- software and AI when intended for a therapeutic purpose.

Under 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
- monitor compliance of therapeutic goods on the market, including through laboratory testing where appropriate
- implement a range of regulatory actions that are proportionate to the risk arising from non-compliance or emerging safety concerns.

Our aim is to enhance public health outcomes through best practice regulation, build trust through active stakeholder engagement and foster innovation to address emerging regulatory challenges.

Principles

We undertake our regulatory functions in alignment with the Resource Management Guide 128 (RMG 128), which promotes the following 3 principles for regulators:[1]

- **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, 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.

[1] https://www.finance.gov.au/government/managing-commonwealth-resources/regulator-performance-rmg-128

Our Strategic Objectives

Informed by internal and external stakeholder consultation and the 3 principles of best practice regulation, our strategic objectives are:

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

Performance Indicators

The following performance indicators align with assessment, monitoring and compliance activities. All are key aspects of a national regulatory system. In the annual TGA Performance Report for 2026-27, we will report performance against targets where specified and volume-based results where no target is specified.[2]

Percentage of therapeutic goods evaluated within statutory timeframes **Target – 100%**
This indicator captures the percentage of therapeutic goods evaluations completed by the relevant statutory timeframe. It includes evaluations for prescription medicines, listed medicine ingredients, registered complementary medicines, assessed listed medicines, medical devices preliminary assessments, medical devices conformity assessments and biologicals. It is analogous to performance measure 1.8A reported in the department's Annual Report.[3] This performance indicator: • reflects the TGA's ongoing commitment to timeliness of the assessments of safety, efficacy, quality and performance over a range of therapeutic goods • provides transparency on the timeliness of evaluations held to statutory timeframes • underscores the importance of meeting statutory timeframes by highlighting a target of 100%.

Percentage of therapeutic goods evaluated within target timeframes (non-statutory) **Target – 80%**
This indicator captures the percentage of therapeutic goods evaluations completed by the relevant non-statutory, target timeframe. It includes evaluations for registered over-the-counter medicines and mandatory medical device application audits. This performance indicator: • reflects the TGA's ongoing commitment to timeliness of the assessments of safety, efficacy, quality and performance over a range of therapeutic goods • provides enhanced transparency on the timeliness of the identified non-statutory timeframes • establishes a high baseline target to reflect the TGA's commitment to timely processing.

[2] Each reporting cycle opens with a TGA Business Plan and closes with a TGA Performance Report. Available from the TGA website https://www.tga.gov.au/resources/publication/corporate-reports/performance-reports

[3] The inclusion of biologicals in this indicator is a point of difference with performance measure 1.8A.

Number of batch release assessments of vaccines by the TGA found to be compliant with required quality standards **No target**
This indicator captures all batch release assessments of vaccines by the TGA where the batch was found to be compliant with internationally recognised quality standards that are approved by the TGA. Every batch of vaccine supplied in Australia undergoes this independent quality assessment. This performance indicator: • demonstrates that vaccine quality is maintained following registration and acceptable for use in Australia • provides an example of the TGA's monitoring capabilities to ensure goods continue to meet standards while being supplied in Australia • enhances transparency and supports trend monitoring.

Number of post-market compliance actions initiated by TGA (ARTG goods) **No target**
This indicator captures compliance actions initiated by the TGA that relate to goods in the ARTG and range from education letters and warning letters through to the cancellation of ARTG entries and criminal prosecutions. There can be multiple actions related to one therapeutic good or identified issue. This performance indicator: • demonstrates the TGA takes action to promote and enforce post-market compliance with regulatory requirements for goods in the ARTG • reflects the monitoring activities by the TGA that necessarily precede compliance activities • enhances transparency through a simple, aggregated result and supports trend monitoring.

Percentage of alleged non-compliance reports relating to advertising or therapeutic goods outside of approval pathways or exemptions that have been finalised **Target – 65%**
This indicator captures compliance action related to advertising and goods that are not in the ARTG or being accessed via the alternative routes permitted under the Act. This performance indicator: • demonstrates the TGA effectively promotes and enforces post-market compliance via public-good-funded compliance measures • highlights non-compliance reports, which are a key element of the compliance response • acknowledges, through the target of 65%, the time taken to complete a compliance report appropriately varies with the case complexities.

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

We will balance the dual regulatory responsibilities of facilitating access to, and ensuring the safety, quality, performance and efficacy of, therapeutic goods. Australia's expertise in regulation is globally recognised enabling us to shape as well as respond to best practice.

Our focus for 2026-27

1A We will conduct efficient and effective pre- and post-market evaluations of therapeutic goods.

1B We will monitor and mitigate the impact of medicine shortages and discontinuations, and medical device supply disruptions to support continued patient access.

1C We will advance appropriate regulatory frameworks for therapeutic goods that are not entered in the ARTG, including closed-loop supply chains, compounding, and point-of-care manufacturing and distribution.

1D We will work to fulfil obligations to meet and maintain WLA status and leverage this recognition to strengthen reliance pathways and international collaboration.

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

We will be open and responsive to feedback about our practices and regulatory decisions. We engage regularly with our stakeholders and in a variety of ways.

Our focus for 2026-27

2A We will enhance engagement and collaboration with domestic and international regulators, enforcement agencies, digital platforms and knowledge partners including scientific and academic institutions, to improve regulatory efficiency, strengthen intelligence-sharing and reporting of safety issues, harmonise practices, and proactively address compliance risks.

2B We will provide clear information including comprehensive education and public awareness programs about regulatory obligations and the safe use of therapeutic goods, including targeted approaches to address health mis- and disinformation, to support the public, health practitioners, academia and industry.

2C We will partner with regulatory authorities and health authorities across the Pacific and South-East Asia through the RSP to strengthen regulatory systems, improve access to quality-assured medicines, and contribute to improved public health outcomes throughout the region.

2D We will respond promptly to requests for information from the public.

Strategic Objective 3 – Promote and enforce compliance with regulatory requirements

We will promote and enforce compliance with regulatory requirements in a risk-based manner. We will use information collected from risk and intelligence assessments, allegations, and our monitoring activities to identify trends in non-compliance, prioritise our activities and allocate resources proportionate to risk.

Our focus for 2026-27

3A We will undertake compliance monitoring of therapeutic goods, their sponsors and manufacturers based on assessed risks.

3B We will strengthen proactive compliance and disruption capabilities, focusing on high-risk products, entities and digital supply pathways.

3C We will respond to safety, quality, performance and compliance issues based on assessed risks.

3D We will continue to administer the vaping reforms through regulation, compliance and enforcement activities that deter and disrupt unlawful activity and preserve access to therapeutic vapes where clinically appropriate.

Strategic Objective 4 – Innovate and continuously improve

We will continuously improve our performance by optimising regulatory pathways, reforming business processes and strengthening the capability needed to capture future regulatory opportunities whilst anticipating and responding to challenges.

Our focus for 2026-27

4A We will optimise regulatory pathways, reform business processes, and promote regulatory efficiency, including through international work-sharing and reliance mechanisms.

4B We will maintain staffing excellence by strengthening the TGA's diverse regulatory, scientific and technical expertise, and by building the capability needed to respond to future regulatory challenges.

4C We will progress digital transformation to modernise regulatory services, improve user experience and equip the TGA with better digital platforms, data and tools to support efficient, risk-based regulation.

4D We will ensure financial sustainability through the ongoing enhancement of the TGA's funding models and efficient delivery of its regulatory activities, where the cost to deliver aligns with revenue derived from cost recovery or appropriated by government.

4E We will enhance the TGA's capability to identify and effectively regulate emerging technologies across all therapeutic goods.

Reporting

The TGA contributes to the department's reporting obligations under *the Public Governance, Performance and Accountability Act 2013* through the department's Corporate Plan, Annual Report and Portfolio Budget Statements.

While this TGA Business Plan complements these documents, it can also be read as a stand-alone document. The corresponding TGA Performance Report will be published at the conclusion of the 2026-27 reporting period and will detail how we performed against the performance indicators and focus areas outlined above.

We will also continue to publish a range of performance information on the TGA website[4] including:

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

[4] https://www.tga.gov.au/