Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Therapeutic Goods Administration

Performance Report 2024-25

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 and work, and benefit from each day. We recognise the strengths and knowledge Aboriginal and Torres Strait Islander peoples provide to our health, disability and aged care systems and thank them for their ongoing contributions to those systems and the wider community. We extend this gratitude to all health, disability and aged care workers who contribute to improving health and wellbeing outcomes with, and for, First Nations peoples and communities.

Table of contents

Copyright

Message from the Deputy Secretary

I am pleased to present the 2024-25 Performance Report for the Therapeutic Goods Administration (TGA). As stewards of our national regulatory system for therapeutic goods, our mission is to safeguard Australians' health and wellbeing through best practice regulation.

This report demonstrates our commitment to best practice regulation, continuous innovation, risk management, and stakeholder engagement. We continue to streamline and strengthen our regulatory practices, adapting to emerging challenges and opportunities. This report also reflects our dedication to maintaining a transparent, evidence-based regulatory system that applies a risk-based approach and aligns with national and international standards.

A snapshot of key outputs in 2024-25 indicates an incredibly busy year, particularly when compared to the previous year:

- **Prescription medicines**- 4,164 submissions approved, increased from 4,112
- **Over the counter (OTC) medicines**- 237 new applications and 647 variation applications completed, increased from 102 and 521 respectively
- **Listed medicines**- 2,143 new products added, increased from 1,854
- **Medical devices**- 6,068 inclusion applications completed, increased from 5,032
- **Medical device change requests (DCR) and variations**- 1,271 applications completed, increased from 1,034, and
- **Good Manufacturing Practice (GMP) clearances**- 9,575 applications completed, increased from 9,542.

Our strengthened regulatory compliance functions, with improved intelligence and governance processes, help us to anticipate and respond to emerging regulatory challenges. Our expanded partnerships enable us to address non-compliance issues more swiftly and effectively.

We further advanced the implementation of the vaping regulatory reforms. These focused on improving access to therapeutic vapes for nicotine dependence, strengthening product standards for vaping devices and substances, and enhancing our associated IT systems and educational resources. We continued to contribute to national efforts to tackle illegal vaping goods, supported by strong enforcement partnerships and a new framework.

In March 2025, we launched the Australian Unique Device Identification (UDI) system. The culmination of over 4 years of work, this important milestone of the Action Plan for Medical Devices strengthens post-market surveillance and improves patient safety. The enhanced monitoring and traceability of medical devices reflects our commitment to building a more transparent and responsive, and safer, regulatory environment.

As part of a review of how Attention-Deficit/Hyperactivity Disorder (ADHD) medications are prescribed across Australia, we held collaborative discussions with health professional peak bodies and Chief Health Officers from all states and territories. The rise in prescription of ADHD medications, and the variability across jurisdictions of the rules governing prescribing, highlight the need for reform. These discussions were critical in establishing a nationally consistent approach that balances access, safety and the risk of misuse. It was encouraging to see the Joint Health and Mental Health Ministers agree to discuss options for national harmonisation at their meeting in June 2025.

As mis- and disinformation become more prevalent both locally and globally, we are strengthening our role and reputation as a trustworthy source of accurate and reliable information on therapeutic goods. It is no accident that themes of education and communication feature prominently throughout this report. We delivered targeted initiatives to support public understanding of the safe use of therapeutic goods, including educational resources for vaping regulation reforms, public consultations on medicinal cannabis safety, and communication campaigns on paracetamol pack sizes, complementary medicines and unapproved therapeutic goods.

We have also been active in demonstrating the strongly positive risk/benefit ratio of our approved and recommended vaccines. This has included by presenting information on the evidence and our processes in response to public enquiry and at Senate Estimates and issuing statements in my role as Commonwealth Chief Medical Officer. These initiatives demonstrate our proactive role in public health education and effective risk communication.

There is strong and growing interest in the application of Artificial Intelligence (AI) in health settings. Over the course of 2024-25, we reviewed the legislative framework for the use of AI in medical software. While extensive consultation with key stakeholders found that the TGA's existing framework for AI is broadly suitable, we identified opportunities for improvement and will deliver a work plan targeting 5 priorities areas in 2025-26.

Looking ahead, the TGA remains focused on progressing our reform program, including for medical devices and medicines, and responding proportionately to emerging technologies and innovations. Working closely with our national and international partners, our collective goal is to provide patients with safe, effective and high quality medical products. We are steadfast in our commitment to continuously improving all elements of our regulatory environment to improve public health outcomes.

The TGA will continue to maintain its strategic focus on international engagement with the aim of harmonising regulation and facilitating global information and work-sharing arrangements. The TGA contributes to a range of international regulatory networks with similar values and approaches to decision making.

In a significant step forward for the TGA's leadership in international regulation, in December 2025 we achieved WHO-Listed Authority designation. This will be detailed further in the 2025-26 Performance Report.

The TGA continues to participate in several international fora including the International Medical Device Regulators Forum, the Pharmaceutical Inspection Convention/Cooperation Scheme, and the International Pharmaceutical Regulators Programme. I was also recently elected Chair of the International Coalition of Medicines Regulatory Authorities, again indicating the global leadership role of the TGA. We support regulatory capability uplift across the region through the Regulatory Strengthening Program and the Pacific Medicines Testing Program, funded by the Department of Foreign Affairs and Trade (DFAT).

On behalf of the TGA, I thank our stakeholders for their continued engagement, expertise and support. We will continue to build on the achievements, lessons and momentum of 2024-25 as we strengthen our regulatory frameworks, safeguard public health, adapt to emerging challenges, and manage risk on behalf of the Australian public. Together, we are shaping a more responsive, transparent and effective therapeutics regulatory system for all Australians.

Professor Anthony Lawler

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

Our purpose and strategic intent

The TGA was established to administer the *Therapeutic Goods Act 1989* (the Act), and regulates the safety, quality and performance of therapeutic goods to protect the health, safety and wellbeing of all Australians. Our work contributes significantly to the Health Protection, Emergency Response and Regulation program of the Australian Government Department of Health, Disability and Ageing (the department).

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

- prescription, complementary and OTC medicines
- vaccines
- blood and blood products
- cellular therapies
- biologicals
- sunscreens
- medical devices, and
- software used as a medical device, including AI where relevant.

Under the Act, we:

- apply scientific and clinical expertise to assess whether the benefits of a therapeutic good outweigh relevant risks to health and safety
- assess the suitability of therapeutic goods for supply, import to 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, and
- implement a range of regulatory actions that are proportionate to the potential risk arising from non-compliance or emerging safety concerns.

To enhance public health outcomes through best practice regulation, we undertake our regulatory functions in alignment with the principles of the Department of Finance's Resource Management Guide 128 (RMG 128):

- **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.

Our vision

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

Our strategic objectives

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

- Improve public health outcomes through best practice regulation
- Build trust by actively engaging with our stakeholders and the community
- Promote and enforce compliance with regulatory requirements
- Innovate and continuously improve.

Structure of this report

This report details TGA's performance across the 31 focus areas within our 4 strategic objectives, as outlined in the *TGA Business Plan 2024-25*.

Each strategic objective is supported by guiding principles, which underpin our activities and achievements.

The Appendices of this report include detailed performance statistics for the period from 1 July 2024 to 30 June 2025, by product theme and work program. This report also includes insights from the *TGA Stakeholder Survey Report 2025*.

Given the breadth and volume of work undertaken in the 2024-25 financial year, it is not practical to mention all of the TGA's activities and achievements in this report. We provide regular updates throughout the year via various platforms, including the TGA website, email newsletters, social media posts, events, webinars and stakeholder fora.

For further context, we refer readers to related documents that complement this report:

- TGA Business Plan 2024-25
- TGA Stakeholder Survey 2025
- TGA International Engagement Strategy 2021-2025.

Strategic objective 1
Improve public health outcomes through best practice regulation

The TGA applies its globally recognised expertise to regulate therapeutic goods for improved public health outcomes for Australians. In maintaining best practice regulation domestically, and in shaping and responding to international best practice, we help Australians to stay healthy and safe. We continue to reform and improve our regulatory systems, pathways and processes to benefit all stakeholders.

Guiding Principles

1.1 Ensure product approvals and regulatory assessments are delivered in accordance with both statutory timeframes and non-statutory targets, to maintain trust and reliability and to ensure timely access to innovative therapies and emerging technologies.

1.2 Adapt regulatory approaches where necessary, to facilitate expedited access to critical therapies and technologies in response to public health need.

1.3 Propose and support the design of regulatory reforms based on evidence of value and benefit, or appropriate risk management, to ensure regulatory frameworks remain fit-for-purpose.

Insights from the TGA Stakeholder Survey

The TGA endeavours to strike the right balance between safety and access to therapeutic goods. The TGA Stakeholder Survey 2025[1] asked whether we get this balance right. Almost two thirds of all respondents agreed we "get the balance right between safety for consumers and access to products". This was an increase of 4% among consumers from the 2024 survey.[2]

Part of getting the regulatory balance right is monitoring and enforcing compliance with the laws that regulate therapeutic goods in Australia. Of all stakeholders, 73% believed the TGA responds effectively to serious, deliberate and repeated non-compliance. Approximately three quarters also agreed that the TGA takes appropriate action where a safety issue is identified in relation to medicines and medical devices, an increase from 2024.

Overall, approximately 73% of stakeholders agreed that the TGA regulates prescription medicines and medical devices appropriately.[3]

Vaping reforms

1a- Implement Australian Government reforms to the regulation of vaping goods, including legislative design, system development, and education and enforcement activities to ensure compliance

In 2024-25, we continued the staged rollout of vaping regulation reforms in Australia. Additional measures supported public health outcomes by accommodating a range of options for accessing therapeutic vaping goods for smoking cessation and nicotine dependence. We enhanced our IT platforms and educational resources to support the reforms and assist sponsors in meeting new requirements, demonstrating the TGA's commitment to reforms based on evidence and appropriate risk management.

---

[1] The TGA Stakeholder Survey captures input from consumers, industry representatives, and government officials, providing actionable insights that inform enhancements to regulatory frameworks, services, and stakeholder engagement.

[2] Available at: www.tga.gov.au/resources/publication/corporate-reports/tga-stakeholder-survey-report-2025 ; page 8.

[3] Ibid: page 4.

Access to therapeutic vapes

Australians aged 18 and over gained improved access to therapeutic vapes containing nicotine concentrations of 20 mg/mL or less, following regulatory changes that reclassified these products as Pharmacist Only Medicines (Schedule 3). These vapes may be obtained from pharmacies without a prescription, specifically for smoking cessation or the management of nicotine dependence. Pharmacies retained discretion over whether to stock or supply these products.

Access is facilitated through the Special Access Scheme (SAS) Category C pathway. From the implementation of these changes on 1 October 2024 to the end of the reporting period, 56,734 Schedule 3 SAS C notifications were submitted to the TGA. Pharmacists are required to submit notifications to the TGA within 28 days of supply.

Enhanced legislation, system and enforcement

To enhance public health and safety, the Australian Government undertook comprehensive reforms to regulate vaping goods through coordinated legislative, system and enforcement measures. These reforms were enacted through the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*, and several supporting regulations and other legislative instruments. Most reform measures commenced in July and October 2024, and were implemented in partnership with states and territory agencies and the Australian Border Force (ABF) throughout 2024 and 2025.

The TGA strengthened product standards, including the Therapeutic Goods (Medical Device Standard-Therapeutic Vaping Devices) Order 2023, to better support the quality and safety requirements for therapeutic vaping goods, including accessories. Key changes included plain design and packaging, details on labelling and instructions for use, risk management initiatives, and stricter technical product requirements.

The TGA established a robust regulatory framework, including new licensing arrangements, import controls and expanded enforcement powers. These systems enable targeted investigations, seizure of unlawful products, and improved information sharing across jurisdictions.

Enforcement activities prioritised compliance through expanded investigation authority, application of civil and criminal penalties, and a strict ban on advertising unless specifically authorised. Flavour restrictions on therapeutic vapes further supported reform objectives.

The TGA completed 801 investigations into suspected unlawful vaping goods advertising.

Throughout 2024-25, the TGA actively disrupted and responded to the illegal importation, advertising and supply of nicotine vapes by:

- collecting and using intelligence to identify instances of non-compliance
- working in partnership with law enforcement and other health agencies to share information and intelligence, with a growing focus on targeting unlawful distribution and supply, and
- enforcing measures against illegal advertising of vaping goods to Australians.

The TGA completed 801 investigations into suspected unlawful vaping goods advertising, and 566 investigations into suspected unlawful supply of vaping goods. Increased collaboration with the states and territories resulted in 26 multi-agency activities, implementing a range of enforcement actions:

- sending educational letters to food delivery services and social media platforms to inform them of the updated regulations and laws

- making legal requests to internet service providers (ISP) to block access to unlawful websites suspected of advertising vaping goods illegally, and
- removing prohibited advertising posts from social media and online marketplace platforms.

IT platform and education enhancement

We continued to enhance our IT platforms, helping sponsors to comply with the new vaping requirements. This included a new sponsor notification form, updates to the consent to supply system, and sponsor-focussed education activities, such as webinars to promote compliance and improve understanding of regulatory requirements.

We also delivered comprehensive guidance materials and web content to help existing and prospective sponsors to navigate regulatory processes. These resources promote transparency and consistency and align with the guiding principle of adapting regulatory approaches in response to public health need.

We also engaged directly with sponsors to communicate regulatory obligations and conducted product reviews of therapeutic vaping goods to monitor the compliance.

Medicines repurposing

1b- Identify and evaluate potential new uses for older medicines through research and evidence, leveraging insights from the Medicines Repurposing Program's initial implementation phase

The Medicines Repurposing Program encourages industry to explore new therapeutic uses for existing medicines. The Program commenced on 1 March 2024 and is scheduled to run until 30 June 2027. It offers fee waivers for regulatory applications seeking extensions of indications and, where possible, Pharmaceutical Benefits Advisory Committee consideration of Pharmaceutical Benefit Scheme listing.[4]

We continue to receive and assess possible repurposing opportunities from clinicians, medical researchers, patient groups and pharmaceutical companies.

Program refinement and review

Using lessons learned from the first 6 months of operation and stakeholder feedback, we have refined and enhanced the program over 2024-25. Changes to strengthen eligibility criteria and improve the quality of nominations received include pre-nomination meetings, updates to the nomination form, and the requirement for upfront sponsor engagement.

The TGA will commence an evaluation of the program in 2025-26, working closely with stakeholders to assess its effectiveness, identify ongoing challenges, and explore opportunities for future program design.

[4] Pharmaceutical Benefits Advisory Committee and the Pharmaceutical Benefit Scheme are managed in areas of the department outside of the TGA.

Reforms to recall processes

1c- Continue the implementation of reforms to improve recall processes for all therapeutic goods

In 2024-25, the TGA delivered the second and final package of key reforms to the conduct of recalls and other market actions in Australia.

These reforms reduce the regulatory burden for sponsors while maintaining our strong emphasis on public safety. They include a simplified and more flexible reporting process, increased stakeholder communication, and improvements to our documentation and guidance.

In March 2025, our new Procedure for Recalls, Product Alerts and Product Corrections (PRAC)[5] officially replaced the longstanding Uniform Recall Procedure for Therapeutic Goods. Our publicly facing database, the System for Australian Recall Actions (SARA), was updated and renamed the Database for Recalls, Product Alerts and Product Corrections (DRAC).[6]

Drawing on several years of targeted and public consultations, the TGA implemented a comprehensive package of reforms informed by stakeholder feedback. These reforms modernise and simplify regulatory processes, improve digital functionality, enhance sponsor guidance and strengthen communication with stakeholders. The major reform initiatives are grouped under the themes of process, IT platform, guidance, and stakeholder communication.

Process

- Replaced the previous categories of 'recall' and 'non-recall' actions with the single, unified category of 'market actions', reducing confusion and improving clarity
- Streamlined the recall process from 10 steps to 5, making it easier to navigate while maintaining the integrity of the original framework
- Strengthened specific process steps for actions that may result in shortages or supply disruptions, or require extended timeframes, with greater transparency around these requirements

IT platform

- Enhanced the functionality of our internal and external facing IT systems by:
  - introducing new fields and search capabilities to improve usability, and
  - removing outdated or unnecessary requirements to streamline the submission and assessment processes

Guidance

- Condensed and clarified guidance materials to support easier compliance
- Presented information visually using tables and graphics, with alternate text to ensure accessibility for screen readers
- Developed Help Guides, hover text, and embedded guidance to assist sponsors in navigating the online notification system, and improve timeliness and trust in our systems

---

[5] Available at: www.tga.gov.au/safety/recalls-and-other-market-actions/procedure-recalls-product-alerts-and-product-corrections-prac

[6] Available at: https://apps.tga.gov.au/PROD/DRAC/arn-entry.aspx

While our recall reforms are largely complete, our commitment to continuous improvement remains. We are currently preparing additional guidance for sponsors on our legislation and the regulatory framework relating to market actions. This follows a substantial legislative review and will be published on the TGA website once completed.

Evaluations and post-market safety and performance

1d- Prioritise evaluations and post-market safety and performance monitoring of new products, including developing an Australian Sunscreen Exposure Model for sunscreen ingredient safety evaluation

The TGA safeguards the use of therapeutic goods in relation to their safety, quality, and efficacy or performance. Risk-based evaluations[7], assessments and monitoring processes are conducted throughout all stages of a therapeutic good's entry to and presence on the Australian market. The more complex or higher the risk profile, the more rigorous these processes.

After a therapeutic good enters the market, the TGA remains alert to post-market signals and concerns relating to safety, quality, and efficacy or performance.

Detailed statistics on the types and volumes of evaluations, assessments and post-market monitoring actions undertaken during 2024-25 are available in the Appendices of this report.

Risk-based laboratory testing of therapeutic goods

TGA laboratories continued to undertake market authorisation assessment of therapeutic goods, as well as post-market monitoring and compliance testing, investigations, and reviews. Consistent with *ISO 31000: Risk Management principles and guidelines,* we prioritise products with a higher risk of not complying with the required quality standards.

In 2024-25, the TGA tested 1,662 samples. The effectiveness of our risk-based, targeted approach to testing is reflected in a failure rate of only 31% across all product types. This outcome demonstrates the important role the TGA plays in ensuring the quality of therapeutic goods available to the Australian public.

Sunscreen Safety and Efficacy

In 2023-24, we developed the *Australian Sunscreen Exposure Model (ASEM)*[8] to enhance our ability to assess the safety of sunscreen ingredients based on local usage patterns in the Australian context.

[7] Where relevant, noting that some lower-risk therapeutic goods are entered in the ARTG on the basis of certifications made by the sponsor of the goods, rather than comprehensive pre-market evaluation.
[8] Available at: https://www.tga.gov.au/resources/publication/corporate-reports/australian-sunscreen-exposure-model

During the 2024-25 reporting period, the TGA consulted a diverse range of stakeholders to refine the model. The ASEM was adopted in January 2025 and will play a key role in the TGA's safety assessment of common and new sunscreen ingredients. The model allows the TGA to determine safe concentrations of sunscreen ingredients based on Australian conditions and the latest scientific data, rather than relying solely on international models.

This more accurate estimate of regular sunscreen exposure for Australians promotes consistent evaluation supported by predictive data analytics to assess risk. As well as enhancing public confidence in sunscreen safety, it provides certainty for industry applicants of new sunscreen ingredients by improving the transparency of the evaluation process and supporting innovation.

The TGA conducted a safety review for 7 active ingredients in therapeutic sunscreens.

The TGA conducted a safety review for 7 active ingredients in therapeutic sunscreens, drawing on national and international safety assessment reports and peer-reviewed publications on ingredient safety and toxicokinetics.

These ingredients were prioritised for review due to the availability of nonclinical safety data to the TGA, their reported use in a higher number of sunscreen products marketed in Australia, and safety signals reported overseas. The review, *Literature search and summaries of seven sunscreen active ingredients*[9], was published in February 2025.

Based on the review, the TGA advised on updated regulatory controls for homosalate, oxybenzone and the degradant benzophenone, to restrict their permitted concentrations and use in therapeutic sunscreens. Decisions on the recommended controls are expected in 2026.

On 1 July 2024, the *Australian/New Zealand Standard: Sunscreen products- Evaluation and classification (AS/NZS 2604:2021)* was adopted in Therapeutic Goods legislation. The standard includes the latest International Organization for Standardization (ISO) testing methods and new label requirements for aerosol sunscreens, to support their safe and effective use.

This adoption follows extensive consultation and aligns domestic regulatory requirements with international sunscreen testing methodology. All new sunscreens must comply with the new standard, and transitional arrangements are in place for products included in the Australian Register of Therapeutic Goods (ARTG) prior to 1 July 2024.

Signal assessment of medicines

The TGA implemented a new signal assessment and prioritisation (SAP) process for medicine surveillance. This supports prompt review of signals for new and established products, and timely recommendations for regulatory action. Under the new SAP process, more in-depth evaluations could be conducted for signals requiring detailed critical appraisal of clinical evidence.

During 2024-25, we conducted rapid reviews to clear a backlog of 242 historical signals, while contemporaneously completing 321 SAPs and 27 detailed signal evaluations.

The Advisory Committee on Medicines provided expert advice on high-profile signals, including Privigen AU (increased adverse events) and glucagon-like peptide1 receptor agonists (GLP-1 RA) (suicidal ideation), resulting in enhanced monitoring and published statements to raise awareness among healthcare professionals and consumers.

[9] Available at: https://www.tga.gov.au/resources/publication/corporate-reports/literature-search-and-summaries-seven-sunscreen-active-ingredients

Strengthening pharmacovigilance and vaccine evaluation

The TGA expanded pharmacovigilance activities to reflect changes in vaccination programs across Australia and ensure comprehensive monitoring of vaccine safety. This included for the respiratory syncytial virus (RSV) vaccine Abrysvo for pregnant women, listed on the National Immunisation Program, and the RSV monoclonal antibody Beyfortus, available through state and territory-based programs. Our coordinated approach enabled timely detection of safety signals and the implementation of appropriate regulatory actions, helping to maintain public confidence in these critical therapeutic products.

Post-market reviews and investigations of medical devices

The TGA continued its risk-based approach to prioritising post-market reviews and investigations of medical devices, including proactive and reactive surveillance activities:

- horizon scanning for new and emerging safety signals
- monitoring high-risk medical devices newly included in the ARTG through annual reporting requirements and reviewing compliance with conditions of ARTG inclusion
- investigating device incident reports, and
- conducting post-market reviews of medical device types where a safety or performance issue has been identified.

Contributing to International Standards

The TGA represents Australia on several ISO working groups and committees strengthening and amending the relevant international standards. Our participation ensures issues identified through our post-market review process are shared and addressed globally. In December 2024, as the convenor of the ISO working group for breast implants, we led the delivery of updated global standards addressing an increased range of safety and performance attributes, safeguarding future use of breast implants.

Closed-loop supply chains, compounding, and access to unapproved goods

1e- Review and improve the regulation of closed-loop supply chains, compounding of therapeutic goods, and the access to unapproved goods

The TGA is enhancing access pathways for unapproved therapeutic goods, ensuring that regulatory oversight remains robust while supporting timely access to necessary treatments. The SAS and the Authorised Prescriber (AP) scheme are addressed in Section 4b.

Closed-loop supply chains and compounding

The TGA is actively reviewing and strengthening the regulation of closed-loop supply chains and the compounding of therapeutic goods, particularly in response to emerging public health concerns.

This includes addressing risks associated with large-scale pharmacy compounding of medicines such as GLP-1 RAs, a relatively new and high-profile classes of medicines that are used to treat type 2 diabetes mellitus and/or obesity.

Our regulation of therapeutic goods has clear and crucial overlap with the regulation of health services and health professionals. These are the responsibilities of other bodies both within and outside the department, and we work closely with these other regulators.

The Personal Importation Scheme

The Personal Importation (PI) Scheme provides a pathway for consumers to import unregistered therapeutic goods for personal or family use, if certain conditions are met. Throughout 2024-25, the TGA prioritised the review of referrals from the ABF for medicines subject to domestic shortage. Our approach supported timely access to critical medicines through an expedited assessment process. The TGA remains committed to exploring and implementing alternative approaches for products affected by domestic shortages, so it can ensure timely release of products to the consumer, where appropriate.

Shortages and supply disruptions

1f- Report and manage medicine shortages and medical device supply disruptions to support continued patient access to important therapeutic goods

Shortages of medicines and supply disruptions of medical devices present ongoing challenges for healthcare professionals, services and consumers across Australia. The TGA works with key stakeholders to anticipate and manage these issues promptly to minimise their impact on Australians' access to therapeutic goods.

Managing medicine shortages

The TGA continued to implement management actions and strategies to address shortages of important medicines and reduce the impact on patients and healthcare professionals. These actions included:

- approving overseas-registered alternatives to supply under Section 19A of the Act
- implementing Serious Scarcity Substitution Instruments (SSSIs), enabling pharmacists to dispense certain substitute medicines without the need for a new prescription, and

- publishing web statements and alerts on the TGA website to provide timely updated information and guidance on numerous medicine shortages for patients and healthcare professionals.

We worked closely with key stakeholder groups, including pharmaceutical companies, health professionals, jurisdictional authorities and stakeholder organisations. We monitored and responded to medicine shortages collaboratively, by:

- convening Medicine Shortages Action Groups to work with medical colleges and health professional groups on the management of significant medicine shortages, and to develop advice for the healthcare professionals assisting affected patients
- chairing the monthly Medicine Availability Working Group (MAWG), comprising representatives from state and territory health departments and expert advisers, to discuss medicines of concern and provide expertise on supply and demand forecasting
- working with pharmaceutical companies to increase supply or expedite delivery timelines where possible, and
- collaborating with wholesalers to prevent stockpiling and allow fair access for all patients.

The TGA strengthened its data analysis and modelling capabilities to assist with forecasting future availability and potential supply gaps for important medicines, including throughout the intravenous (IV) fluid shortage.

Case Study- The IV fluid shortage

IV fluids are essential medicines used in hospitals for routine and critical care. They are crucial for fluid replacement, resuscitation and administering other medications directly into the bloodstream.

Across 2024-25, Australia experienced shortages of multiple IV fluid products from all 3 Australian suppliers- Baxter Healthcare, B. Braun and Fresenius Kabi.

The shortages particularly affected multiple bag sizes of Sodium Chloride 0.9% (saline) and Compound Sodium Lactate products.

Several factors contributed to the IV fluid shortages, including global supply limitations, unexpected increases in demand and manufacturing issues.

To improve supply, the TGA approved multiple overseas-registered alternative saline fluids under Section 19A of the Act.

In August 2024, a National IV Fluid Response Group was formed, comprising state and territory health representatives, private hospitals, the Australian Medical Association, the Australian and New Zealand College of Anaesthetists and the Australian Veterinary Association. The Group worked collaboratively on IV fluid supply issues to coordinate a national response. The TGA was an integral part of the National IV Fluid Response Group.

During the shortage period, the TGA worked collaboratively with state and territory health departments through the MAWG, as well as with suppliers of Australian and overseas-registered IV fluids. Drawing on the expertise in the MAWG, we were able to forecast future availability of IV fluids and identify supply gaps using data provided by sponsors.

IV fluid supply modelling was conducted using the Dynamic Model of Medicine Availability (the Model) developed by the then Department of Health and Aged Care. The Model offers an overview of current and future medicine availability based on various assumptions and demand data.

While the Model's outputs serve as early-warning signals of potential supply gaps, modelling is limited to those IV fluid presentations where we have received complete datasets.

Over the shortage period, the TGA conducted quarterly rounds of modelling to inform recommendations on management strategies.

We shared the outcomes of this modelling with the MAWG and the IV Fluid Response Group to develop updated recommendations and strategies to assist with managing supply during this period. The TGA continues to collaborate with jurisdictional health departments and suppliers of Australian-registered IV fluid products to monitor the situation and address any regulatory barriers to supply.

Improvements to medicine shortage and discontinuation management

The TGA continues to improve how it monitors and reduces the impact of medicines shortages and discontinuations in Australia. Consumers and health professionals need access to timely and accurate information about medicine shortages and discontinuations to effectively plan and manage their response to a supply disruption. To address high priority issues identified in this space, we are pursuing a program of regulatory, digital and process improvements.

In 2024-25 we focussed on updating the medicine shortages regulatory framework to better meet public information needs. We consulted on and updated the legislative instrument that requires sponsors of specific non-prescription medicines to report any shortages or discontinuations of these medicines. Taking effect in March 2025, this update added 25 essential non-prescription medicines important for consumer health.

In late 2024, we also consulted on 2 proposals to update the Act, to:

- enable the TGA to require detailed supply information from sponsors of any medicines on the ARTG, and
- require sponsors to provide 12 months' notice to the TGA of a decision to permanently discontinue supply of any reportable medicine in Australia.

The TGA is continuing to progress these legislative amendments.

Managing medical device supply disruptions

The TGA engages proactively with sponsors, state and territory health departments, and international regulatory counterparts to monitor emerging signals of medical device supply disruptions. This collaborative approach enables the TGA to identify and help manage potential risks effectively, ensuring timely advice on alternative devices to respond to supply disruptions.

In 2024-25, the TGA received 35 notifications of potential medical device supply disruptions. Of these, we successfully resolved 14, with the remainder subject to ongoing investigation or monitoring. Several disruptions were linked to delays arising from global regulatory changes that impacted the availability of such devices in Australia.

Through consistent communication with key stakeholders, the TGA facilitated sharing of critical information and coordinated actions to mitigate the impact of supply issues on patient access to essential medical devices.

Medical devices adverse event reporting

1g- Implement enhancements to medical device adverse event reporting, including developing processes for mandatory reporting by healthcare facilities and managing relevant programs, while enhancing the Database of Adverse Event Notifications to increase transparency and provide greater access to adverse event information

Following the Australian Government's amendments to the Therapeutic Goods (Medical Devices) Regulations 2002, we started implementing mandatory reporting requirements for healthcare facilities to report adverse events involving medical devices to the TGA. From March 2026, public, private and day hospitals across Australia will commence submitting reports on adverse events involving Class III medical devices and Class 4 *in vitro* diagnostic (IVD) medical devices. From 1 April 2028, mandatory reporting of adverse events involving Class IIa and IIb medical devices and Class 3 IVD medical devices will commence.

The implementation has been informed by a steering committee and a technical working group, which provided guidance on the development of data fields and data transfer mechanisms. This ensured a consistent and harmonised approach to data collection nationwide.

The TGA is also working with the Australian Commission on Safety and Quality in Health Care to update the third edition of the National Safety and Quality Health Service Standards to include reporting of medical device adverse events as an accreditation requirement for health care facilities.

We launched the Adverse Signal Detection and Event Reporting solution.

In June 2025, the TGA launched the Adverse Signal Detection and Event Reporting (ASDER) IT solution. This platform supports the systematic collection of adverse event data, enabling the use of data analytics to detect emerging safety signals, providing timely feedback to system users.

Members of the technical working group participated in user testing to familiarise themselves with the reporting processes and ensure readiness for implementation. ASDER establishes a foundational capability that will be progressively enhanced as part of the TGA's broader digital transformation agenda.

During 2025, healthcare facilities worked with the TGA to build awareness of the new regulatory requirements, undertake necessary staff training, and upgrade IT systems to support improved interoperability. This transition phase was critical to ensuring a smooth and effective rollout of mandatory reporting across the healthcare sector.

Unapproved therapeutic goods authorised by healthcare professionals

1h- Reform regulatory frameworks and guidelines to facilitate domestic manufacture, importation, prescribing and distribution of unapproved therapeutic goods by authorised healthcare professionals

In line with our commitment to regulatory reform, the TGA is modernising frameworks and guidelines to better support the domestic manufacture, importation, prescribing and distribution of unapproved therapeutic goods by authorised healthcare professionals. We streamline processes, reduce administrative burden, and ensure that patients and health practitioners can access critical treatments in a timely and safe manner, where approved alternatives are unavailable.

Our reforms related to accessing therapeutic vapes, which are unapproved products, are detailed under Section 1a.

The AP Scheme and the SAS, allowing certain registered health practitioners to access unapproved therapeutic goods for patients under their care, are detailed under Section 4b.

The TGA recognised growing concerns regarding unapproved medicinal cannabis products, including the effectiveness of regulatory oversight, and the quality and safety controls of both domestically manufactured and imported products. In 2024-25, the TGA initiated a consultation process to explore reform options, to better understand and address these safety and regulatory concerns. We will progress this and associated reform development in 2025-26.

Therapeutic Goods Orders

1i- Integrate updated quality standards via Therapeutic Goods Orders to support manufacturers and suppliers of unapproved products

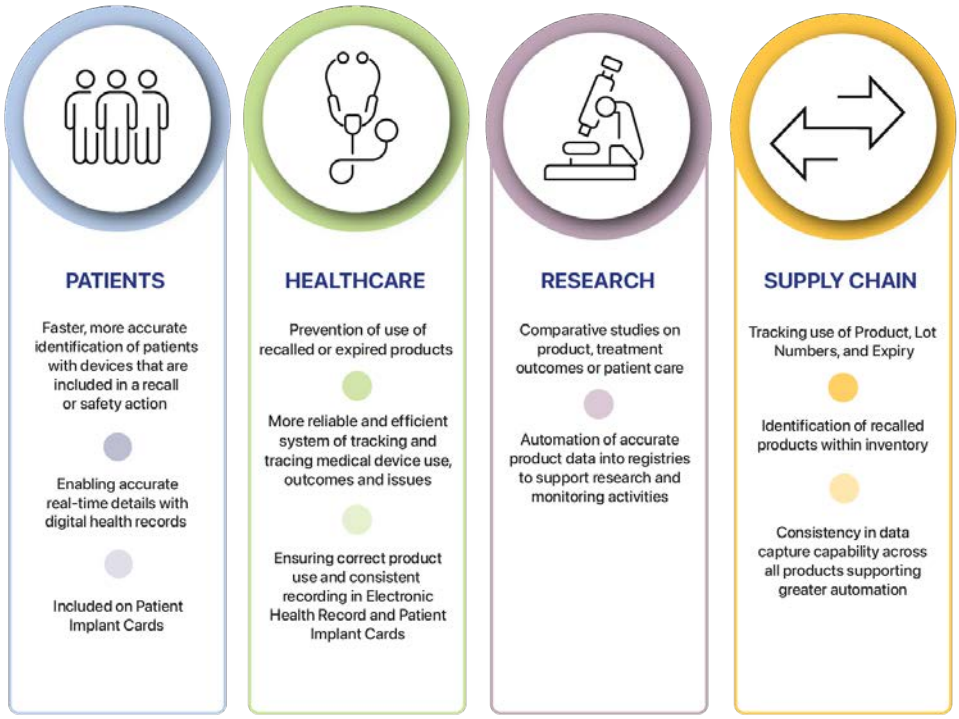
The TGA integrates updated quality standards by revising relevant Therapeutic Goods Orders (TGOs). TGOs are essential to maintaining the safety, efficacy and quality of unapproved therapeutic goods. These updates support manufacturers and suppliers by providing clear, contemporary benchmarks for compliance. They help to ensure that unapproved products meet rigorous standards that are comparable to those expected of approved therapeutic goods.

In August 2024, following targeted stakeholder engagement and public consultation, the TGA established quality standards in TGOs for methylenedioxymethamphetamine (MDMA) (TGO 112) and psilocybine (TGO 113), under Section 10 of the Act. These commenced on 6 January 2025, allowing manufacturers and testing laboratories to develop and validate methods to test the active pharmaceutical ingredients (API) and finished products.

Digital transformation for medical devices

1j- Enhance digital transformation initiatives for medical devices to advance product safety and surveillance in the Australian supply chain, aligning with global standards

In March 2025, the Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025 was introduced. This was a key milestone in establishing the UDI System, establishing the Australian UDI Database and requirements for the inclusion of unique device identifiers, including scannable barcoding, and related information. It will enable the tracking of a medical device or an IVD device through all stages in the healthcare system, enhance product safety and improve surveillance across the Australian supply chain.



Unique Device Identifier Overview

A medical device is assigned a UDI at the point of manufacture. The UDI enables improved tracking of devices through hospital procurement, use in clinical procedures, and inclusion in a patient's record and in clinical quality registries. The UDI, along with technical data about each model of medical device, will be available from the public Australian UDI database. These data will be able to be accessed by the medical devices industry, healthcare professionals and organisations, and patients and consumers. The system will enable increased data sharing, interoperability and the tracking and tracing of medical devices across the healthcare system. Compliance with UDI requirements will commence from 1 July 2026.

Supporting sponsors through regulatory processes

1k- Expand regulatory approvals for therapeutic goods by assisting sponsors in navigating regulatory processes, including by increasing pre-submission and pipeline meetings with TGA staff

The TGA has improved support for medical device sponsors through enhanced regulatory engagement meetings during its premarket processes. We offer assistance via scoping pipeline, application support and pre-submission meetings, and strategic and compliance meetings. Our webpages were updated with specific information and guidance for applicants on regulatory engagement meetings for medical devices. This helps sponsors to understand Australia's regulatory framework, and supports a smoother and timely application process.

The number of regulatory engagement meetings with medical device sponsors and manufacturers more than doubled, from 38 meetings in 2023-24 to 102 meetings in 2024-25. Sponsors sought clarification on regulatory requirements, classifications, advertising and clinical evidence.

Post-meeting feedback from sponsors has been extremely positive. The meetings have assisted sponsors to navigate the Australian regulatory framework and submit more comprehensive and quality applications.

In 2024-25, we redesigned the 'Guidance and resources' section of the TGA website to make guidance clearer and more accessible to industry.

Activities to support sponsors of medicines are detailed under Section 2b.

Reforming clinical trials regulation

1l- Review and reform clinical trials regulation to provide clear guidance, expand formal technical advice relating to clinical trial design, enhance access to scientific advice throughout product development, and address safety concerns by increasing oversight of high-risk therapeutic goods

Clinical trials conducted in Australia are subject to various regulatory controls to ensure the safety of participants and the robustness of evidence generated. The TGA administers the Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) schemes. Under the Act, these schemes allow access to unapproved therapeutic goods in Australian clinical trials. The TGA also undertakes inspections of clinical trial sites to monitor compliance with regulatory requirements. In 2024-25 we improved engagement and education, refined written material and hosted a new discussion forum on both schemes.

Stakeholder engagement and education

To support clinical trial sites to comply with their Good Clinical Practice (GCP) responsibilities, the TGA published a metrics report in March 2025: *Good Clinical Practice (GCP) Inspection Program 2023-2024: A report on Therapeutic Goods Administration (TGA) clinical trial compliance activities.*[10] The report provided an overview of education activities, areas of compliance and non-compliance with GCP standards, and examples of identified critical and major deficiencies.

[10] Available at: www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials/good-clinical-practice-gcp-inspection-program#metrics-reports

To supplement this report, the TGA hosted a webinar on 9 May 2025, attended by almost 550 stakeholders. It provided an overview of key areas of compliance and non-compliance and provided an opportunity to ask GCP inspectors questions: *Insights into Good Clinical Practice (GCP) Inspection Program activities 2023-2024*.[11]

First meeting of the Human Research Ethics Committee and Therapeutic Goods Administration Clinical Trials Discussion Forum

In November 2024, the TGA hosted the first meeting between the TGA and Australia's Human Research Ethics Committees (HRECs). The Forum allowed for informal discussion and information sharing on a range of emerging regulatory challenges and opportunities for clinical trials in Australia. A second meeting was held in May 2025. This meeting will be held 3 times a year.

Updated guidance for sponsors

The TGA published new and updated webpages, including on the CTN scheme and the ongoing review of the CTA scheme. These updated pages make guidance clearer and more accessible.

Legislative changes

In September 2024, legislative amendments expanded the TGA's capacity to share information about the conduct of clinical trials involving medical devices with the approving authority and responsible ethics committee. This includes the outcomes of GCP inspections.

Enhanced oversight of medical device clinical trials

From 5 April 2024, the TGA started screening all CTNs involving medical devices and reviewed those involving the highest risk devices- implantable cardiac and neurosurgical devices. In the first year, almost 300 CTNs were screened, with 10 high risk trials identified. Of these, 2 involved correspondence between the TGA, the HREC and the sponsor that led to the sponsor voluntarily discontinuing the trial. Feedback from stakeholders has been positive, suggesting an improved safety profile for clinical trials with minimal increase in regulatory burden. Trials involving medical devices are also now included in the Good Clinical Practice Inspection Program.

Strengthening regulatory systems in the Pacific and South-East Asia

1m- Continue collaboration with regulatory bodies and health authorities within the Pacific and South-East Asian regions, primarily through the Indo-Pacific Regulatory Strengthening Program and the Pacific Medicines Testing Program

The TGA remains committed to collaborating and working with its regional regulatory counterparts, as reflected in the TGA's International Engagement Strategy 2021-2025.[12] Working with our international regulatory counterparts and strengthening regulatory capability across the region benefits Australians through a more globally aligned regulatory framework.

---

[11] Available at: www.tga.gov.au/resources/industry-guidance-and-resources/tga-learn/online-education-events/webinars/insights-good-clinical-practice-gcp-inspection-program-activities-2023-2024-9-may-2025

[12] Available at: www.tga.gov.au/resources/publication/corporate-reports/tga-international-engagement-strategy-2021-2025

Pacific Medicines Testing Program

The TGA administers the Pacific Medicines Testing Program (PMTP), due to conclude in June 2026. Between 1 July 2024 and 30 June 2025, the program tested 79 samples for the 13 participating countries, with 28% failing to meet the required testing standards. Of the 17 antibiotics samples tested, 35% did not meet testing requirements.

The PMTP also remains vigilant to the global issue of contaminated oral liquid preparations. During the reporting period, 13 samples were screened for the presence of the contaminants diethylene glycol and ethylene glycol. Although both were detected in all the 13 samples tested, the level of contamination was within the limit specified by the WHO's advice and the TGA's applied safety limits for these compounds.

Indo-Pacific Regulatory Strengthening Program

The TGA continues to implement the Indo-Pacific Regulatory Strengthening Program (RSP), under the Australian Government's *Partnerships for a Healthy Region* initiative. The RSP works with National Regulatory Authorities (NRAs) and Ministries of Health from 22 countries across Southeast Asia and the Pacific, to strengthen local regulatory systems to achieve better health outcomes for our region.

The RSP plays an active and dynamic role in contributing to more resilient and equitable regulatory systems. This facilitates improved access to quality-assured, safe and effective medical products for those that need them. Delivery of the RSP has improved regulatory practices, fostered collaboration and supported health goals.

Opening ceremony of the inspector training workshop on GMP for Active Pharmaceutical Ingredients, Cambodia October 2024

Capacity building

Across the Indo-Pacific region, regulatory systems vary in the range and extent of the functions performed, impacting on access to quality-assured medical products. This in turn affects local ability to support the health of populations.

The TGA works with partner countries to understand their medical products regulation objectives and address regulatory capability needs. The RSP design, activity prioritisation and implementation all align to country-specific goals. This includes bilateral and multilateral activities and responsive support, to strengthen the knowledge, skills and regulatory systems and promote the availability of quality-assured medical products.

Workshops and knowledge sharing

The RSP primarily delivers activities through targeted workshops. In 2024-25, 6 workshops were hosted by the RSP, bringing together regulators from across the Indo-Pacific region.

The *Protecting our people: quality of medicines in Pacific Island Countries* workshop, held in Suva, Fiji, focused on the importance of quality-assured medicines, in line with the strengthening of Fiji's regulatory frameworks. The workshop engaged more than 40 participants and was hosted by the RSP team in collaboration with the Fiji Medicines Regulatory Authority and the WHO Division of Pacific Technical Support.

Delegates and RSP staff at the Medicines Quality Workshop, Fiji, November 2024

In October 2024, the *Regulation of Advertising and Online Sales of Medicines* workshop was supported by the TGA's Regulatory Compliance Branch. Over 135 participants from 10 Indo-Pacific NRAs attended the virtual event, engaging on understanding and reducing risks from purchasing substandard and falsified medicines.

The RSP delivered pre-market assessment workshops on API and impurity controls to support technical capabilities with Malaysia's National Pharmaceutical Regulatory Agency (NPRA) and with Indonesia's National Agency of Drug and Food Control (BPOM).

A workshop on GMP was delivered for the Lao People's Democratic Republic (PDR) NRA, jointly by the RSP and the Thai Food and Drug Administration. A second GMP workshop was delivered to the Cambodian NRA, in collaboration with the WHO. Regional collaboration supports the continued efforts to improve quality of medicines.

NRA staff from Lao PDR and Thailand, and RSP staff at the GMP Workshop, October 2024, Lao PDR.

RSP Collaboration

The RSP provides support and assistance to participating NRAs on regulatory approval of important medical products. RSP focuses on strengthening technical knowledge and skills, supporting the use of recognition and reliance mechanisms as well as collaborating with industry on regional filing.

WHO Engagement

The TGA continues to contribute significantly to WHO initiatives. We are the Australian representative to the WHO's Member State Mechanism on Substandard and Falsified Medical Products as an elected representative for the Western Pacific region, and Vice Chair of the Steering Committee.

Indonesian National Agency of Drug and Food Control (BPOM) Chairperson Dr Taruna Ikrar (centre right) and BPOM staff with TGA staff at API Workshop, Indonesia September 2024.

RSP staff participate in related working groups addressing the significant global risks posed by substandard and falsified medicines. Australia's involvement extends to participation in the WHO Coalition of Interested Parties at both regional and global levels. This contributes to high-level regulatory strengthening strategy and advocacy for the needs for South-East Asia and the Pacific. This continued participation and leadership demonstrate the TGA's ongoing commitment to improved regional and global public health.

Indonesian National Agency of Drug and Food Control (BPOM) Chairperson Dr Taruna Ikrar (centre right) and BPOM staff with TGA staff at API Workshop, Indonesia September 2024.

The WHO is an important partner for the RSP, with engagement at headquarters, regional (South-East Asia Regional Office and Western Pacific Regional Office), and country office levels.

WHO engagement complements bilateral activities with NRAs and collaborations with other technical assistance providers. Working closely with the WHO, the RSP has led numerous strengthening

initiatives, including workshops and in-country training and support for the Association of Southeast Asian Nations Joint Assessment.

During 2024-25, the RSP supported the WHO through participating in Global Benchmarking Tool (GBT) assessments for Papua New Guinea, Timor-Leste, Cambodia and Vietnam. These assessments are the primary means to objectively evaluate regulatory systems. The GBT and benchmarking methodology enables the WHO and regulatory authorities to:

- identify strengths and areas for improvement
- facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the identified gaps
- prioritise IDP interventions, and
- monitor progress and achievements.

Regulatory Agencies Network against Antimicrobial Resistance

Through the RSP, Australia confirmed its commitment to addressing antimicrobial resistance (AMR) in 2024 by joining the Regulatory Agencies Network against AMR (RAGNA). This is a global network of regulators from across the human and veterinary medicines sectors under the WHO's Quadripartite. The TGA participates in quarterly meetings of RAGNA, and in February 2025 delivered a 2-hour deep dive on the impact of substandard and falsified medical products on increasing antimicrobial resistance. Participation in RAGNA enables Australia to shape global One Health responses and promotes participation in regional mechanisms to partner NRAs.

First Assistant Secretary, Nick Henderson (right) with Katarina Lönnquist from RAGNA, which is coordinated by the Swedish Medical Products Agency in Uppsala

Monitoring and refining frameworks for emerging technologies

1n- Monitor and refine regulatory frameworks to support new technologies, including digitally enabled testing and treatment methods, software, medicine dosage, genomic sequencing, point-of-care manufacturing and hybrid access models

We monitored and refined various frameworks for emerging technologies and supported sponsors, users and other stakeholders to better understand and comply with regulatory requirements.

In 2024, the TGA reviewed the legislative framework for the regulation of therapeutic goods under the Clarifying and Strengthening Regulations stream of the Australian Government's 2024 Supporting Safe and Responsible AI initiative. We sought to determine whether the existing framework is appropriate for current and projected future use of AI. More than 600 stakeholders from across the therapeutic goods sector participated, including consumers, clinicians, members of industry and state and territory governments.

The TGA's report on its AI Review was published in July 2025.[13] It confirmed that the existing therapeutic goods legislative framework was flexible, robust and largely fit for purpose to meet the current risks associated with AI technology. Some key areas were identified as requiring further review and public consultation.

To address the 14 findings of the report, we have commenced a forward plan of work to:

- clarify terms such as 'developer' and 'deployer', and their respective regulatory obligations, in the Act
- review current exclusions for certain products, such as digital mental health tools and low-risk consumer health products
- review the requirements for software based medical devices intended to provide a prediction or prognosis
- clarify the regulatory exemption for low-risk clinical decision support system software
- refine the current advertising and labelling requirements to improve transparency for the use of AI in healthcare and by consumers, and
- commence compliance activities to ensure AI and software-based medical devices meet Australia's regulatory requirements.

We also commenced review of the patient-matched medical device (PMMD) regulations, with a specific focus on devices manufactured at the point of care (POC). As part of this process, we held 11 targeted workshops with state and territory representatives, the POC Manufacturing Steering Committee, and sector-specific working groups. Stakeholders identified several challenges, including the differences between POC and traditional manufacturing, the regulatory burden on small volume manufacturers, and the need to prioritise oversight of higher risk PMMDs. The TGA will explore potential options for regulatory refinements via a public consultation in 2026.

The TGA has developed information to help manufacturers and developers of digital therapeutics for software as a medical device.

The TGA has developed detailed information to help manufacturers and developers of digital therapeutics (DTx) to meet regulatory requirements for software as a medical device (SaMD). The TGA recognises the increasing use of software or DTx that delivers treatment interventions based on clinical evidence for the prevention, management or treatment of diseases and disorders. Many of these tools meet the definition of a medical device because they support or manage a range of conditions, including obesity, mental health or chronic diseases, or contribute to medication management.

We also consulted publicly about changes to the definitions and regulatory classification system for IVD medical devices, including those that are software.

[13] Available at: www.tga.gov.au/news/news-articles/tga-ai-review-outcomes-report-published

Regulatory Science Strategy

1o- Implement elements of the Regulatory Science Strategy to increase the TGA's capability to identify and effectively regulate emerging technologies across medicines and medical devices, including a horizon scanning framework and collaboration with regulatory agencies, professional associations and relevant industries

The *Regulatory Science Strategy*[14] applies to the work of the Health Products Regulation Group (HPRG), including the TGA. It outlines how HPRG will maintain and build its regulatory science capability. In 2024-25, the TGA focused on embedding its Academic Outreach Program and developing of a group-wide horizon scanning framework.

Academic Outreach Program

Within the last year the program has grown external knowledge of our role in regulatory science and therapeutic goods regulation. This has been by increasing HPRG-specific course content and direct lecturing/meeting opportunities with undergraduate and postgraduate students and academics.

The TGA also established a framework to facilitate Memoranda of Understanding with partners to collaborate on topics of mutual interest. These include highly technical subjects for the purpose of research, advice relating to horizon scanning, knowledge transfer, capability uplifts in health science graduates, and staff training.

Horizon Scanning Framework

Advances in healthcare technologies will have substantial impacts on therapeutic goods regulation. Globally, health advances are already monitored carefully, including through established systematic horizon scanning models from other jurisdictions[15], WHO and other international organisations. By remaining up to date with the latest scientific innovations and the evolving landscape of therapeutics, the TGA is well positioned to respond effectively to emerging innovations, so that Australians are able to access safe and effective therapeutic products.

To increase our preparedness, we have established a formal, structured and iterative mechanism to capture and assess technological advances. Key benefits of a formal horizon scanning framework include:

- centralised collection of categorised intelligence with contributions from both external signals from existing global activities and internally from across the TGA
- improved in-house awareness and understanding of scientific developments
- informed workforce planning to address staffing gaps
- ability to anticipate the need for policy review and regulatory development, and
- increased transparency of monitoring and actions to external stakeholders.

[14] Available at: www.tga.gov.au/resources/publication/corporate-reports/health-products-regulation-group-regulatory-science-strategy-2020-2025

[15] MHRA Innovation Accelerator, EMA EU Innovation Network, Canada's Drug Agency and CADTH Horizon Scans

Modernising testing regulations

1p- Modernise and streamline Australia's Therapeutic Goods Testing Regulations to improve efficiency, flexibility and alignment with current standards

Review of Part 5 of the Therapeutic Goods Regulations 1990

The TGA commenced a review of Part 5 of the Therapeutic Goods Regulations 1990 (the Regulations), which relates to the examination, testing and analysis of goods.

The review aimed to increase the clarity and consistency of Part 5, so that testing under the Regulations remains responsive to advancing therapeutic goods technology and exemplary laboratory management.

Strategic objective 2
Build trust by actively engaging with our stakeholders

The TGA builds trust with its stakeholders through active engagement and transparent, timely and consistent communication. We collaborate closely with industry, consumers, health professionals and government partners to support a shared understanding of regulatory responsibilities. Our targeted engagement initiatives address stakeholder needs and priorities. The TGA promotes confidence in its regulatory decisions by clearly communicating the rationale behind its actions. Inclusive consultation and co-development of regulatory frameworks further enhance trust and reinforce the TGA's role as a responsive and accountable regulator.

Guiding Principles

2.1 Be responsive to enquiries and provide clear, timely explanations of our regulatory decisions, to build trust and transparency

2.2 Communicate effectively to empower consumers, health professionals and industry with the information they need to understand and meet their regulatory obligations

2.3 Engage and collaborate proactively with stakeholders impacted by our regulatory activities, to ensure their perspectives are considered, and

2.4 Collaborate with domestic and international health system stakeholders to address regulatory issues and adapt to evolving policies, practices and services.

Insights from the TGA Stakeholder Survey

Building trust through continuous improvement is fundamental to the TGA's role as a responsive and transparent regulator. By actively engaging with stakeholders and refining communication and education initiatives, we strengthen confidence in our regulatory decisions and foster meaningful collaboration and consultation across the health system.

One of the ways we measure the effectiveness of our stakeholder engagement is our annual TGA Stakeholder Survey, in which we ask TGA business system users, health professionals and consumers about their experiences. While there is always room for improvement, the 2025 survey showed that 62% of business system users and 56% of consumers agreed that 'the TGA provides opportunities for input into key decisions that impact me'. These figures were comparable to the results we achieved in 2024. Of the 438 respondents who participated in a consultation process with the TGA, approximately 76% were satisfied with their consultation experience.[16] These findings illustrate our commitment to collaborative practice.

The survey found 82%[17] of all stakeholders agreed with the statement that "I trust the TGA to perform its role ethically and with integrity". Among consumers who were aware of the TGA, we saw the highest level of agreement since 2018 at 81%, an increase of 4% on 2024 levels.[18] These results show continued high levels of trust in the TGA.

Stakeholder satisfaction with communication also improved, with 70% of industry respondents rating their experience positively, representing a 4% increase from the previous year.

---

[16] Available at: www.tga.gov.au/resources/publication/corporate-reports/tga-stakeholder-survey-report-2025; page 13-14
[17] Ibid; page 4.
[18] Ibid; page 8.

Education and public awareness activities continue to play a vital role in strengthening engagement. 58% of industry respondents reported participating in TGA educational initiatives in the past 12 months and more than 98% found these initiatives useful. 16% of consumers recalled seeing TGA social media campaigns. These findings demonstrate that targeted education and transparent communication are key drivers of trust and confidence in the TGA's regulatory system.[19]

Engagement and collaboration

2a- Strengthen engagement and collaboration with relevant domestic and international stakeholders, including equivalent regulators, to ensure regulatory efficiency, proactively address quality and defect issues, share risk signals associated with non-compliance, and harmonise practices

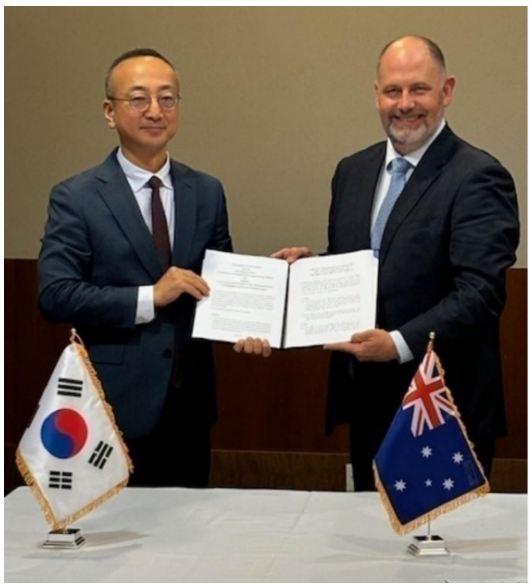
Engagement and collaboration are central to the TGA's ability to administer an effective and efficient regulatory system. The TGA cooperates and collaborates with domestic and international regulators and stakeholders. These efforts strengthen our own regulatory system, create opportunities for efficiencies, and build trust in our regulatory decisions.

Agreements to facilitate information sharing

We maintain formal agreements with our international regulatory counterparts, to enable collaborative activities and the sharing of confidential information. These arrangements help to reduce duplication and expedite certain assessments, facilitating Australia's access to high quality, safe and effective therapeutic goods. The TGA has over 30 agreements in place for the sharing of confidential information with overseas regulatory authorities and is a party to 5 treaty-level country mutual recognition agreements.

During 2024-25, the TGA signed new international agreements with the Ministry of Food and Drug Safety of the Republic of Korea, and the South African Health Products Regulatory Authority (SAHPRA).

We also progressed negotiations on agreements with the Central Drugs Standard Control Organization of India, and the NPRA of Malaysia.



Mr Sang Bong Kim, Director General of the Pharmaceutical Safety Bureau, Ministry of Food and Drug Safety, Republic of Korea with Professor Lawler (right) at the signing ceremony.

[19] Ibid; page 16

International Medical Device Regulators Forum

The TGA remains committed to global harmonisation of medical device regulation through its active involvement in the International Medical Device Regulators Forum (IMDRF). In 2024-25, we participated in 4 meetings focussed on supporting less mature regulators to build their capabilities, including through developing a Reliance Handbook. We contributed to 8 IMDRF Working Groups, chairing the Personalised Medical Devices Working Group and the Adverse Event Maintenance Terminology Working Group. Through our roles on the IMDRF Management Committee and Working Groups, we shaped and strengthened regulatory capability to meet emerging trends and technology advancements, along with robust governance processes to ensure the forum's long-term sustainability.

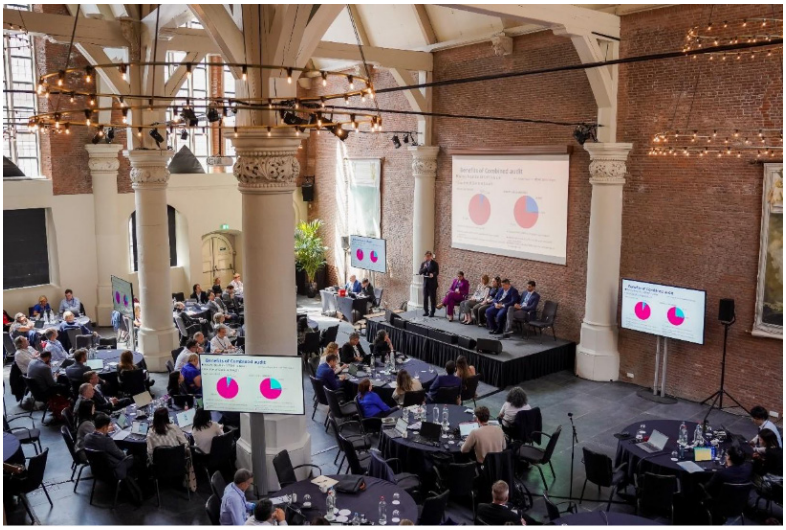
Australia also supports IMDRF collaboration by hosting and managing online platforms, including the IMDRF.org website and the IMDRF Collaboration Hub on SharePoint.

Medical Device Single Audit Program

As a founder of the Medical Device Single Audit Program (MDSAP) and 2024-25 Chair of its Regulatory Authority Council (RAC), the TGA is leading the transition of MDSAP from a pilot to a fully operational model. MDSAP enables recognised Auditing Organisations (AOs) to conduct a single audit of a medical device manufacturer's quality management system (QMS), satisfying the regulatory requirements of multiple regulatory authorities. This approach promotes global regulatory convergence, strengthens oversight, and reduces the regulatory burden on manufacturers, facilitating faster access to safe and effective medical devices in Australia.

We have driven key MDSAP enhancement projects to modernise and expand program capacity, monitor performance, improve audit timeliness, and elevate audit quality. These initiatives position MDSAP for sustainable growth, underpinned by transparency and accountability.

The TGA chaired the 2025 MDSAP Forum in Amsterdam, bringing together MDSAP Regulatory Authorities, Observers, Affiliates, AOs, European Union (EU) Notified Bodies, manufacturers and industry representatives. The Forum featured panel discussions, training sessions and workshops on the MDSAP program and its enhancement initiatives. During the Forum, we officially launched the new MDSAP independent public website following collaborative efforts led by the TGA and supported by international working groups and key industry stakeholders.



Delegates at work at the 2025 MDSAP Forum in Amsterdam, The Netherlands

On behalf of the MDSAP RAC, the TGA has played a critical role in reopening the process for new AO applications, supported by newly introduced prioritisation criteria. These criteria better align demand for MDSAP assessments with available resources and prioritise applicants with strong potential for timely recognition and long-term participation.

In March 2025, after a successful 18 month Remote and Hybrid Pilot Program, the MDSAP RAC endorsed full implementation of the program, allowing hybrid and remote audits to be conducted as part of the MDSAP audit and certification process.

Australian industry and TGA representatives at the 2025 MDSAP Forum in Amsterdam, The Netherlands

International Coalition of Medicines Regulatory Authorities

The TGA continued to play a key role in the International Coalition of Medicines Regulatory Authorities (ICMRA). Through the strategic leadership of the Heads of NRAs, ICMRA provides strategic leadership in enhanced communication, information sharing and crisis response.

As a member of ICMRA's Executive Committee, and co-chair of its Vaccines Pharmacovigilance Network (VPN) since its inception in 2020, the TGA is an active member of ICMRA. Our initiatives align with ICMRA priorities, leveraging the power of ongoing international cooperation, collaboration and reliance between NRAs.

ICMRA conducts the ICMRA Summit, an annual meeting to discuss the future of medicines regulation. The summit also presents the opportunity to conduct one of the ICMRA Plenary meetings, which occur twice a year, face-to-face. Here, ICMRA members provide updates on the technical work conducted by ICMRA working groups and regulatory networks.

In November 2024, TGA representatives attended the ICMRA Summit and Plenary in Brasilia, hosted by the Brazilian Health Regulatory Agency ANVISA. Representatives from medicines regulatory agencies from around the world were present, and experts from the WHO. The forum is a vital platform for international regulators to collaborate on strategic solutions in public health, and to consider the rapidly evolving landscape of medicines regulation.

The 3 key discussion topics and scientific sessions for the summit were:

- COVID-19 Pandemic: Lessons Learned and Future Preparedness for the next Global Health Emergency
- Beyond Accelerated Pathways: Expanding Regulatory Strategies to Improve Patient Access to Essential Medicines, and
- Antimicrobial Resistance.

Professor Anthony Lawler represented the TGA and presented on the benefits and associated frameworks of the provisional registration pathway in the Australian context. Professor Lawler spoke on how the TGA employs the pathway to make safe and effective vaccines and treatments available, on an expedited timeline, to the Australian public and beyond.

The 3 scientific sessions were linked by the common theme of global regulatory collaboration, facilitating the coordination of a global approach to current and emerging issues. The Summit also highlighted reliance mechanisms, international collaboration and proactive trust and capacity building efforts as important considerations for ICMRA moving forward.

Drug Information Association Conference

In June 2025, the TGA participated in the Drug Information Association Conference in Washington, D.C. This key international meeting brings together medicines regulators, industry, academia and healthcare providers to explore the latest developments in healthcare and the life sciences. The TGA's ongoing attendance demonstrates Australia's role at the forefront of medicines regulation and technological innovation.

As well as attending sessions of interest, TGA officers participated in conference presentations and panels:

- Project Orbis: Six Years Later, presentation from Dr Sarah Golding, Medical Officer.
- Paediatric Cluster Town Hall, presentation from Professor Robyn Langham, Chief Medical Adviser.
- Regulators and Communication in a Changing World: The ICMRA Role, chaired by Professor Anthony Lawler, Deputy Secretary.

The session chaired by Professor Lawler highlighted the key role ICMRA played during the COVID-19 pandemic, ensuring the sharing of vital information, providing common responses and aligning regulatory practices. It focused on communication and trust, ensuring that regulators remain a trusted source of information, and supporting the public to better value information based on scientific evidence. It also explored the very real harm that mis- and dis-information about vaccines, medicines and health regulation inflict on the health of the global population.

Access Consortium

The TGA continued its active participation in the Access Consortium, a coalition of NRAs from Australia, Canada, Singapore, Switzerland, and the United Kingdom (UK). These like-minded regulators collaborate to align regulatory requirements and collaborate on specific regulatory evaluations, ultimately facilitating faster access to safe, effective and high-quality medicines for their respective populations.

During the 2024-25 period, Consortium groups drove work-sharing initiatives and streamlining of regulatory processes, including the:

- New Active Substances Working Group (NASWG)

- Generic Medicines Working Group Information Technology Working Group
- Clinical Trials Working Group
- Advanced Therapy Medicinal Products Working Group, and
- Complementary Health Products Working Group (CHPWG).

In February 2025, the heads of the 5 agencies convened to review progress, endorse the renewed *Access Strategic Plan (2025-2028)*[20], and launch the new Access Consortium website.[21] The Strategic Plan builds on the Consortium's strengths and outlines pathways for enhanced collaboration, particularly regarding:

- work-sharing procedures
- regulatory alignment
- predictability
- industry engagement, and
- implementation of a new collaboration technology platform to streamline the review process.

As part of the Access Consortium, the TGA informed sponsors and industry bodies of the renewed Strategic Plan and the new website, reinforcing its commitment to engaging with industry.

A key highlight from 2024-25 was a productive virtual session at the Asia Regulatory Conference in December 2024. Representatives from the TGA and Access Consortium partners engaged with Medicines Australia and the International Federation of Pharmaceutical Manufacturers and Associations.

Participants engaged in open conversation about Access Consortium work-sharing, highlighting its successes and considering potential refinements that would benefit all parties and ultimately the Australian public.

Complementary health products

The TGA collaborated with the CHPWG to share information on the safety, quality and efficacy of complementary health products. This collaboration supported information exchange to identify risk signals related to non-compliance and promote harmonisation of regulatory practices for complementary medicines.

New Active Substances Work-Sharing Initiative

The New Active Substances Work-Sharing Initiative (NASWSI) is an innovative work-sharing procedure for the coordinated assessment of new chemical or new biological entity applications, or for new indication applications that are submitted to 2 or more Access Consortium agencies. Through this initiative, the TGA can coordinate regulatory review procedures, increasing its capacity

[20] Available at: https://accessconsortium.info/
[21] https://accessconsortium.info/

to facilitate timely access to high quality, safe and effective therapeutic goods. Through this mechanism, we can receive prescription medicine applications significantly earlier than through standard national pathways. These collaborations also foster the exchange of technical expertise and minimise duplication of regulatory effort across partner agencies.

In 2024-25, the TGA contributed to the ongoing work of the Access Consortium to align processes for applications lodged under NASWSI. The NASWG prepared responses to questions from Medicines Australia and other Access Consortium countries' industry bodies about the Promise Pilot Pathway, an aligned process for priority application review launched in November 2023. This clarified the criteria and processes for this pathway, and feedback prompted refinements to the Promise Pilot Pathway along with updates to the NASWSI Operational Procedures.

The TGA approved 14 applications through the NASWSI in 2024-25.

The TGA approved 14 applications through the NASWSI in 2024-25. This comprised 9 new prescription medicines and 5 extensions of indication for existing prescription medicines.

Generic Medicines Work-Sharing Initiative

The Generic Medicines Work-Sharing Initiative (GMWSI) is a work-sharing submission pathway for the coordinated assessment of generic applications that are filed with multiple Access Consortium agencies.

In August 2024, the Access Consortium made significant updates to the GMWSI Operational Procedures. These built on previous discussions between partners and consultations with relevant sponsors and industry bodies. The updates provided increased clarity regarding application eligibility for work-sharing, particularly when data from foreign comparator products forms part of the submission. Ongoing discussions with industry on these matters reflect the Access Consortium's continuing commitment to improving regulatory alignment.

Pharmaceutical Inspection Cooperation Scheme

The TGA made substantial contributions to the activities of the Pharmaceutical Inspection Cooperation Scheme. These included chairing and actively participating in subcommittees and working groups to harmonise international GMP standards.

In parallel, the TGA maintained regular engagement with its MRA partners through routine meetings, supporting the ongoing implementation and enhancement of the TGA's internal GMP Inspection Reliance Framework.

Project Orbis collaboration for prescription medicines

The TGA continues to collaborate with international regulatory partners through Project Orbis, a global initiative to expedite the review and approval of oncology products. Led by the United States Food and Drug Administration, the network includes regulatory authorities from Australia, Canada, Switzerland, Singapore, the UK, Brazil and Israel.

The TGA approved 23 applications through Project Orbis.

During 2024-25, the TGA approved 23 applications through Project Orbis. The joint evaluation framework enables concurrent submissions and parallel review, facilitating earlier access to innovative cancer therapies.

This initiative reinforces international regulatory cooperation and advances streamlined processes to more effectively meet community need.

Engagement and surveillance

Strong international and domestic stakeholder collaboration enhances the TGA's capability to detect and respond to signals associated with emerging therapeutic products.

We participate in monthly meetings with international medical device regulators to address emerging safety and performance risks, supply disruptions and policy considerations related to medical devices and IVDs. These meetings enable early identification of internationally recognised issues, allowing the TGA to respond proactively.

We also work closely with state and territory health departments, providing regular updates on the status, progress and outcomes of post-market surveillance activities. This collaboration strengthens communication channels and offers valuable insights into stakeholders' challenges, including potential device supply disruptions and safety signals.

On 12 September 2024 the TGA co-chaired a meeting of the VPN, alongside the UK's Medicines and Healthcare products Regulatory Agency (MHRA), with representatives from 25 international regulators. The VPN is a critical forum for real-time information exchange on potential vaccine safety signals. This collaboration enables the use of large-scale international data and supports the development of harmonised approaches that reduce duplication of effort across jurisdictions.

The TGA maintained regular engagement with academic institutions and centres of excellence in vaccine safety to strengthen our capability to detect and respond to emerging vaccine safety signals. Key collaborators included the National Centre for Immunisation Research and Surveillance, Surveillance of Adverse Events Following Vaccination in the Community, the Murdoch Children's Research Institute, and state and territory Jurisdictional Immunisation Coordinators.

The TGA contributed to the monthly International Post-Market Surveillance Teleconference and the Senior Australia and New Zealand Evaluators Meeting with Medsafe, the New Zealand regulator, by developing discussion questions and providing expert responses. We also responded to medicine safety signals identified by international regulatory counterparts, and shared signal evaluation reports to support capability-building among evaluators.

Our collaboration with academic stakeholders, including the Medicines Intelligence Centre for Research Excellence, continued through monthly meetings on current research to inform and strengthen signal detection and evaluation activities.

Meeting with our international regulatory counterparts

Throughout 2024-25, the TGA engaged in a series of bilateral and multilateral meetings with international regulatory counterparts.

In September 2024, we hosted a delegation from the Taiwan Food and Drug Administration (TFDA), with a focus on the regulation of Chinese herbal and traditional medicines. Discussion included the governance structure for traditional Chinese medicine (TCM) in Australia, GMP inspection processes for overseas manufacturers, and opportunities for future collaboration between regulatory authorities. The visit provided a valuable platform for knowledge exchange, reinforcing the TGA's commitment to international engagement.

In the margins of the ICMRA summit and Plenary in November 2024, the TGA conducted bilateral meetings with representatives from the TFDA, Health Canada (HC), MHRA, the European Medicines Agency, and SAHPRA. While specific discussion varied across agencies, the overarching theme was the ongoing enhancement and promotion of global cooperation and collaboration.

On 4 December 2024, the TGA met with representatives from the National Institute of Health Sciences in Japan on the application of pharmacogenomics in pharmacovigilance, establishing important professional contacts between the organisations. Our Japanese counterparts presented on identifying pharmacogenomic biomarkers associated with severe adverse reactions to medicines, and how pharmaceutical post-market safety operates in Japan. In turn, the TGA provided a summary of its pharmacovigilance regulatory framework followed by discussion of our shared challenges and opportunities in this space.

Following the 2025 Drug Information Association Conference in June, the TGA held bilateral meetings with HC, the Health Sciences Authority of Singapore, and MHRA. These meetings further strengthened relationships well-established through the Access Consortium and highlighted the history of ongoing cooperation and collaboration with each regulatory agency. Discussions included strategic priorities and common challenges shared by each regulator.

Also in June 2025, the TGA hosted round table bilateral meetings with the Thailand Food and Drug Administration (Thailand FDA) at TGA head offices in Fairbairn, Canberra. We were joined by colleagues from the Department of Agriculture, Fisheries and Forestry, and the Australian Embassy in Thailand, who facilitated the study tour.

Key topics included the classification of functional foods versus therapeutic goods, regulatory frameworks for complementary medicines, and Thailand FDA's interest in health claims, product approvals, and accelerated registration pathways. The meeting reinforced ongoing collaboration under the DFAT-funded RSP, with potential next steps, including technical exchanges or a follow-up virtual meeting to continue the dialogue.

Engagement and advertising compliance

The TGA engaged regularly with industry stakeholders through the Therapeutic Goods Advertising Consultative Committee (TGACC), which met twice in 2024-25 to discuss matters related to the advertising of therapeutic goods.

This engagement complements broader collaboration with state and territory regulators, law enforcement, and key sector and industry bodies to ensure that compliance activities remain targeted and responsive to areas of greatest need.

The TGA's collaboration with digital platform providers continued to strengthen, resulting in significant increases in disruption activities targeting unlawful online advertising of therapeutic goods. These collaborations span multiple social media platforms and a network of ISPs, enhancing the reach and effectiveness of regulatory interventions in the digital environment.

Operation Pangea XVII

The TGA collaborates closely with international partners, sharing intelligence and resources to combat the global trade in illicit and counterfeit therapeutic goods, with a focus on reducing risks to consumers through this initiative.

In 2024-25, the TGA led Australia's continued participation in INTERPOL's Operation Pangea XVII, a global initiative targeting the online sale and distribution of counterfeit and illicit medicines and medical devices. As part of this operation, the TGA facilitated the seizure of millions of counterfeit and illegal therapeutic goods, representing the largest seizures globally. This sustained international collaboration reflects the TGA's strategic commitment to safeguarding the safety and quality of therapeutic goods, underscoring the importance of coordinated global action in addressing cross-border regulatory challenges.

Collaboration and engagement with domestic fora and groups

The TGA also worked closely with Australian-based industry bodies, exemplified by our regular meetings with industry bodies including Medicines Australia and the Generic and Biosimilar Medicines Association. Here we explored opportunities to streamline regulatory processes and improve access to high-quality medicines. Discussions focussed on labelling, international harmonisation, and updates to our framework for managing minor variations for prescription medicines.

For medical devices, the TGA met with industry via the Regulatory and Technical Consultative Forum for Medical Devices. This provided an efficient way to address priority concerns raised by sponsors and manufacturers and provided a channel for consistent engagement with industry. The TGA directly clarified regulatory requirements via weekly member communications.

Our engagement with the Medical Device Consumer Working Group also provided valuable insights into consumer experiences and expectations. Through this group, we work closely with consumer representatives to identify safety concerns, address emerging issues, and improve the clarity and accessibility of our communications.

For medicines, we held 2 meetings with the TGA/industry consultative forum, which includes representatives from the Association of Therapeutic Goods Consultants, Accord Australasia,

Consumer Health Products Australia, and Complementary Medicines Australia. We also participated in several conferences and stakeholder meetings hosted by these groups.

In January 2025, following extensive targeted and public consultation, the TGA published guidance outlining the quality requirements for listed probiotic medicines. In April 2025, we hosted a stakeholder webinar, *Q&A session in relation to new guidance material 'Demonstrating the quality of listed probiotic medicines'*.[22] The webinar provided the 207 industry and regulatory affairs consultants who attended with an opportunity to ask questions and strengthen their understanding of legislative requirements for probiotic listed medicines.

GMP Forum

The TGA successfully delivered its GMP Forum on 19 and 20 November 2024. The Forum was an opportunity to engage with a range of stakeholders and allowed the TGA to provide targeted education to more than 600 delegates, including manufacturers, sponsors, academics and regulatory agents. More than 30 sessions covered a wide range of topics including sterile manufacturing, GMP Clearance, updates to the latest GMP guidance and recall reform. The TGA hosted 'conversation stations' where delegates asked questions and sought clarification directly of TGA staff. Post-event feedback was overwhelmingly positive, with 98% of attendees indicating the forum met or exceeded their expectations and 97% praising the new 2-day format.

GMP Forum 2024- Conversation Station

ARCS Annual Conference- June 2024

The TGA collaborated with ARCS Australia to plan and support its Annual Conference, Regulatory Summit and Pharmacovigilance Summit. This partnership reflects the TGA's commitment to meaningful industry engagement and the provision of direct regulatory support and expertise.

The Annual Conference attracted approximately 1,500 attendees over 3 days, while the Regulatory and Pharmacovigilance Summits welcomed more than 230 participants. Feedback from these events highlighted the interactive nature of the presentations and the value of the up-to-date guidance provided.

[22] Available at: www.tga.gov.au/resources/industry-guidance-and-resources/tga-learn/self-paced-online-learning/presentations/qa-session-relation-new-guidance-material-demonstrating-quality-listed-probiotic-medicines

TGA Information Booth at ARCS Annual Conference

Supporting Non-Animal Technologies

The TGA is part of the NSW Non-Animal Technologies Network (NAT-Net), a research community established by the NSW Government. NAT-Net focuses on facilitating collaboration and advancing new technologies that do not rely on animal testing in medical research, through networking, advocacy and innovation. The initial focus of the network was mapping Australian capabilities in this area, and the network has now started discussions on navigating regulatory pathways to support the community and build upon our strengths.

Software and AI presentations and engagement

The TGA has continued to support industry to understand regulatory requirements for software and AI. Ongoing education and engagement activities have included a wide range of software and AI-focused presentations, workshops and training sessions at universities, symposia, conferences and industry-arranged fora. These include the Medical Software Industry Association, Pathology Technology Australia (PTA), the Australasian College of Dermatologists, Medical Insurance Group Australia and the Medical Technology Association of Australia.

In 2024-25, we continued our partnership with ANDHealth- Australia's National Digital Health Initiative, to support hundreds of participants from the digital health industry to engage with the TGA regulatory system. Our regulatory and technical experts provided tailored guidance and training to assist companies navigating regulatory requirements for medical device software products.

Faster and safer access to medicines

2b- Aim for faster and safer access to high-quality medicines while minimising regulatory burden and maintaining a robust regulatory system

Improving pathways to facilitate timely access to safe, effective and high-quality medicines remains a priority for the TGA. Through targeted reforms, stakeholder engagement and enhanced regulatory guidance, we are improving the timeliness of processes while maintaining robust safety and quality standards. These efforts reflect our commitment to innovation, transparency and continuous improvement.

Prescription Medicine Registration Process Reforms Program

The TGA has initiated comprehensive reforms to the prescription medicine registration process. Improvements to the pre-market process will reduce time to decision in the short-term and promote system sustainability in the medium-term. We engaged with industry to identify key issues and areas for improvement to enhance the experience for sponsors, uphold regulatory standards, and encourage earlier submission of medicine applications.

We have also strengthened our data reporting capabilities to support better allocation of evaluation resources. Through improved data-informed prioritisation, the TGA's new medicine median approval timeframes decreased by 15 days to 366 calendar days as at June 2025.

Our improvements to the pre-market process support system sustainability, and we will continue to work with industry engagement identifying key issues and areas for enhancement.

Updates for Listed Medicines

Listed medicines can only contain low risk ingredients included in the *Therapeutic Goods (Permissible Ingredients) Determination (No.4) 2025,* and use low level indications included in the *Therapeutic Goods (Permissible Indications) Determination (No.1) 2025*. This allows an expedited market access, as these medicines are not required to undergo a TGA pre-market evaluation.

In 2024-25, the TGA updated the Permissible Indications Determination to clarify existing regulatory requirements. We also added 6 new ingredients for use in listed medicines through 3 updates to the Permissible Ingredients Determination.

The TGA continues to support sponsors to meet their responsibilities supporting the safe use of medicines. We updated regulatory information pages on the TGA website and published revised guidance to assist understanding labelling and presentation requirements for listed medicines.

Effective communication channels

2c- Enhance transparency and trust through effective communication channels

The TGA continued to strengthen its strategic and integrated approach to timely and effective communication. This included through responses to enquiries, public awareness campaigns, social media initiatives, and conferences with industry groups and other key stakeholders. A range of communication channels helps us to deliver up-to-date information and guidance, tailored to each stakeholder group, including sponsors, health professionals, state and territory health agencies, and consumers.

Media enquiries

By responding to media enquiries, we enhance transparency, share important information, and foster trust with the community. In 2024-25, the TGA responded to or contributed to 598 media enquiries. We received over 35% of the total media enquiries directed to the department.

Effective communication on medicine shortages

To enhance transparency and trust, our communication must be targeted and tailored. This is particularly important when challenges arise, such as medicine shortages and discontinuations.

In 2024-25, the TGA continued to improve how we monitor and mitigate the impact of shortages and discontinuations in Australia. We pursued a program of regulatory, digital and process improvements to address high priority issues. Our initial focus was on updating the TGA's medicine shortages regulatory framework to better meet public information needs.

Once information was confirmed in our public-facing database, we published updates on the TGA website using clear language and accessible terminology to explain the medicine shortages situation. Our communications experts tailored advice specifically for pharmacists, prescribers, and patients and carers to ensure clarity and relevance for each audience. This approach strengthens public trust, confidence and transparency in the TGA's responses to medicine shortages.

We also actively pursued opportunities to explain and promote the TGA's role in medicine shortages. We developed content for information campaigns for consumers, pharmacists and prescribers on the TGA's supportive regulatory actions. This included general information about the scope of the TGA's role during shortages and specific guidance for pharmacists on accessing overseas-registered and alternative medicines.

These efforts helped affected health professionals and consumers to navigate the shortages and to be empowered to take appropriate action.

New enquiry management model

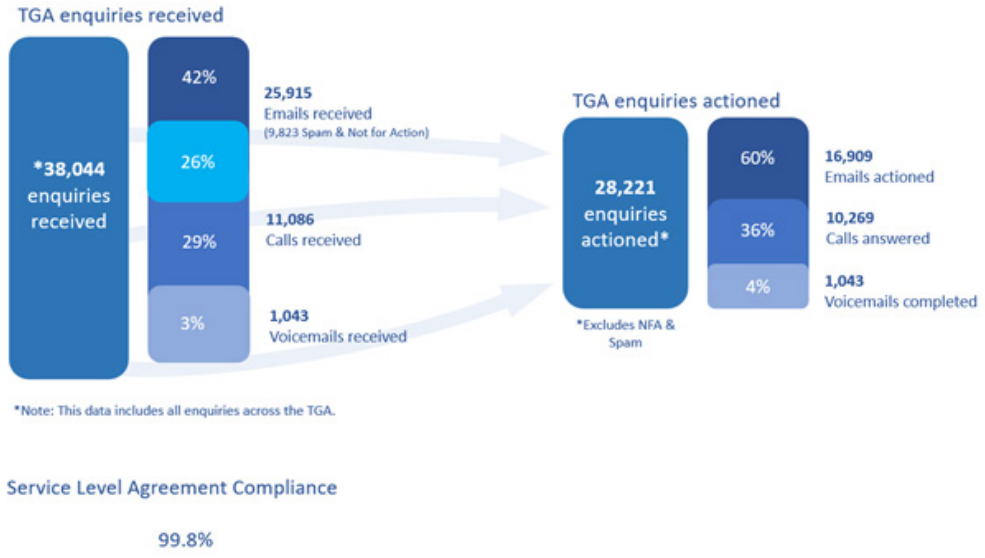
We aim to deliver a better customer experience and consolidate enquiry channels for external stakeholders.

In 2024-25, the TGA continued to embed a new enquiry management model, improving the timeliness, efficiency and documentation of how the TGA responds to enquiries from sponsors, health professionals and the public. The model will also strengthen data management and support enhanced staff training and TGA-wide knowledge sharing in best practice enquiry handling. This work will be carried forward into 2025-26.

For non-prescription medicines, we updated the process for fielding incoming enquiries from sponsors. We also established a centralised triage point for enquiries coming in via email and telephone, improving the efficiency of the enquiry process.

The TGA Contact Centre

In 2024-25, the TGA Contact Centre received more than 38,044 enquiries and actioned 28,221 of those available for response, while maintaining a 99.8% compliance rate with service level targets for enquiry response times. These results reflect a 2.8% improvement compared to the previous reporting period.



TGA Contact Centre enquiry volumes and service level performance (2024-25)

Digital platforms supporting stakeholder engagement

2d- Continuously improve our digital platforms to support stakeholder engagement

Productive use of digital platforms are key to effective communication and stakeholder engagement. The TGA continued to update its website in consultation with stakeholders to improve searchability, refresh content and make structural improvements. A new information architecture will be published in 2025-26.

As an example, the TGA published progress and outcomes of medical device post-market reviews on the TGA website[23] to keep the public informed of identified safety or performance issues. In 2024-25, this included post-market reviews of spinal cord stimulators (SCS), energy-based vaginal rejuvenation devices, ventilators, Continuous Positive Airway Pressure and Bilevel Positive Airway Pressure devices, human immunodeficiency virus nucleic acid tests, neonatal incubators, home-use foetal dopplers, and avian influenza A nucleic acid tests.

In 2024-25, the TGA reviewed and improved the language used in automatic acknowledgment messages sent to consumers and health professionals reporting adverse events. Our first round of digital platform improvements applied clear and inclusive language principles.

Improvements to digital platforms are further discussed under Section 4a.

[23] Available at: www.tga.gov.au/products/medical-devices/monitoring-and-compliance/medical-device-post-market-reviews

Education and public awareness

2e- Provide comprehensive education and increase public awareness about regulatory obligations and the safe use of therapeutic goods

Education and public awareness campaigns empower consumers, sponsors and health professionals, and promote the safe use of therapeutic goods. In 2024-25, we expanded our education and outreach efforts through targeted campaigns and high-quality learning tools. These initiatives support informed decision-making and enhance stakeholder confidence in the regulatory system.

Online Professional Development Module

The TGA launched a new Adverse Event Reporting e-learning module, *Safety Through Reporting,* via NPS MedicineWise, in November 2024. Practitioners were able to use this module for their own Continuing Professional Development.

The module explains:

- 'why' health professionals should report adverse events
- 'what' to report, and
- 'how' to report.

New Continuing Professional Development module received a 99.6% completion rate.

The CPD module achieved a strong completion rate of 99.6% within the first 8 months. The 3 largest participant groups were nurses and midwives, pharmacists and students. When asked to rate the satisfaction with 7 different learning outcomes, 90% of respondents reported that their needs were 'entirely met'.

A targeted communication campaign supporting the rollout reached health professionals and colleges, and included an explainer published in the journal *Australian Prescriber*.[24]

Raising public awareness of therapeutic goods

We continued to invest in public awareness campaigns and education targeting consumers, health professionals and industry, promoting the safe and effective use of therapeutic goods.

Awareness campaigns exceed Australian Government benchmarks for success.

In 2024-25, we delivered 9 paid public awareness and education campaigns focused on priority topics and emerging regulatory issues. These included paracetamol pack size changes, unapproved therapeutic goods, influencer and direct marketing, tools to manage medicine shortages, understanding complementary medicines, and recalls and market actions.

Each campaign reached large audiences and demonstrated the relevance and effectiveness of the TGA's communication efforts. Across the 9 paid campaigns, we achieved more than 61 million impressions and attracted over 25,000 visitors to the TGA website. Each campaign exceeded the

[24] Available at: https://australianprescriber.tg.org.au/articles/pharmacovigilance-in-australia-how-do-adverse-event-reports-from-clinicians-contribute-to-medicine-and-vaccine-safety.html

Australian Government benchmark for reach, impressions and engagement, including interactions such as sharing, commenting and reactions.

In addition to paid campaign activity, the TGA used a mix of communication channels, including social media and subscription newsletters, to enhance transparency and keep audiences informed of safety alerts, regulatory changes, updates and key initiatives.

We used creative and innovative content and channel strategies to ensure our campaigns reached and resonated with our target audiences. This included animated GP screens and pharmacy panels, shortform video for social media engagement, display advertising on websites where consumers are buying therapeutic goods, and tailored email content. We also developed several translated resources and delivered multi-lingual campaigns to reach culturally and linguistically diverse audiences.

Compliance education with industry

The TGA engaged effectively with industry, delivering education to key stakeholders to support improved compliance.

During 2024-25, we presented at conferences, training workshops and webinars, including:

- PTA's IVD training day
- Australasian Society of Aesthetic Plastic Surgeons
- the Australasian Society of Cosmetic Dermatologists symposium
- the 6th International Conference on UV and Skin Cancer Prevention- Sunscreen Workshop, and
- the Medical Technology Association of Australia (MTAA) advertising workshop.

The TGA's Advertising and Compliance Education Plan 2024-25[25] (the Plan) outlined planned education tools and activities and described our approach to identifying, engaging with and educating stakeholders about regulatory requirements. The Plan complements the broader therapeutic goods import, advertising, and supply compliance education strategy[26], which details the activities we undertake to maximise compliance and minimise inadvertent non-compliance with advertising requirements.

In line with the Plan, we redeveloped advertising-related content on the TGA website. Guidance materials and information published in the 2024-25 financial year included updated guidance/ frequently asked questions (FAQ) on advertising of health services[27], and information related to the PI Scheme.[28]

We commenced updates to several key advertising guidance documents and developed new guidance for priority areas. This included new material on advertising rules for prescription medicines and guidance on compounding exemptions. The updates provide greater clarity for advertisers to determine whether their content is advertising, as well as revised guidance for social media and health services advertising. These documents are progressing through consultation and will be published in 2026.

---

[25] Available at: www.tga.gov.au/resources/publication/corporate-reports/therapeutic-goods-advertising-and-compliance-education-plan-2024-25

[26] Available at: www.tga.gov.au/resources/publication/corporate-reports/therapeutic-goods-import-advertising-and-supply-compliance-education-strategy

[27] Available at: www.tga.gov.au/products/regulations-all-products/advertising/specialised-advertising-issues-and-topics/advertising-health-services-and-cosmetic-injections-frequently-asked-questions-and-answers

[28] Available at: www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/personal-importation-scheme

In 2024-25, we received 442 advertising-related enquiries through the advertising enquiry portal and dedicated email inbox. Most enquiries came from regulated entities seeking clarity on the correct interpretation of legislative requirements for advertising therapeutic goods. Like 2023-24, the TGA received numerous enquiries relating to the advertising of:

- medicinal cannabis products
- cosmetic injectables
- social media, and
- health services that may include therapeutic goods.

We also supported and promoted regulatory compliance through informational webinars. In August 2024, we delivered a webinar to help stakeholders to prepare for the regulatory changes that started on 1 October 2024 regarding compounded GLP-1 RA products. This webinar supported stakeholder readiness for change, complementing the updated guidance materials published following the announcement in May 2024.

The TGA also continued to publish media releases on compliance activities, in order to raise consumer awareness and act as a general deterrent to non-compliance.

Safety alerts

In 2024-25, we issued multiple safety alerts, including for counterfeit weight-loss (semaglutide or similar) and ivermectin products. Additional alerts addressed products containing undeclared substances such as sildenafil, tadalafil and related compounds.

Date published	Safety alert
22-Jul-24	Robust Extreme capsules
30-Sep-24	Suspected counterfeit Ozempic pens seized
28-Oct-24	Ivermectin (various brands)
28-Oct-24	Ziyinzhuangyang tablets
28-Oct-24	African Vigorous Max Strength
4-Dec-24	Gold Max Blue Capsules
4-Dec-24	MAXMAN tablets
4-Dec-24	Dynamint X tablets
3-Apr-25	Counterfeit Ozempic pens
3-Apr-25	Magnum XXL capsules
19-Jun-25	Nhan Sam Tuyet Lien Truy Phong Hoan Capsules
24-Jun-25	Counterfeit ivermectin
24-Jun-25	Counterfeit Fitaro Semaglutide
24-Jun-25	Counterfeit Roche- Laroscorbine Platinum
25-Jun-25	Counterfeit Rybelsus Semaglutide

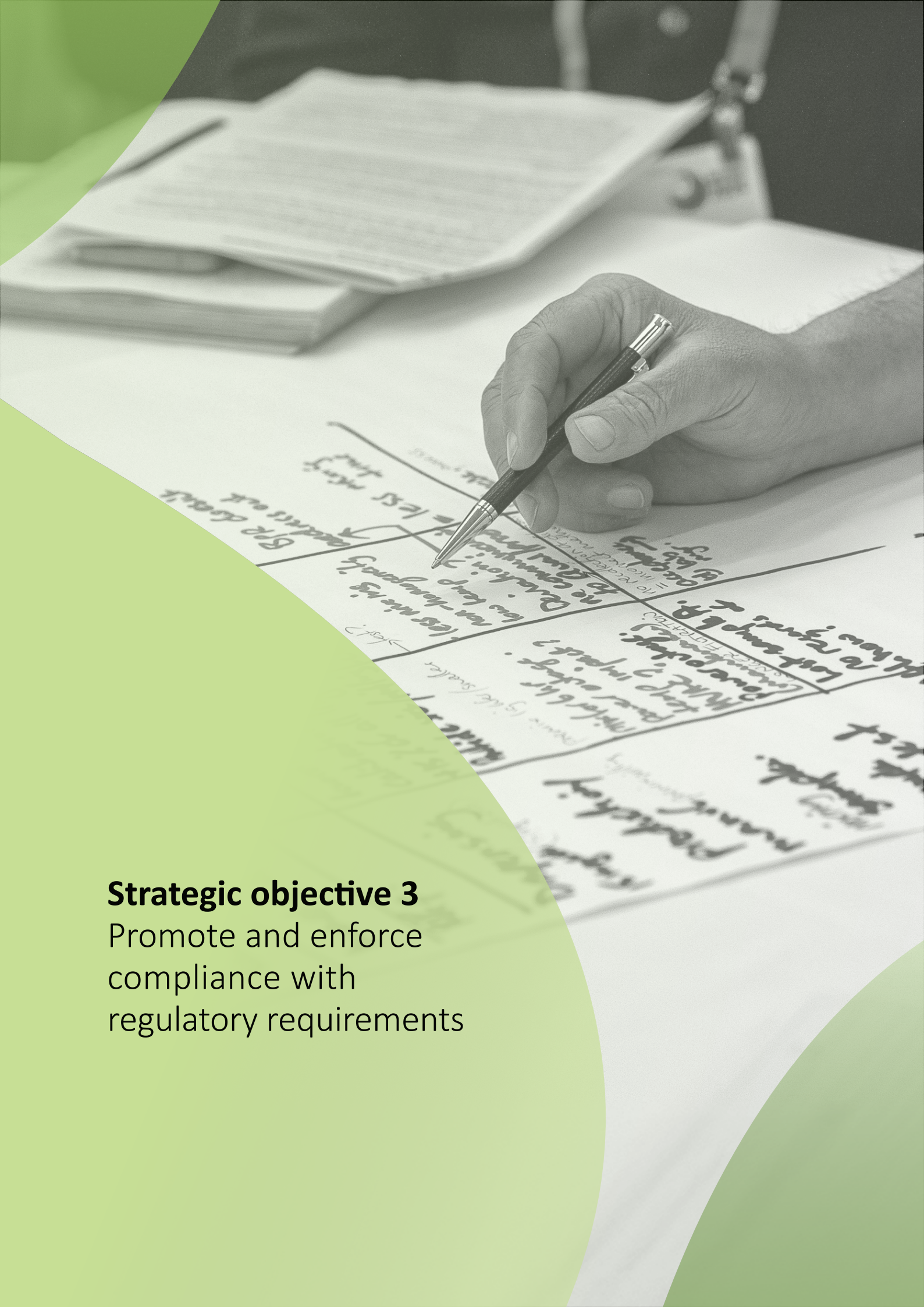
Efficiency of internal processes and decision-making

2f- Ensure internal preparedness and foster collaboration across all relevant business units to support decision-making and effective stakeholder engagement regarding emerging technologies

The TGA operates in a collaborative and cooperative manner. We recognise that sharing of information across the streams of work within TGA is essential for effective operations. Senior staff from evaluation and governance branches meet fortnightly to engage in a range of matters including emerging technologies. One example from 2024-25 was the consideration of combination and boundary products, which are therapeutic goods that combine elements of medicines, medical devices and/or biologicals. Through its Regulatory Policy and Practice Committee, which met 3 times in 2024-25, the TGA also:

- shares information and experiences to inform effective regulatory policy and operational work
- ensures consistency of advice and approaches (where relevant) across HPRG and the broader department
- explores emerging issues and strategic priorities including to address cross-cutting challenges, and
- supports continuous improvement.

In 2024, the department established a strong foundation for responsible AI adoption, guided by principles of transparency, accountability and ethical use. The TGA's internal systems are now equipped to integrate AI tools such as Microsoft Copilot, supported by robust governance and risk management frameworks. Human oversight remains central to all AI-generated outputs, ensuring decisions are transparent and trustworthy. The TGA continues to prioritise data security and legislative compliance to maintain integrity throughout implementation. These measures position us to leverage AI effectively, improve productivity and efficiency, and maintain public confidence.



Strategic objective 3
Promote and enforce compliance with regulatory requirements

The TGA promotes and monitors the quality, safety, efficacy and performance of therapeutic goods to support community confidence. The TGA continued its risk-based approach to monitoring, managing and enforcing regulatory compliance. It uses data and intelligence to identify instances of non-compliance, enabling timely and proportionate responses. The TGA assists businesses and individuals to comply with regulatory requirements and promote trust with the regulated community.

Guiding Principles

3.1 Use data and intelligence to identify and manage non-compliance risks

3.2 Prioritise and address serious non-compliance through a risk-based approach, and

3.3 Ensure proportional assessment of product safety, quality, efficacy and performance issues.

Insights from the TGA Stakeholder Survey

A national regulator's role in building trust and confidence in the regulatory system relies on its ability to promote and enforce compliance and communicate its compliance role.

The TGA Stakeholder Survey 2025 results indicate that stakeholders generally believe the TGA acts in response to non-compliance with therapeutic goods legislation. 72% of consumers and 74% of opt-in industry stakeholders agreed with the statement *'I am confident the TGA addresses serious, deliberate and repeated non-compliance'.*

Improving compliance with regulatory requirements

3a- Promote and enforce compliance with regulatory requirements through targeted education initiatives and risk-based, intelligence-informed enforcement activities

Activities to promote compliance with regulatory requirements include in-person conversations with sponsors, mass media campaigns, and targeted enforcement activities. In 2024-25, the TGA continued to respond to the changing compliance environment using risk-based approaches and data-informed analysis to identify non-compliance trends and guide targeted interventions. The TGA remains focused on its compliance priorities and working with enforcement partners to safeguard Australians and support sponsors to understand and meet regulatory requirements.

TGA compliance priorities

The TGA's Import, Advertising and Supply Compliance Priorities 2023-25[29] focused on detecting, deterring and disrupting non-compliance in 5 key areas:

- unlawful import, advertising and supply of nicotine vaping goods
- unlawful advertising of medicinal cannabis, psilocybine and MDMA
- unlawful supply and advertising of unapproved and high-risk medicines and medical devices used in the wellness and beauty industries, including those intended to alter the body's performance and appearance

[29] Available at: www.tga.gov.au/safety/compliance-and-enforcement/compliance-management-enforcement/import-advertising-and-supply-compliance-priorities-2023-25

- unlawful import and supply of substandard and falsified therapeutic goods with a particular focus on those products that declare, or otherwise are suspected to contain, higher risk substances that pose a risk to human health and/or safety, and
- unlawful import, advertising and supply of medicines and medical devices advertised as traditional or alternative treatments, particularly those that contain substances that pose a risk to human health and/or safety.

In 2024-25, the TGA maintained a robust risk-based approach by enhancing its regulatory compliance prioritisation tools, including updating the risk prioritisation matrix. These enhancements enable the TGA to prioritise reports of non-compliance effectively to inform timely, proportionate action. The TGA identifies non-compliance with the Act via various channels and mechanisms, including:

- community reports or complaints
- reports from other regulators, including state and territory regulators
- reports from health professionals or industry
- law enforcement agency advice, such as border and law enforcement, and
- proactive scanning.

Its analysis of therapeutic goods industries and observed non-compliance trends supports the TGA's identification of and response to non-compliance.

Promoting compliance with education and enhanced digital activities

4,835 digital platform removal requests issued.

The rapid advancement of technology and the rise of sophisticated, data-driven advertising campaigns have led to a significant increase in non-compliant advertisements. In 2023-24, we issued 4,835 digital platform removal requests. This figure surged to almost 13,500 in 2024-25, a 170% increase on the previous year. In 2024-25 the TGA also requested the removal of nearly 200 non-compliant advertiser profiles, reflecting our strengthened approach to managing both advertisements and advertiser accounts.

To address this increase, the TGA implemented a targeted compliance program in 2025. The program provides education and guidance to entities where alleged non-compliance with the Act has been reported. The TGA publishes guidance and sends targeted educational letters and factsheets to relevant industry sectors to build knowledge of legal obligations, maximise engagement and encourage voluntary compliance. The targeted letter campaigns are a new approach taken by the TGA, employing behavioural economic principles.

The first letter campaign was launched in May 2025. It focussed on the cosmetic injectables industry following increased concerns about unlawful advertising and other activity in the sector.

To further support this work, the TGA communicates program objectives and focus areas to relevant industry representatives through the TGACC[30] and other TGA fora. The program has had a positive response from industry, including those receiving targeted campaign letters. A number of recipients accessed the web resources and contacted the TGA for further guidance or clarification.

[30] Now called the Therapeutic Goods Advertising Consultative Forum.

The TGA also expanded its monitoring activities for digital platform advertising to include the ability to request the removal of entire online profiles. Previously, the TGA could only request the removal of single advertisements. This enhancement to our process is enabled through our strong collaboration with digital platforms and social media sites. It allows the TGA to act when a profile is identified as primarily engaging in the unlawful advertising of therapeutic goods. This capability supports the TGA's proactive online scanning and strengthens our approach to detecting and addressing unlawful advertising.

The TGA received over 32,000 referrals, reports, and tip-offs in 2024-25.

Using powers under Section 313(3) of the *Telecommunications Act 1997*[31], the TGA continued its work to disrupt websites containing unlawful content surrounding therapeutic goods. In 2024-25, over 300 websites were redirected to the TGA website landing page. The "Website blocked" message[32] provides information on why the redirection has occurred, providing opportunistic public education on our regulatory role.

The TGA actively monitors the global impacts of the rapidly evolving digital landscape, and potential consequent increases in unlawful advertising. We will continue to work with digital platforms to address non-compliance as it is identified, and to proactively monitor online content.

Promoting compliance for AI medical devices

The TGA engaged with Government agencies and industry bodies commissioning and developing SaMD and AI medical devices, to promote compliance with regulatory requirements. Compliance activities target the advertising and supply of SaMD that is not included on the ARTG. This will include reviewing digital scribes that have additional features, such as diagnostic and therapeutic functionality.

Non-compliance referrals

Where non-compliance with therapeutic goods advertising, import, export, manufacture or supply requirements is suspected, the TGA uses proportionate regulatory action to achieve compliance. We also address repeated, deliberate and serious non-compliance activities. We collaborate with local and international health and law enforcement agencies and other regulators as required and appropriate.

The TGA received over 32,000 non-compliance referrals, reports and tip-offs in 2024-25, doubling the amount of the previous year. We also continued to refer a high volume of goods for destruction by the ABF following our assessment.

Deter and disrupt unlawful advertising of medicinal cannabis, psilocybine and MDMA

Public promotion and unlawful advertising of prescription medicines may inappropriately influence demand, disrupt the relationship between patients and medical professionals, and bring disrepute to the industry. It also risks delaying consumer access to appropriate care should they not seek appropriate medical assistance.

This is particularly the case for medicinal cannabis, psilocybine and MDMA which are almost entirely accessed as unapproved therapeutic goods.

[31] s313(3) requires that carriers and carriage service providers give officers and authorities of the Commonwealth, states and territories such help as is reasonably necessary to enforce the criminal law and laws imposing pecuniary penalties- TELECOMMUNICATIONS ACT 1997- SECT 313 Obligations of carriers and carriage service providers (austlii.edu.au)

[32] Available at: www.tga.gov.au/website-blocked

Medicinal cannabis

In 2024-25, the TGA acted against several entities regarding the unlawful manufacture and advertising of medicinal cannabis products. We have seen a continued trend of media, industry and public queries regarding medicinal cannabis advertising.

Alleged unlawful advertising of medicinal cannabis

In 2024-25 the TGA considered that 2 media outlets allegedly published online articles that unlawfully advertised medicinal cannabis. This was part of a public relations campaign by an online medicinal cannabis clinic, assisted by a public relations company. The clinic also allegedly advertised medicinal cannabis on its website and social media pages.

Advertising prescription medicines, including medicinal cannabis, to the public can create an inappropriate demand for these medicines and undermine the relationship between a patient and their treating health practitioner. Appropriate treatment options should be determined by a health professional in consultation with their patient. The advertisements allegedly promoted the use or supply of medicinal cannabis, including for the treatment of serious diseases, conditions or disorders.

Some advertisements allegedly included a range of euphemisms for medicinal cannabis, such as 'plant medicine'. They also allegedly included endorsements from health professionals and persons involved in the marketing of medicinal cannabis, in breach of the Therapeutic Goods Advertising Code.

The director of the clinic allegedly facilitated the preparation of the media articles and approved their publication.

We commenced civil penalty proceedings in the Federal Court of Australia against all the persons and entities mentioned for the alleged unlawful advertising.

Over this reporting period, the TGA:

- commenced civil penalty proceedings[33] against several entities for alleged unlawful advertising of medicinal cannabis
- issued 3 infringement notices totalling over $50,000 to a media outlet[34] for alleged unlawful advertising of medicinal cannabis
- issued 4 infringement notices totalling over $75,000 to an entity[35] for the alleged unlawful manufacturing of medicinal cannabis products, and
- removed several unlawful advertisements of medicinal cannabis products from digital platforms.

[33] See media release: www.tga.gov.au/news/media-releases/atlus-mamamia-and-news-life-media-face-court-alleged-unlawful-advertising-medicinal-cannabis

[34] See media release: www.tga.gov.au/news/media-releases/news-life-media-fined-alleged-unlawful-advertising-medicinal-cannabis

[35] See media release: www.tga.gov.au/news/media-releases/summit-pharmacy-pty-ltd-issued-infringement-notices-alleged-unlawful-manufacturing-medicinal-cannabis-products

Psilocybine and MDMA

Throughout 2024-25, the TGA continued to action reports of non-compliance related to psilocybine and MDMA. We engaged with industry on their regulatory obligations through targeted meetings, formal communications and warning letters. We also proactively monitored online platforms and other channels to ensure potential advertising issues were addressed promptly. The TGA issued several warning letters for alleged unlawful advertising, resulting in voluntary compliance in most cases.

Therapeutic goods in the wellness and beauty industry

Therapeutic goods used in the wellness and beauty industry include medications or medical devices intended to alter the body's appearance. Examples include cosmetic injectables, weight loss medications, skin tanning injections and nasal sprays, IV drips and vitamin injections. These may include prescription-only medicines, which are prohibited from being advertised directly to consumers.

Consumers seeking to enhance their physical performance or appearance may be more vulnerable to advertisements promoting therapeutic goods, particularly those boasting health, physical and performance benefits. Non-surgical enhancements using cosmetic injections, such as dermal fillers, are increasing in popularity in Australia. In response, the TGA issued revised guidance on advertising rules and safety warnings to help consumers better understand the risks and considerations associated with these treatments.

The TGA continues to see unlawful activity in the advertising of these types of therapeutic goods. We have publicly detailed our concerns through safety alerts and guidance on our website, to inform consumers of the risks associated with seeking information or purchasing therapeutic goods online without appropriate consultation with their treating health practitioner.

Our monitoring and investigation activities confirm the continued import of cosmetic injectable and weight-loss products. We have identified counterfeit botulinum toxin and semaglutide products, further highlighting the risks in consumers accessing such treatments without adequate medical advice.

In 2024-25, the TGA:

- conducted warrant activity in response to the alleged import, supply, manufacture and advertising of semaglutide products
- issued 18 infringement notices valued at more than $245,000 to various telehealth businesses for alleged unlawful advertising of wellness and beauty products, primarily weight loss, on websites
- accepted an enforceable undertaking from an entity[36] regarding advertising of prescription-only compounded medicines for weight loss, and
- removed over 3,000 unlawful advertisements of wellness and beauty therapeutic good products from digital platforms sites, predominantly cosmetic injectable, weight-loss, and skin tanning products.

[36] See media release: www.tga.gov.au/news/media-releases/your-solution-compounding-pharmacy-undertakes-comply-advertising-rules-weight-loss-medicines

Advertising prescription-only medicines

We considered that multiple businesses and individuals unlawfully advertised prescription-only medicines on websites and online order forms.

The advertisements allegedly:

- promoted the use and supply of weight loss and erectile dysfunction medicines such as Ozempic, Mounjaro, Saxenda and Viagra, and Schedule 4 substances such as semaglutide and tirzepatide
- contained unapproved references to the treatment of serious diseases or conditions, and
- implied the goods had been recommended or approved by a government or government authority.

Advertising prescription-only medicines directly to consumers is prohibited, as it could create an inappropriate demand for these medicines and lead to unnecessary or harmful prescribing.

The businesses and individuals, including online telehealth clinics, paid over $245,000 in infringement notices given by the TGA. We also accepted a court-enforceable undertaking from an online pharmacy.

Other compliance priorities and activities

Alternative and other treatments

The TGA maintained its focus on unregistered therapeutic goods marketed to consumers as traditional or alternative treatments. These goods may contain higher-risk substances including poisons, heavy metals, and Schedule 4 and Schedule 8 medicines. Consumers who are facing a serious disease or condition with limited treatment options may be particularly vulnerable to advertising claims.

Over the reporting period the Commonwealth Office of the Director of Public Prosecutions (CDPP) laid 12 charges against an individual for alleged criminal offences under the Act following a TGA investigation regarding the advertisement and supply of black salve products and other unapproved therapeutic goods.[37]

[37] See media release: www.tga.gov.au/news/media-releases/individual-charged-alleged-illegal-supply-and-advertising-black-salve-products

In 2024-25, the TGA:

- issued an infringement notice valued at over $18,000 to an entity[38] for the alleged unlawful supply of Thorne Basic Prenatal capsules not registered on the ARTG
- accepted a court-enforceable undertaking from an entity[39] in relation to the alleged unlawful manufactured, supply and advertisement of an unregistered prescription-only strength Vitamin D3 (colecalciferol), and
- accepted a court-enforceable undertaking from an entity in relation to the unlawful import and supply of unregistered bacterial vaginosis tests and pregnancy test kits.

Investigation leading to criminal charges being laid

The TGA considered that an individual illegally advertised and supplied black salve, bloodroot capsules and other unapproved therapeutic goods.

The individual allegedly made claims about the products' ability to treat serious health conditions, including anxiety and cancer.

The TGA has strongly advised consumers against purchasing or using black salve or bloodroot capsules. There is no credible scientific evidence to substantiate the benefits of these products for the management of serious conditions, and serious harm may result from their use.

Following an investigation, we referred the individual to the CDPP for consideration of criminal prosecution.

The CDPP laid 12 criminal charges against the individual for alleged offences under the Act.

Falsified and counterfeit goods

The TGA actively monitored for any indicators of substandard, falsified or counterfeit products within Australia. In line with current compliance priorities, we worked with domestic and international partner agencies to reduce the risk of counterfeit products entering Australia.

Through our frequent collaborations with the ABF, counterfeit goods were identified, intercepted at the border and thus prevented from being imported, with safety alerts issued to the public when required. We also monitored international signals of products and emerging risks.

[38] See media release: www.tga.gov.au/news/media-releases/nourishmeorganics-pty-ltd-issued-infringement-notice-alleged-unlawful-supply-therapeutic-good

[39] See media release: www.tga.gov.au/news/media-releases/aussie-gelatin-company-undertakes-comply-rules-manufacture-supply-and-advertising-therapeutic-goods

In 2024-25, the TGA:

- seized counterfeit weight loss injections, unregistered and counterfeit ivermectin, and erectile dysfunction medicines detected by the ABF[40]
- tested a number of substandard, counterfeit and falsified products in the TGA Laboratories
- issued several safety alerts regarding intercepted and identified counterfeit and sub-standard products[41], and
- made 13 reports into the WHO's Global Surveillance and Monitoring System (GSMS).[42]

Counterfeit Ozempic

The TGA received a referral regarding 2 unique consignments purporting to contain genuine, branded Ozempic products. The products were purchased online from an overseas website and imported.

On evaluation, packaging inconsistencies were identified and, on engagement with the product's manufacturer, item batch numbers were confirmed as counterfeit. There was also a separate adverse event associated with the use of an Ozempic pen purchased offshore.

Knowingly importing, supplying and/or giving away counterfeit therapeutic goods is illegal. It poses a significant public health and safety risk.

In addition to seizure of the products, laboratory testing was completed, and reports were submitted to the WHO GSMS. Safety alerts were issued in relation to these products as soon as the counterfeit status was confirmed.

Compliance of listed medicines

'Listed medicines' refers to medicines on the ARTG denoted by an 'AUST L' number. These medicines are categorised as relatively lower risk than other medicines, as they can only contain pre-approved ingredients and indications as stipulated by the relevant determinations. Since they do not undergo pre-market evaluation, the TGA safeguards consumers by undertaking appropriate post-market compliance activities.

In 2024-25, the TGA took a total of 896 compliance and enforcement actions on listed medicines, ranging from low level education to higher level actions such as infringement notices and market actions. Of medicines receiving a low to medium level action, 72% were brought into compliance by their sponsor. Our compliance activities facilitated outreach to 32% of sponsors of listed medicines in 2024-25.

[40] Seized products included products with undeclared API that pose a risk to human health.
[41] Safety Alerts are available at: www.tga.gov.au/safety/safety-monitoring-and-information/safety-alerts
[42] The goal of the WHO GSMS is improving the quantity, quality and analysis of accurate data concerning substandard and falsified medical products, and to use that data in the better prevention, detection and response to those products, to protect public health, globally. The TGA is an Australian focal point for the WHO GSMS.

Supporting voluntary compliance for listed medicines

To support voluntary compliance for listed medicines, we conducted 4 targeted educational campaigns for medicines that were at risk of non-compliance in 2024-25. Focus topics included:

- medicines at risk of non-compliance with evidence requirements due to having a large number of therapeutic claims
- medicines at risk of non-compliance with presentation requirements due to their potential to encourage excessive or harmful consumption of alcohol
- stability requirements for listed medicines, and
- limits for elemental impurities in TCM.

These activities reached sponsors of over 250 listed medicines, raising awareness of how non-compliance can arise.

ARTG scanning

Throughout 2024-25, we continued weekly ARTG scanning to review newly listed medicines for potential non-compliance, before sponsors are likely to begin marketing their medicines. This early engagement allowed sponsors to address compliance issues in a timely and proactive manner.

Targeted compliance actions

The TGA continued to centre targeted compliance efforts for listed medicines in areas that may pose a risk to the integrity of the post-market framework or consumer safety. For example, we conducted 45 targeted reviews of listed medicines to ensure compliance, as non-compliance with mandatory warning statement requirements can result in adverse health outcomes for consumers.

Our focus included compliance with mandatory warning statements that are required for medicines containing *Valeriana officinalis*, helping to mitigate risks of potential liver harm. Another focus was compliance with mandatory warning statements that are required for medicines using indications related to diarrhoea. Listed medicines with names that implied a non-permitted therapeutic use and sponsors with a history of non-compliance were also a focus.

The TGA conducted several investigations into alleged or suspected non-compliant products, including one investigation that resulted in a market action involving over 50 listed medicines.

Compliance of medical devices

The TGA monitors the safety and performance of medical devices included on the ARTG through adverse event reports, annual reporting, engagement with other regulators, and horizon scanning. We apply a risk-based approach addressing identified safety, compliance and behavioural issues.

Identified concerns are addressed via meetings and targeted education with sponsors and manufacturers. For issues that involve a risk to patients, our approach may also include relevant market and regulatory actions to remove devices with an unacceptable risk of harm.

Where the TGA identifies significant breaches of the Act, it may address these with proportionate fines or by applying to the Court for civil penalties. In 2024-25, the Court ordered a sponsor to pay $22 million, the largest ever penalty for unlawful supply of therapeutic goods.[43]

[43] Available at: www.tga.gov.au/news/media-releases/medtronic-australasia-pty-ltd-ordered-pay-22-million-largest-ever-penalty-unlawful-supply-therapeutic-goods

$22 million penalty for unlawful supply of therapeutic goods

The Federal Court of Australia ordered a sponsor to pay $22 million in penalties for unlawfully supplying 16,267 units of a therapeutic good between 2015 and 2020.

The Court's judgment comes after the TGA commenced proceedings against the sponsor in August 2021. The Court also ordered that the sponsor pay $1 million as a contribution to the TGA's legal costs.

Sponsors should take their obligations seriously and be aware that import or supply of unauthorised goods can result in significant penalties.

The TGA continues to monitor all situations of unlawful supply of therapeutic goods.

Post-market reviews and investigations of medical devices

The TGA continued to review annual reports submitted by sponsors for Class IIb implantable medical devices, Class III medical devices, and Class 4 IVD medical devices. This enabled us to ensure compliance with conditions of these products' ARTG inclusion. During 2024-25, we issued 49 notices of proposal to take regulatory action on sponsors who failed to submit annual reports within legislated timeframes. Several products were removed from the ARTG following the TGA-initiated action.

Throughout 2024-25, we conducted post-market reviews across a range of medical devices to assess their continued safety and performance. These included reviews of energy-based vaginal rejuvenation devices, ventilators, sleep apnoea devices, SCS, plastic syringes, and avian influenza A nucleic acid tests.

Following post-market review of energy-based vaginal rejuvenation devices, the TGA cancelled 10 ARTG entries due to insufficient evidence of compliance with the Essential Principles. A further 2 ARTG entries were voluntarily withdrawn by the sponsors.

A further 4 SCS devices were cancelled from the ARTG and we imposed stringent conditions on 29 other SCS devices to improve their ongoing safety and performance. These actions are part of our post-market review of SCS devices. While this review has now concluded, we will continue to monitor all new applications for market authorisation for devices of this kind to ensure safety and performance in accordance with the Essential Principles.

We also coordinated with sponsors of 2 avian influenza A tests to voluntarily update the instructions for use, after identifying issues with the ability of these tests to detect relevant avian influenza strains and clades.

Collaboration with co-regulators and enforcement agencies

3b- Collaborate and continue to build relationships with co-regulators and other local and international health and law enforcement agencies

The TGA continued to work closely and collaborate domestically and internationally with relevant stakeholders, including regulators, law enforcement and other agencies.

In 2024-25, we collaborated with a range of entities, including:

- state and territory health departments
- law enforcement agencies including the ABF, state and territory police services, and the Australian Federal Police
- the Australian Criminal Intelligence Commission
- the Australian Health Practitioner Regulation Agency
- the Australian Competition and Consumer Commission
- Sports Integrity Australia
- the Australian Pesticides and Veterinary Medicines Authority
- the Australian Industrial Chemicals Introduction Scheme
- the Office of the Gene Technology Regulator
- the Office of Drug Control (ODC)
- other Australian Government departments such as the Department of Agriculture, Fisheries and Forestry and the Department of Climate Change, Energy, the Environment and Water
- the New South Wales Health Care Complaints Commission, Victorian Health Complaints Commissioner, and Queensland Office of the Health Ombudsman, and
- INTERPOL.

Our strong partnership with the ABF remains critical to an effective regulatory compliance program.

Our engagement included mutual assistance with executing search warrants and regulatory inspections, consultation on updated guidance materials, and lawfully sharing information relevant to investigations.

The TGA works with domestic and international agencies to detect, intercept and investigate unlawful therapeutic goods imported into Australia. Our strong partnership with the ABF remains critical in building and applying an effective regulatory compliance program.

The TGA's participation in domestic and international fora continues to strengthen its relationships and compliance response capability. We participated in several domestic conferences related to medicinal cannabis, cosmetic injectables, complementary medicines and other matters relating to therapeutic goods and regulatory compliance.

We also attended and spoke at the:

- Permanent Forum on International Pharmaceutical Crime, an international enforcement forum aimed at protecting public health through the exchange of information and ideas to foster mutual cooperation
- Global Programme on Criminal Network Disruption of the United Nations Office on Drugs and Crime expert group meeting on Strategic and Tactical Interventions to Address Medical Products Related Crimes
- Dental Amalgam Working Group, and
- WHO's Global Surveillance and Monitoring System Focal Point Network.

Strengthening regulatory compliance through ANAO recommendations

3c- Implement the agreed recommendations from the Australian National Audit Office Performance Audit of the TGA's regulatory compliance activities

As reported in 2023-24, the TGA implemented 4 of the 6 recommendations from the Australian National Audit Office (ANAO) audit of the *Management of non-compliance with the Therapeutic Goods Act (1989) for unapproved therapeutic goods*.[44] The remaining 2 recommendations relate to matters that are relevant to the whole department.

Recommendation 1 called for the department to review its annual reporting performance information for its regulation of therapeutic goods, to ensure the information is appropriate and covers the significant components of its key activities. The TGA updated processes relating to the calculation of the performance measure 1.8A for implementation in 2025-26. We have commenced a significant review and uplift of our performance reporting to capture the TGA's activities in the departmental corporate reporting documents.

Recommendation 5 related to complaint handling channels. In 2024-25, the TGA established a clear and easily accessible complaint handling channel by adding a complaint submission webpage and form to our website.

[44] Available at: www.anao.gov.au/work/performance-audit/therapeutic-goods-administration-management-non-compliance

Supporting government vaping reform through compliance and communication

3d- Enforce the changed regulatory requirements for vaping goods in accordance with the Australian Government's reform program across 2024, ensuring effective communication strategies are in place to educate stakeholders on compliance obligations

Throughout 2024-25, the TGA enforced revised regulatory requirements for vaping goods as part of its comprehensive reform program. This included implementing new laws and standards that prohibited the domestic manufacture, importation, supply and advertising of non-therapeutic and disposable vapes, while maintaining access to therapeutic vapes under specific conditions.

To support compliance, the TGA developed and delivered targeted communication strategies to educate stakeholders about their obligations under the new regulations. This included consumers, prescribers, pharmacists, importers, manufacturers, wholesalers and retailers. These strategies provided detailed guidance on regulatory changes, notification requirements and enforcement measures. We also conducted reviews of therapeutic vaping goods to assess compliance by sponsors and products.

The TGA enhanced its enforcement powers to investigate non-compliance, seize unlawful products, and apply penalties for violations. Public awareness campaigns and stakeholder engagement activities clarified new restrictions such as advertising bans and flavour limitations on therapeutic vapes. These included media releases, industry webinars, external communications and the online enforcement hub.

Enforcement activities throughout the year were supported by a strong communication framework that promoted understanding and adherence to the updated vaping regulations. These efforts ensured that the objectives of the reform program were achieved across all sectors involved in the lawful supply and regulation of vaping goods.

The TGA conducted over 6,000 investigations conducted into suspected breaches of vaping restrictions.

Using intelligence to identify suspected breaches, the TGA conducted over 6,000 investigations into activities such as the illegal importation, advertising and supply of vaping goods. This often involved close collaboration with government bodies and law enforcement agencies to share information, coordinate operations and strengthen enforcement across jurisdictions.

Compliance and enforcement actions included issuing educational notices, requesting internet providers to block unlawful websites, seizing unlawful products at the border, and removing illegal advertising from social media and digital platforms. TGA investigators applied the enhanced powers granted under the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024,* enabling them to pursue non-compliance, share intelligence, and impose civil and criminal penalties.

These combined efforts strengthened the national compliance environment and ensured that regulatory requirements were clearly communicated and consistently upheld across all sectors involved in the lawful supply of vaping goods.

Strategic objective 4
Innovate and
continuously improve

Innovation and continuous improvement are woven through the work and culture of the TGA. We continuously improve our performance by building staff capability and identifying and implementing improved practices. In 2024-25, we have enhanced digital tools and online platforms to improve usability and accessibility. We also strengthened internal systems and business processes ranging from the work in our laboratories to our desktop evaluations.

Guiding Principles

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

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

Insights from the TGA Stakeholder Survey

The TGA is committed to innovation and continuous improvement, and this is reflected in the results of the TGA Stakeholder Survey 2025.

The survey showed that 59% of industry respondents noticed improvements in the TGA's systems and processes, with the most common being 'timeliness or quality of responses to enquiries' (27%) and 'new and updated regulatory information and guidance' (27%). Improvements to the TGA website were mentioned by a quarter of respondents (25%), recognising work over the past 12 months to improve the website content and usefulness[45].

Reflecting innovations in the regulatory environment, new questions were added to the 2025 survey, including exploring respondents' awareness of our role in regulating AI as a medical device. Other new questions sought more information on respondents' understanding and perception of the way therapeutic goods are advertised through telehealth services and when therapeutic goods are referred to by colloquial names.

Adapting the survey to an evolving regulatory environment demonstrates our commitment to continuously improving processes so that they are fit for purpose and continue to yield useful insights.

Delivering modern digital tools for regulatory processes

4a- Enhance and continuously improve digital tools and platforms to provide a user-centred, modern digital service experience

The TGA progressed modernisation of the Adverse Event Management System through its Medicine Adverse Event Data Exchange program, preparing for full transition of its data model to the cloud. This will continue into 2025-26.

The TGA also built on previously delivered digital platform improvements to design the ASDER solution for healthcare facility medical device adverse event mandatory reporting. We engaged extensively with stakeholder groups to ensure transparency of how information provided for medical devices is used, including by designing digital tools and analytics platforms for both internal and external users.

In July 2024, the department launched the Health Business Services Portal (HBSP). The first users were onboarded, enabling businesses engaging with the ODC to process Narcotics Drug and Medicinal Cannabis Licence applications. This initial release provided an opportunity for feedback from industry, with enhancements being incorporated into the next iteration of the HBSP for both the ODC and the TGA.

---

[45] Available at: www.tga.gov.au/resources/publication/corporate-reports/tga-stakeholder-survey-report-2025 ; page 17

Since the launch of the HBSP, the TGA has progressed with building a new, more user-friendly and stable service management layer that will replace the existing TGA Business Services Portal, known as TGA Business Services. Throughout 2024-25, the TGA engaged with the Industry Working Group and other stakeholders through user research and testing to shape the features and functionality under development. The TGA has also progressed its program to modernise internal systems, including the case management system used to process industry applications.

The TGA will continue to explore future solutions throughout 2025-26 as part of the TGA digital transformation agenda.

Enhancing the Special Access Scheme and Authorised Prescriber Online System

4b- Enhance the Special Access Scheme and Authorised Prescriber Online System to uplift performance, usability and accessibility, while reducing the burden on health professionals

The SAS and the AP Scheme are 2 pathways allowing the import or supply of therapeutic goods not included in the ARTG. These are known as unapproved therapeutic goods, and may include medicines, medical devices or biologicals.

SAS allows prescribing for a single patient on a case-by-case basis. Any unapproved therapeutic good may be supplied through the SAS, although drugs listed in Schedule 9 of the Poisons Standard remain prohibited in most states and territories.

The AP scheme enables medical practitioners to prescribe unapproved therapeutic goods to a defined class of patients with a particular medical condition.

During 2024-25, access to unapproved therapeutic goods continued to increase, with the combined total of SAS notifications and applications for medicines and medical devices growing by 40% from the previous year.[46] This shows an increasing reliance on the SAS and AP scheme to meet patient needs not addressed by approved products.

The TGA continued to enhance the SAS and AP Online System to improve performance, usability and accessibility, while reducing the administrative burden on healthcare professionals. The updated system and processes streamlined the submission pathways for accessing unapproved therapeutic goods and includes features such as real-time submission tracking, submission cloning, and integrated reporting tools.

Key improvements included:

- completing the move to online-only submissions by October 2024 for improved data quality, reduced processing times and more efficient compliance monitoring
- introducing new functionality to support hospital pharmacy teams and allow administrative accounts to manage applications and collaborate more effectively across departments
- updating the SAS and AP system to align with changes to the NSW medicinal cannabis prescribing requirements ensuring consistency with state legislation

[46] Further data, including comparison data 2023 and 2024 is provided in the Appendices.

- updating email and decision letter templates for currency and clarity, strengthening communication with stakeholders, and
- developing a suite of short instructional videos to support users navigating the system.

Further application form instructions, system user guides and health practitioner guidance materials were updated to improve clarity and reduce reliance on helpdesk support.

Future enhancements are under review, exploring further system improvements including integration, reporting tools, and accessibility upgrades.

Modernising TGA Laboratories

4c- Improve the technology, systems and business processes of TGA Laboratories through the implementation of an integrated and unified laboratory software solution

During 2024-25, TGA Laboratories completed the design and build of a new integrated and unified laboratory software solution. The new system, which commenced in August 2025, supports improved sample and consumables management, environmental monitoring, stability management, and data retrieval and reporting functionality.

TGA staff working in the laboratory

Improving management of evaluation activities

4d- Enhance our ability to manage an increasing number of evaluation activities by streamlining processes, leveraging technology, and fostering collaboration with stakeholders, including by implementing updated guidelines and holding regular meetings with sponsors and peak bodies to ensure understanding of current regulatory requirements

Strategic Objective 2 focused on stakeholder engagement to build transparency and trust. This engagement also provides opportunities to improve how we manage increasing application volumes and complexity, and support stakeholders' understanding of regulatory requirements.

New training modules for improved evaluation processes.

Regular fora and meetings provide critical access points for stakeholders to raise regulatory concerns directly with the TGA. Our reform program was informed by valuable feedback from industry representatives at regular meetings with Medicines Australia's Regulatory Affairs Working Group.

In 2024-25, we developed a series of internal training modules for OTC medicine evaluators to strengthen onboarding processes and improve consistency in evaluations.

We also updated existing guidance and developed new educational tools to support sponsors in compiling high quality applications. These resources improve processing and evaluation efficiency while ensuring sponsors understand their regulatory obligations. In April 2025 the TGA published updated online guidance *Understanding Labelling and Presentation Requirements for Listed Medicines*[47], which provides detailed information on regulatory requirements for medicine labels and overall presentation.

Streamlining processes and improving understanding of regulations

Awareness campaigns foster understanding of and compliance with new regulations. In 2024-25, the TGA delivered several public awareness campaigns to help businesses and individuals meet their obligations under the Act. As an example, the vape surrender scheme public notice educated the public and retailers about their responsibilities under new vaping regulations and outlined options for surrendering non-compliant products. This campaign generated more than 6.4 million impressions and resulted in nearly 8,000 visits to the TGA website.

The TGA regularly engaged with key stakeholders to strengthen understanding of regulatory requirements for medical devices, including IVDs. We participated in meetings convened by the MTAA, and learning fora hosted by PTA. Our presentations on topics such as the Essential Principles and the importance of high-quality submissions and responses to information requests were well received by participants.

We supported industry by improving regulatory clarity and streamlining processes for medical device applications. On 1 July 2024, following public consultation and legislative amendments, the TGA introduced a new risk-based application audit framework (AAF) for medical device applications. Mandatory audits now only apply to higher-risk devices lacking approvals from comparable

[47] Available at: www.tga.gov.au/resources/guidance/understanding-labelling-and-presentation-requirements-listed-medicines

overseas regulators. We clarified the criteria for selecting applications for non-mandatory audits and streamlined the process to enhance timelines and communication. To support these reforms, the TGA co-developed guidance with industry.

The TGA also commenced a project to reform the management of changes to existing entries in the ARTG. A time-limited working group is reviewing the definition of variation requests, the appropriate level of regulatory review, and the circumstances under which a new application is required, particularly for sponsors relying on approvals from comparable overseas regulators.

The TGA participated in 2 meetings of the Access Consortium pharmacovigilance working group in 2024-25. This new collaboration was initiated in February 2025. We regularly review international pharmacovigilance guidelines and incorporate relevant practices into our processes, where appropriate. The TGA contributed to 2 submissions involving risk management plan (RMP) work-sharing during 2024-25.

Our new signal assessment and prioritisation process, reported under Strategic Objective 1d, is a further example of a streamlined process to ensure timely action on medicines safety issues.

WHO-Listed Authority

4e- Transition from Stringent Regulatory Authority (SRA) to WHO-Listed Authority, under the WHO's assessment framework

Launched in March 2022, the WHO-Listed Authority (WLA) framework transparently designates NRAs that operate at an advanced level of performance, replacing the previous list of Stringent Regulatory Authorities (SRAs). WLA designation facilitates global access to safe, effective, and quality-assured medical products, and encourages regulatory harmonisation to enhance global health governance.

In 2024-25, the TGA was a transitional WLA, given its previous status as an SRA. Achieving WLA designation would uphold the TGA's position as a mature regulator, meeting international standards for ensuring the quality, safety, and efficacy of therapeutic goods.

Achieving WLA status would also promote reliance and trust in the TGA globally, allowing the TGA to continue to collaborate, workshare, and exchange information with other respected medicines regulators. This ultimately facilitates decision-making, reduces duplication, and improves regulatory efficiency.

As a previously listed SRA, the TGA continued to undergo evaluation via the WHO's Abridged Tool, covering 65 total indicators across key regulatory functions to become a WLA.

Appendices

The Appendices provide detailed statistical information on our performance during 2024-25

1. Prescription medicines

Applications for new or variations in prescription medicines is supported by scientific evidence, within legislated time frames and associated business rules.

The framework for prescription medicines includes the following categories, which are subject to legislated and/or target timeframes:

Table 1: Categorisation of prescription medicine applications

Application category	Description	Timeframe in working days
Category 1	An application to register a new prescription medicine (other than an additional trade name) or to make a variation to an existing medicine that involves the evaluation of clinical, preclinical or bio-equivalence data. For example, new chemical entities, extensions of indication and new routes of administration.	Legislated timeframe: 40 working days for notification of whether the application has passed preliminary assessment and 255 working days for the completion of the evaluation and notification of the decision. For the priority review pathway, the target timeframe is 150 working days.
Comparable Overseas Regulator (COR) report-based process	An application accompanied by an unredacted assessment report package from a comparable overseas regulator.	Legislated timeframe: 40 working days for notification of whether the application has passed preliminary assessment. The timeframe for completion of the evaluation and notification of the decision depends on the COR pathway: COR- A[a]: 120 working days COR- B[a]: 175 working days
Category 3	An application to register or to vary the registration of a prescription medicine where the application does not require the support of clinical, preclinical or bio-equivalence data. For example, broader changes to the product specifications, manufacturing and labelling or a change in trade name.	Legislated timeframe: 45 working days to notify the applicant of the decision.

[a] Under COR-A, the TGA regulatory decision will be based on a critical review of the COR assessment reports and an evaluation of the Australian label, Product Information and where required, the RMP. Under the COR-B approach, the TGA regulatory decision will still be mostly based on a critical review of the COR assessment reports, and where required, the RMP.

Application category	Description	Timeframe in working days
Correction to, or completion of, a Register entry	An application to vary the registration of a prescription medicine to correct or complete information that was inadvertently recorded incorrectly or omitted from the Register entry. For example, errors to product information, or quality-related documentation.	No legislated timeframe: the TGA processes as soon as possible.
Safety-related request (SRR)	An application to vary the registration of a prescription medicine to either: reduce the patient population that can receive the medicine or add a warning or precaution.	No legislated timeframe: the TGA processes as soon as possible.
Notification request to vary an ARTG entry	An application to vary the registration of a prescription medicine, where the application has been determined to pose a very low risk under certain conditions. For example, the removal of a redundant manufacture site.	No legislated timeframe: automatic approval on submission of e-form and full payment of fee.
Self-assessable request (SAR)	An application to register or to vary the registration of a prescription medicine where the application: does not require the support of clinical, preclinical or bio-equivalence data and where no data are necessary or where the data can be self-assessed by the applicant. For example, certain changes to the pack size or approved product label.	Legislated timeframe: 45 working days for notification of acceptance or rejection of an application, completion of evaluation and notification of the decision.
Additional trade name	An application for an additional trade name for a registered prescription medicine.	Legislated timeframe: 45 working days.

1.1 Submission outcomes

Table 2: Number of completed prescription medicine submissions by type and outcome

Application type	Number approved	Number withdrawn	Number rejected	Total (% approved)
Category 1				
A: New chemical entity/ New biological entity/Biosimilar [a]	62	6	1	69 (89.9%)
B: New fixed-dose combination	2	0	0	2 (100%)
C: Extension of indication	66	2	0	68 (97.1%)
D: New generic medicine	111	14	0	125 (88.8%)
F: Major variation	28	0	0	28 (100%)
G: Minor variation [b]	6	0	0	6 (100%)
H: Minor variation [c]	20	2	0	22 (90.9%)
J: Changes to Product Information	144	5	0	149 (96.6%)
S: Provisional registration to full registration	5	0	0	5 (100%)
T: Provisional registration extension	10	0	0	10 (100%)
Comparable Overseas Regulator (COR)- A				
A: New chemical entity/ New biological entity/Biosimilar	3	0	0	3 (100%)
C: Extension of indication	1	0	0	1 (100%)
Comparable Overseas Regulator (COR)- B				
A: New chemical entity/ New biological entity/Biosimilar	5	0	0	5 (100%)
C: Extension of indication	1	0	0	1 (100%)
D: New generic medicine	6	0	0	6 (100%)
F: Major variation	1	0	0	1 (100%)
Minor variations				
Category 3				
G: Minor variation [b]	76	2	0	78 (97.4%)
H: Minor variation [c]	1,445	19	0	1,464 (98.7%)
Correction [9D(1)]	201	9	0	210 (95.7%)
Additional trade name [ATN]	27	3	0	30 (90%)
Extension of Indications- Generic	8	1	0	9 (88.9%)
Internal review	2	0	0	2 (100%)
Minor editorial change [MEC]	150	5	0	155 (96.8%)
Self-assessable request [SAR]	785	12	0	797 (98.5%)
Safety-related request [SRR]	999	11	0	1,010 (98.9%)
Total	4,164	91	1	4,256 (97.8%)

[a] Includes submissions processed via the priority review.

[b] Type G minor variations result in a new ARTG entry, which may or may not result in a new AUST R number. Type G applications are typically 'Category 3' changes unless the supporting scientific package contains nonclinical or clinical data in which case the application is a 'Category 1' application.

[c] Type H minor variations refer to applications that vary the existing good. Type H applications are typically 'Category 3' changes unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

In accordance with the legislation, registered medicines must comply with numerous standards at the time they are registered and throughout their lifecycle. Following an appropriate application and review of the scientific data and safety considerations, approval may be sought to supply a product when it does not meet a particular standard.

Table 3: Number of other prescription medicine applications- Consent to supply/import/export when not conforming to a standard (s.14 and s.14A)

Consent to supply/import/export when not conforming to a standard [S.14 and S.14A]	2023-24 number (% of total)	2024-25 number (% of total)
Approved	74 (100%)	71 (100%)
Rejected	0 (0%)	0 (0%)
Total (excluding withdrawals)	74	71

1.2 Approval times

Table 4: Prescription medicine application approval time

		Approval time (TGA working days)			
Application type	Submissions approved	Legislated timeframe	Mean	Median	Range
Category 1					
A: New chemical entity/New biological entity/Biosimilar [a]	54	255	187	196	101-234
B: New fixed-dose combination	2	255	169	169	151-187
C: Extension of indication [b]	63	255	199	207	42-255
D: New generic medicine	111	255	132	130	52-203
F: Major variation	28	255	153	168	42-236
G: Minor variation	6	255	131	138	49-196
H: Minor variation	20	255	122	126	17-224
J: Changes to Product Information requiring the evaluation of data	143	255	120	137	6-249
S: Provisional registration to full registration	5	255	186	175	153-231
T: Provisional registration extension	10	255	30	21	8-118
Comparable Overseas Regulator (COR-A)					
A: New chemical entity/New biological entity/Biosimilar	3	120	102	110	78-117
C: Extension of indication	1	120	97	97	97-97
Comparable Overseas Regulator (COR-B)					

Application type	Submissions approved	Approval time (TGA working days)			
		Legislated timeframe	Mean	Median	Range
A: New chemical entity/New biological entity/Biosimilar	5	175	162	162	150-174
C: Extension of indication	1	175	143	143	143-143
D: New generic medicine	6	175	131	131	111-147
F: Major variation	1	175	105	105	105-105

[a] Application type A figures do not include 8 submissions processed via the priority review pathway
[b] Application type C figures do not include 3 submissions processed via the priority review pathway

Table 5: Prescription medicine median approval time comparisons between 2023-24 and 2024-25

Application type	Median approval time (TGA working days)		
	Legislated timeframe	2023-24	2024-25 (% Change)
Category 1			
A: New chemical entity/ New biological entity/ Biosimilar [a]	255	201	196 (▼3%)
B: New fixed-dose combination	255	228	169 (▼26%)
C: Extension of indication [b]	255	197	207 (▲5%)
D: New generic medicine	255	129	130 (▲1%)
F: Major variation	255	172	168 (▼2%)
G: Minor variation	255	171	138 (▼19%)
H: Minor variation	255	177	126 (▼29%)
J: Changes to Product Information requiring the evaluation of data	255	186	137 (▼26%)
Comparable Overseas Regulator (COR)- A			
A: New chemical entity/ New biological entity/ Biosimilar	120	107	110 (▲3%)
C: Extension of indication	120	108	97 (▼10%)
Comparable Overseas Regulator (COR)- B			
A: New chemical entity/ New biological entity/ Biosimilar	175	154	162 (▲5%)
D: New generic medicine	175	120	131 (▲9%)
Minor variations			
Category 3			
G: Minor variation [c]	45	42	41 (▼2%)

	Median approval time (TGA working days)		
Application type	**Legislated timeframe**	**2023-24**	**2024-25 (% Change)**
H: Minor variation [d]	45	39	40 (▲3%)
Additional trade name [ATN]	45	42	41 (▼2%)
Extension of Indications - Generic	45	34	36 (▲6%)
Safety-related request [SRR]	N/A	29	25 (▼14%)
Self-assessable request [SAR]	45	38	37 (▼3%)
Minor editorial change [MEC]	45	23	26 (▲13%)
Correction [9D(1)]	N/A	42	72 (▲71%)

[a] Application type A figures do not include submissions processed via the priority review pathway.
[b] Application type C figures do not include submissions processed via the priority review pathway.
[c] Type G minor variations result in a new ARTG entry, which may or may not result in a new AUST R number. Type G applications are typically 'Category 3' changes unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.
[d] Type G applications are typically 'Category 3' changes unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

1.3 Orphan drug designations

The orphan drug program incentivises sponsors with a 100% waiver of TGA fees for application/ registration, to commercialise niche market medication for patients in need.

Prior to the registration application process, the designation process allows the TGA to determine if a medicine is eligible for orphan drug classification or possible waiver of fees keeping in mind the criteria of an unmet medicine in the market.

Table 6: Number of orphan drug registrations

	2023-24		2024-25	
Application Type	Number approved (% of total)	Median approval time[a]	Number approved (% of total)	Median approval time (% change)
A: New chemical entity/ New biological entity/ Biosimilar	13 (68%)	189	18 (67%)	171 (▼10%)
C: Extension of indications	4 (21%)	162	6 (22%)	213 (▲31%)
S: Provisional registration to full registration	0 (0%)	N/A	1 (4%)	231 (N/A)
T: Provisional registration extension	2 (11%)	22	2 (7%)	63 (▲186%)
Total	19 (100%)	N/A	27 (100%)	N/A

[a] The median approval time, in TGA working days, across different application types has not been provided as each application has different parameters.

Orphan drug registrations and approval times are also included in the total number of applications reported in each respective application category.

1.4 Priority review pathway

The priority review pathway supports patient access to vital and lifesaving prescription medicines months earlier than through the standard pathway. Priority review applies the same standards and involves the same amount and type of evidence as the standard review process. However, it is much more resource intensive and so is reserved only for medicines that represent a major therapeutic advance. The determination process is used to assess whether a medicine is eligible for the priority pathway but does not mean that the medicine will be approved after evaluation and registered on the ARTG.

Table 7: Number of medicines approved through the priority review pathway [a]

	2023-24		2024-25	
Application type	Number approved (% of total)	Median approval time (TGA working days)	Number approved (% of total)	Median approval time (% change)
A: New chemical entity/New biological entity/ Biosimilar	1 (25%)	141	8 (73%)	150 (▲6%)
C: Extension of indications	3 (75%)	125	3 (27%)	126 (▲1%)
Total	4 (100%)		11 (100%)	

[a] The target timeframe for the priority review pathway is 150 working days.

1.5 Provisional approval pathway

The provisional approval pathway supports patient access to vital and lifesaving prescription medicines earlier than through the standard pathway. Time limited approval through the provisional pathway is based on the evaluation of preliminary clinical data where there is the potential for a substantial benefit to Australian patients. Knowledge of the risks and benefits is less certain than for other approved prescription medicines. Provisional approval is granted for promising new medicines where we assess that the benefit of early availability of the medicine outweighs the inherent risks in requiring additional data.

A prescription medicine must have a valid provisional determination before it can be evaluated for registration under this pathway. The determination process is used to assess whether a medicine is eligible but does not mean that the medicine will be approved after evaluation and provisionally registered on the ARTG.

Table 8: Number of provisional determinations granted

	2023-24		2024-25	
Application type	Number approved	Total applications	Number approved	Total applications
Provisional determination	6	7	5	8

Table 9: Provisional registration approvals

	2023-24		2024-25	
	Number approved (% of total)	Median approval time (TGA working days)	Number approved (% of total)	Median approval time (% change)
Application type				
A: New chemical entity/New biological entity/Fixed dose combination	5 (45%)	195	3 (50%)	229 (▲17%)
C: Extension of indications	3 (27%)	180	2 (33%)	244 (▲36%)
J: Changes to Product Information requiring the evaluation of data	3 (27%)	140	1 (17%)	137 (▼2%)
Total	11 (100%)		18 (100%)	

2. Over the counter medicines

Over the counter (OTC) medicine applications are categorised as new medicine (N) or change (C) applications and are further categorised by risk (N1 and C1 are low risk, N5 and C4 are highest risk). The OTC application categorisation framework defines the different OTC medicine application levels, the key application criteria and target timeframes to complete evaluation of applications. We aim to evaluate 80% of applications within target timeframes.

Table 10: OTC medicine application categorisation framework

Application category	Definition	Target timeframe (working days)
N1	An application submitted as a 'clone'.	45 working days
N2	An application which complies with an OTC medicine monograph.	55 working days
N3	New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4.	150 working days
N4	An application for a 'generic' medicine where the medicine: requires supporting safety and/or efficacy (clinical/ toxicological) data or a justification for not providing such data; and/or requires a higher level of assessment due to the umbrella branding segment of the product name; and/ or has not been previously registered as an OTC medicine following down-scheduling.	170 working days
N5	An application for a new product that is an extension to a 'generic category' product or an application for a product containing a new chemical entity as an active ingredient.	210 working days
CN	'Notification' changes, where their implementation would not impact the quality, safety or efficacy of a medicine. Includes quality and non-quality changes classified as 'negligible risk'.	N/A (Automated validation and approval)
C1	Quality and non-quality changes classified as 'negligible risk'.	20 working days

Application category	Definition	Target timeframe (working days)
C2	Quality and non-quality changes classified as 'low risk'- no safety and/or efficacy data required; quality data may be required.	64 working days
C3	Quality and non-quality changes classified as 'low risk'- safety and/or efficacy data required unless justified; quality data may be required. Umbrella branding segment of new name requires a higher level of assessment.	120 working days
C4	Non-quality changes classified as 'moderate risk'- safety and/or efficacy data required unless justified.	170 working days
B1	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that does not contain clinical data.	20 working days
B3	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that contains clinical data or a justification as to why such data is not needed.	120 working days
Requests for consent under Section 14/14A of the Act	Request for consent by the Secretary under Sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard.	N/A

2.1 Applications

2.1.1 New OTC medicine applications

Table 11: Applications received for new OTC medicines and changes to existing medicines

	2023-24 (% of total)	2024-25 (% of total)
New medicine applications		
N1	91 (43%)	101 (49%)
N2	8 (4%)	17 (8%)
N3	56 (26%)	52 (24%)
N4	30 (14%)	24 (12%)
N5	28 (13%)	13 (6%)
Total	213 (100%)	207 (100%)
Change applications		
CN	149 (20%)	141 (21%)
C1	263 (35%)	206 (30%)
C2	320 (42%)	327 (48%)
C3	12 (2%)	7 (1%)
C4	9 (1%)	6 (1%)
Total	753 (100%)	687 (100%)

2.1.2 Completed applications

Table 12: Outcomes of completed new OTC medicine applications

	2023-24 (% of total)	2024-25 (% of total)
N1		
Approved	46 (92%)	151 (98%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	4 (9%)	3 (2%)
Returned/failed screening	0 (0%)	0 (0%)
Total	50 (100%)	154 (100%)
N2		
Approved	3 (50%)	8 (73%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	3 (50%)	3 (27%)
Returned/failed screening	0 (0%)	0 (0%)
Total	6 (100%)	11 (100%)
N3		
Approved	32 (91%)	57 (89%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	3 (91%)	4 (7%)
Returned/failed screening	0 (0%)	3 (5%)
Total	35 (100%)	64 (100%)
N4		
Approved	19 (86%)	19 (68%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	3 (14%)	3 (11%)
Returned/failed screening	0 (0%)	6 (21%)
Total	22 (100%)	28 (100%)
N5		
Approved	2 (100%)	2 (8%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	0 (0%)	20 (83%)
Returned/failed screening	0 (0%)	2 (8%)
Total	2 (2%)	24 (100%)

Table 13: Outcomes of completed OTC change applications

	2023-24 (% of total)	2024-25 (% of total)
C1		
Approved	242 (96%)	247 (99%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	9 (4%)	3 (1%)
Returned/failed screening	0 (0%)	0 (0%)
Total	251 (100%)	250 (100%)
C2		
Approved	277 (98%)	383 (96%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	7 (2%)	14 (4%)
Returned/failed screening	0 (0%)	0 (0%)
Total	284 (100%)	397 (100%)
C3		
Approved	1 (33%)	12 (92%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	2 (67%)	1 (8%)
Returned/failed screening	0 (0%)	0 (0%)
Total	3 (100%)	13 (100%)
C4		
Approved	1 (100%)	5 (71%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	0 (0%)	2 (29%)
Returned/failed screening	0 (0%)	0 (0%)
Total	1 (100%)	7 (100%)

2.1.3 Other applications

Other application types that we process include requests for advice for the purpose of listing a medicine as a pharmaceutical benefit. In accordance with the legislation, registered goods must comply with numerous standards at the time they are registered and throughout their lifecycle. Following an appropriate application and review of the scientific data and safety considerations, we may grant an exemption from a particular standard for a product.

Table 14: Number of other OTC medicine applications

	2023-24 (% of total)	2024-25 (% of total)
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
Total	4	3
Requests for consent under Section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard		
Approved	14 (100%)	8 (100%)
Rejected	0 (0%)	0 (0%)
Total	14 (100%)	8 (100%)

2.2 Approval times

Table 15: Median approval time for OTC medicine applications

	2023-24	2024-25
New medicine applications (days)		
N1	39	18
N2	63	40
N3	130	182
N4	207	178
N5	231	200
Change applications (days)		
C1	14	20
C2	20	33
C3	14	114
C4	111	378

Table 16: OTC medicine approval time against target time by application category

Application type	Number completed (% of total)	Range	Mean	Median	% within target (% change from 2023-24)
New medicines					
N1	151 (64%)	0-217	27	18	86% (▲46%)
N2	8 (3%)	8-82	41	40	75% (▲127%)
N3	57 (24%)	0-276	173	182	26% (▼61%)
N4	19 (8%)	108-225	178	178	37% (▼12%)
N5	2 (1%)	183-217	200	200	50% (0%)
Total	237 (100%)				
Change applications					
C1	247 (38%)	0-90	24	20	50% (▼15%)
C2	383 (59%)	0-204	32	33	93% (▲6%)
C3	12 (2%)	27-180	114	114	50% (▼50%)
C4	5 (1%)	172-378	337	378	0% (▼100%)
Total	647 (100%)				

3. Registered complementary medicines

Based on their ingredients or the indications for the medicine, registered complementary medicines are of relatively higher risk than listed medicines. These medicines are fully evaluated by the TGA for safety, efficacy, performance, and quality prior to registration on the ARTG.

Table 17: Categorisation of registered complementary medicine applications by outcome

Application category	Description	Evaluation timeframe (legislated)
RCM1	An identical medicine to another registered complementary medicine other than differences between presentation, colour, flavour or fragrance.	45 working days
RCM2	Evaluation of the safety, quality and efficacy of the medicine is based on evaluation reports from a Comparable Overseas Body (COB).	90 working days
RCM3	A generic product that does not require bioequivalence data; OR The application has been evaluated by a COB and only requires TGA evaluation of one of the following: safety; or quality; or efficacy.	150 working days
RCM4	The application has been evaluated by a COB and only requires TGA evaluation of 2 of the following: safety; quality; efficacy; OR A registered medicine with a change to one of the following: extension of indications, new directions for use or wider target population.	180 working days
RCM5	Requires full independent evaluation by the TGA; OR A registered medicine with a change to: new dosage form, new active ingredient, increased strength of active ingredient or additional excipient.	210 working days
CN	'Notification' changes, where their implementation would not impact the quality, safety or efficacy of a medicine. Includes quality and non-quality changes classified as 'negligible risk'.	N/A
RCM C1	Quality and non-quality changes classified as 'negligible risk'.	20 working days

Application category	Description	Evaluation timeframe (legislated)
RCM C2	Quality and non-quality changes classified as 'low risk'- no safety and/ or efficacy data required; quality data may be required.	64 working days
RCM C3	Quality and non-quality changes classified as 'low risk'- safety and/or efficacy data required unless justified; quality data may be required. Umbrella branding segment of new name requires a higher level of assessment.	120 working days
RCM C4	Non-quality changes classified as 'moderate risk'- safety and/or efficacy data required unless justified.	170 working days

Table 18: Registered complementary medicine applications by outcome

	2023-24 (% of total)	2024-25 (% of total)
New medicines		
Approved	8 (53%)	3 (75%)
Rejected	0 (0%)	0 (0%)
Withdrawn	7 (47%)	1 (25%)
Returned/failed screening	0 (0%)	0 (0%)
Total	15 (100%)	4 (100%)
Variations		
Approved	18 (72%)	28 (72%)
Rejected	0 (0%)	0 (0%)
Withdrawn	7 (28%)	6 (15%)
Returned/failed screening	0 (0%)	5 (13%)
Total variations completed	25 (100%)	39 (100%)
Application for consent under Section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard		
Approved	0 (0%)	3 (100%)
Rejected	0 (0%)	0 (0%)
Withdrawn	0 (0%)	0 (0%)
Total	0 (0%)	3 (100%)

4. Assessed listed medicines

Based on their indications, assessed listed medicines are of slightly higher risk than listed medicines, but not as high risk as registered medicines. Assessed listed medicines carry intermediate risk indications, so they are fully evaluated by the TGA for efficacy before listing in the ARTG.

Assessed listed medicine applications are categorised as new medicine ('L(A)') or change (C) applications. The application levels are outlined in Table 19.

Table 19: Categorisation of assessed listed medicine applications

Application category	Definition	Evaluation timeframe (legislated)
L(A)1	Medicines that are identical to an existing assessed listed medicine other than permitted differences, such as its name, colour, printing ink, flavour and/or fragrance.	45 working days
L(A)2	Generic medicines or medicines where a Comparable Overseas Body (COB) has demonstrated their efficacy.	60 working days
L(A)3	Medicines that are not covered by L(A)1 or L(A)2; and require an independent evaluation of their efficacy; or for an existing assessed listed medicine, contain a different active ingredient, indication, dosage form, strength, or excipient.	150 working days
L(A)CN	'Notification' changes, where their implementation would not affect the established efficacy of the medicine.	N/A
L(A)C1	Changes to the medicine label and ARTG entry that do not affect the efficacy of the medicine.	30 working days
L(A)C2	Changes that may affect the efficacy of the medicine.	120 working days

Table 20: Assessed listed medicine applications by outcome

New medicines	2023-24 (% of total)	2024-25 (% of total)
Approved	1 (100%)	1 (100%)
Refused	0 (0%)	0 (0%)
Withdrawn	0 (0%)	0 (0%)
Failed screening	0 (0%)	0 (0%)
Total	1 (100%)	1 (100%)

Table 21: Applications received for new assessed listed medicines and changes to existing medicines

	2023-24 (% of total)	2024-25 (% of total)
New medicine applications		
L(A)1	0 (0%)	0 (0%)
L(A)2	0 (0%)	0 (0%)

	2023-24 (% of total)	2024-25 (% of total)
L(A)3	1 (100%)	1 (100%)
Total	1 (100%)	1 (100%)
Change applications		
CN	0 (0%)	0 (0%)
C1	0 (0%)	0 (0%)
C2	0 (0%)	0 (0%)
Total	0 (0%)	0 (0%)

5. Listed medicines

Listed medicines are of relatively lower risk than other medicines, as they can only contain pre-approved ingredients in the Therapeutic Goods (Permissible Ingredients) Determination, and claim indications in the Therapeutic Goods (Permissible Indications) Determination. If an ingredient or indication is not included in the Determinations, an application for a new ingredient or indication is needed. While we do not assess each listed medicine before it goes onto the market, we do require sponsors to certify that the medicine complies with all relevant legislation, including that they hold evidence that their medicine performs as claimed at the time of listing and while it remains listed.

We may select a listed medicine for a post-market review, where we require the sponsor to provide evidence of compliance with regulatory requirements. This can include an assessment of compliance with standards, efficacy, labelling and advertising. If we find that the medicine does not comply, a number of enforcement actions may be taken on the medicine's listing and the sponsor ranging from warning letters to criminal prosecutions.

5.1 New ingredients permitted for use in listed medicines

Table 22: New listed medicine ingredient applications by outcome

Application outcome	2023-24 (% of total)	2024-25 (% of total)
Approved	9 (82%)	6 (75%)
Rejected	1 (9%)	1 (13%)
Withdrawn	0 (0%)	0 (0%)
Returned/failed screening	1 (9%)	1 (13%)
Total completed	11 (100%)	8(100%)

5.2 Indications permitted for use in listed medicines

Table 23: Permitted indication applications by outcome

Application outcome	2023-24 (% of total)	2024-25 (% of total)
Approved	0 (0%)	0 (0%)
Rejected	5 (100%)	3 (100%)
Withdrawn	0 (0%)	0 (0%)
Total completed	5 (100%)	3 (100%)

5.3 New listed medicines

Table 24: New listed medicines added to the ARTG

	2023-24	2024-25
New listed medicines	1,854	2,143

5.4 Variations to listed medicines

Subsection 9D(1) of the Act provides for variations to be made to an entry on the ARTG where information is incomplete or incorrect. These variations are considered by a delegate. Other types of variations to listed medicines are processed automatically through the online application system.

Table 25: Listed medicine variations under Subsection 9D(1s) of the Act

Listed medicine variation	2023-24 (% of total)	2024-25 (% of total)
Approved	99 (77%)	102 (82%)
Rejected	18 (14%)	6 (5%)
Withdrawn	11 (9%)	17 (13%)
Total	128 (100%)	125 (100%)

5.5 Listed medicine post-market applications

After listing, we may need to consider an application to support compliance with various requirements. We receive applications for consents under Sections 14 and 14A of the Act, which provides consent to import, supply or export therapeutic goods that do not comply with applicable standards. Additionally, some listed medicines require pre-clearance to supply a batch of medicine that contains ingredients that are at risk of containing aristolochic acids (a toxic substance). We also receive applications under Subsection 7(2) of the Act, to declare whether a type of product is/is not a therapeutic good under Section 7 of the Act.

Table 26: Applications assessed

	2023-24	2024-25
Applications Assessed		
Aristolochic Acid clearances		
Approved	13	22
Rejected	0	0
Total number of clearances	13	22
Consents under Section 14/14A of the Act		
Approved	7	23
Extensions [a]	0	0
Rejected	4	1
Withdrawn	2	2
Total number of consents	13	26
Section 7 declaration		
Approved	0	0
Rejected	0	0

	2023-24	2024-25
Withdrawn	0	0
Total number of declarations	0	0
Total completed	26	48

[a] Section 14/14A extensions were given to products that already held a consent to supply goods that did not comply with Subsection 9(2) of TGO92- Labelling that was due to expire in September 2021.

5.6 Conditions of listing

The TGA may impose additional conditions on products after listing on the ARTG. Some of these apply to all listed medicines and are automatically applied at the time of listing. The-Therapeutic Goods (Listed Medicines- Conditions of Listing) Determination 2022 sets out the standard conditions that automatically apply to the listing of certain medicines that are listed in the ARTG under Section 26A or 26AE of the Act.

Other conditions of listing only apply to certain products. Affected sponsors are notified of any conditions of listing after their products are listed in the ARTG.

Table 27: Product specific conditions of listing

Product specific conditions of listing	2023-24	2024-25
Chewing Gum	0	0
HICC (4-(4-hydroxy-4-methylpentyl)-3-cyclohexene carboxaldehyde)	2	0
Other [a]	0	2
Total	2	2

[a] Conditions of listing imposed on specific individual medicines as part of compliance activities.

5.7 Enquiries and education activities for non-prescription medicines

We respond to stakeholder enquiries on the regulation of non-prescription medicines, including OTC medicines, listed medicines, assessed listed medicines and registered complementary medicines. We also respond to enquiries relating to Food Medicine Interface (FMI), the Cosmetic Medicine Interface (CMI), and the safety of non-prescription medicines. We provide educational presentations, guidance materials and other web content to address FAQ and areas with consistent compliance issues.

Table 28: Enquiries and education

Enquiries and education actions	2023-24	2024-25
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines)- emails	3,024	3,191
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines)- emails and phone calls	277	205
FMI/CMI related enquires	25	43
Guidelines, media releases, factsheets, educational web content, social media posts	20	17
FMI/CMI educational correspondences (e.g. follow up on fact-sheet)	6	1

5.8 Food and Cosmetic Medicine Interface activities

We receive FMI/CMI referrals from internal and external stakeholders and triage all referrals based on risk to consumers. External stakeholders include Food Standards Australia New Zealand, state and territory food regulators, the ABF and the Australian Federal Police. Referrals are also received through consumers and industry stakeholders.

Table 29: Food Medicine Interface and Cosmetic Medicine Interface assessments

FMI/CMI assessments	2023-24	2024-25
FMI/CMI referrals triaged and queued	38	58
FMI/CMI referrals triaged and closed via factsheet [a]	3	1
Completed FMI/CMI assessments	29	34
Referral to another TGA area or government organisation	17	18

[a] Using factsheet developed in Table 28

5.9 Compliance and enforcement

The 2024-25 compliance strategy for listed medicines included targeted compliance activities based on intelligence and data.

We conduct a weekly scan of recently listed medicines on the ARTG to proactively capture potential non-compliances prior to sponsor marketing the medicine. This early engagement with the sponsor soon after their listing facilitates the sponsor to make timely amendments.

Signals of potential non-compliances, including those gathered from complaints and referrals, are triaged and assessed for the level of risk they pose before proportionate action is taken for each signal of non-compliance. Higher risk signals may trigger an in-depth investigation, as may available intelligence/data on a compliance topic.

A compliance review will result in one of the following outcomes:

- the medicine remaining on the ARTG if no compliance breaches are identified against selected listing requirements, or if identified compliance breaches are addressed
- additional regulatory actions, such as cancellation from the ARTG, recall, or infringement notices being issued, or
- the review is closed due to the unavailability of information in determining the products' compliance status, such as if the medicine is yet to be manufactured.

Outcomes of listed medicine compliance reviews, cancellations by the TGA, market actions, infringement notices and advertising directions and prevention notices may be published on the TGA website.

Table 30: Listed medicines signals triaging and investigations

Signals monitored	2023-24	2024-25[a] (% change)
Newly listed medicines monitored	1,854	2,137 (▲15%)
Intel signals of non-compliance (complaints and referrals)	131	164 (▲25%)
ARTG signals of non-compliance (ARTG scanning)	262	171 (▼35%)
Signals of non-compliance investigated and completed	307	283 (▼8%)
Signals of non-compliance completed with low to medium level compliance actions[b] [% success[c]]	126 [80%]	96 [78%][d] (▼24%)
Signals of non-compliance transitioned to a compliance review	21	17 (▼19%)
Medicines with potential non-compliance addressed via mass email education[e] [no. of topics]	63 [1]	278 [4] (▲341%)

[a] Certain signals from FY 2024-25 include multiple medicines.
[b] Educational email, obligations notice, warning letters, and any other educational correspondence.
[c] Success is measured as a percentage of medicines brought into compliance by sponsors after receiving a low to medium level compliance action. Success is measured by assurance activities that may be conducted in the same or subsequent financial year. As such, percentages may increase or decrease in future. Furthermore, at the time of publishing the TGA Performance Report 2023-24, only partial data was available, with 65% of medicines reported as brought into compliance. Given the full-year reporting for 2023-24 is complete, this figure has been updated to 80%.
[d] Based on available data.
[e] Educational emails targeted at all listed medicines which could be at risk of the same non-compliance. Educational emails referred either to specific medicines, or a broad category of medicine. Only medicine numbers from the former type of email are included in this table.

Table 31: Listed medicine compliance reviews by type

	2023-24	2024-25 (% change)
Initiated reviews		
Compliance reviews	37	77 (▲108%)
Compliance reviews transitioned from signal investigations[a]	21	31 (▲48%)
Total number of initiated reviews	58	108 (▲ 86%)
Completed reviews		
Compliance reviews	52	95 (▲ 83%)
Compliance reviews transitioned from signal investigations	50	36 (▼ 28%)
Total number of completed reviews	102	131 (▲ 28%)

[a] Compliance reviews may be transitioned from signal investigations completed in previous FYs, and multiple reviews may be initiated from the same signal investigations.

Table 32: Listed medicine compliance and enforcement actions

Compliance and enforcement actions[a]	2023-24	2024-25
Warning letters	21	20
Educational correspondence (e.g. obligations notices, educational emails, other)	58	58
Mass email education[b]	27	481
Cease review notices	9	6
Conclusion notices	83	88
Deficiencies notices	17	23
Proposal to cancel notices	48	31

Compliance and enforcement actions [a]	2023-24	2024-25
Cancellation notices	7	4
Directions/Prevention notice	1	0
Infringement notices	6	5
Published outcomes of compliance reviews	153	141
Referral to another TGA area or government organisation	40	34
Market actions (e.g. recall, product correction, product alert, and quarantine)	13	5
Total actions undertaken [a]	483	896

[a] An investigation or review may give rise to more than one action, and each action may cover multiple listings.
[b] Educational emails targeted at all listed medicines which could be at risk of the same non-compliance.

Table 33: All listed medicine compliance review [a] outcomes

	2023-24	2024-25
All listed medicine compliance review outcomes		
Compliance status determined		
Medicines with no compliance breaches	27	52
Medicines with verified compliance breaches	69	71
Total	96	123
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	2	3
Medicines not yet manufactured	4	5
Total	6	8
Product is not a therapeutic good		
Total	0	0
Total number of completed reviews	102	131

[a] All compliance reviews, including those that transitioned from signal investigations.

Table 34: Listed medicine compliance review outcomes - Medicines with verified compliance breaches

	2023-24	2024-25
Medicines with verified compliance breaches		
Medicine no longer on the ARTG		
Cancelled by the TGA	9	4
Cancelled by the sponsor after being notified of the compliance breaches	27	32
Total	36	36
Medicine remains on the ARTG		
Compliance breaches addressed after low level compliance action [b]	7	11
Compliance breaches addressed after proposal to cancel	26	24
Total	33	35
Total	69	71

[b] For example deficiencies, obligations, or warning letters

Table 35: Reach of compliance activities for listed medicines[a, b]

Sponsors reached	2023-24 (% of total)	2024-25 (% total)/ (% change)
Sponsors who received any compliance interactions	206 (14%)	460 (32%) (▲18%)
Listings covered by any compliance interactions	399 (3%)	698 (4%) (▲1%)

[a] Data is presented as a percentage of the total number of sponsors and listings active on the ARTG during FY 2024-25
[b] Compliance interactions include all notices as well as educational correspondences listed in table 33 which were issued as part of all compliance activities conducted for listed medicines, including signal investigations, compliance reviews, application assessments, imposing conditions of listing and targeted educational email campaigns. Indirect reach of the TGA's compliance activities such as through reading media releases, or publication of compliance review outcomes have not been captured here.

Table 36: Outcomes of completed compliance reviews[a]

Outcomes of completed compliance reviews	Count	2024-25 (% of total)
Cancelled by sponsors after TGA contact	32	26%
Cancelled by the TGA after proposal to cancel	4	3%
Compliant after proposal to cancel	24	20%
Compliant after education	11	9%
Compliant	52	42%
Total	123	100%

[a] A significant proportion of listed medicine reviews are concluded after the sponsor has adequately addressed the compliance breaches identified by us. Under the Act, sponsors are given an opportunity to respond to issues raised during a compliance review.

6. Biologicals and blood components

6.1 Inclusion of biologicals

Table 37: Applications for biologicals and blood received and on hand

	2023-24 (% of total)	2024-25 (% of total)
Applications received[a]		
Technical Master File (TMF)[b] new	0 (0%)	0 (0%)
TMF annual updates	4 (4%)	4 (4%)
TMF variations	6 (6%)	4 (4%)
TMF notifications	11 (11%)	3 (3%)
Plasma Master File (PMF) new[1]	0 (0%)	1 (1%)
PMF[c] annual updates	12 (12%)	9 (8%)
Biological- Priority Determination[2]	0 (0%)	1 (1%)
Biological Class 1- new applications	1 (1%)	0 (0%)
Biological Class 2- new applications	2 (2%)	0 (0%)
Biological Class 3- new applications	0 (0%)	2 (2%)
Biological Class 4- new applications	3 (3%)	1 (1%)
Biological Class 2- variations	34 (33%)	46 (43%)
Biological Class 3- variations	0 (0%)	5 (5%)

	2023-24 (% of total)	2024-25 (% of total)
Biological Class 4- variations	29 (28%)	30 (28%)
Total received	102 (100%)	106 (100%)
Applications on hand		
TMF new	0 (0%)	0 (0%)
TMF annual updates	1 (4%)	1 (3%)
TMF variations	2 (9%)	3 (8%)
TMF notifications	1 (4%)	0 (0%)
PMF new[3]	0 (0%)	1 (3%)
PMF annual updates	0 (0%)	3 (8 %)
Biological Class 1- new applications	0 (0%)	0 (0%)
Biological Class 2- new applications	3 (13%)	3 (8%)
Biological Class 3- new applications	0 (0%)	1 (3%)
Biological Class 4- new applications	3 (13%)	1 (3%)
Biological Class 2- variations	7 (30%)	9 (23%)
Biological Class 3- variations	0 (0%)	0 (0%)
Biological Class 4- variations	6 (26%)	17 (44%)
Total on hand	23 (100%)	38 (100%)

[a] The *Australian Regulatory Guidelines for Biologicals* (published on the TGA website) define the different biological classes.

[b] TMF contain information from manufacturers that demonstrate how product safety and quality standards have been met for Blood, Blood Components and Haematopoietic Progenitor Cells.

[c] PMF contain control strategies that ensure the quality and safety of plasma, from collection through to plasma pooling prior to fractionation and including donor selection criteria and testing, which are part of medicinal products or medical devices.

[1] New category for 24/25 financial year

[2] New category for 24/25 financial year

[3] New category for 24/25 financial year

Table 38: Completed applications for biologicals and blood

Biologicals applications	2023-24 (% of total)	2024-25 (% of total)
Technical Master File (TMF) new	0 (0%)	0 (0%)
TMF annual updates	4 (4%)	4 (4%)
TMF variations	5 (5%)	4 (4%)
TMF notifications	10 (10%)	6 (6%)
Plasma Master File (PMF) new	0 (0%)	0 (0%)
PMF annual updates	12 (12%)	8 (8%)
Biologicals- Priority Determination[1]		1 (1%)
Biological Class 1- new applications	1 (1%)	0 (0%)
Biological Class 2- new applications	1 (1%)	1 (1%)
Biological Class 3- new applications	0 (0%)	0 (0%)
Biological Class 4- new applications	1 (1%)	3 (3%)
Biological Class 2- variations	34 (37%)	40 (40%)
Biological Class 3- variations	0 (0%)	6 (6%)
Biological Class 4- variations	26 (28%)	28 (28%)
Total completed	94 (100%)	101 (100%)

[1] New category for 24/25 financial year representing the first biologicals priority determination.

7. Medicine and vaccine adverse event reports

7.1 Adverse medicine and vaccine event notifications

Table 39: Source of notifications of medicine and vaccine adverse events[a]

	2023-24	2024-25
Received		
Mean number of reports received weekly	588	489
Vaccine reports	12,904	7,074
Total	30,574	25,419
Accepted cases		
Reports by health professionals	4,432	5,529
Patients/consumers	1,530	1,517
Pharmaceutical companies	18,261	12,196
Other source[b]	5,073	5,176
Total	29,296	24,418
Rejected/withdrawn cases	1,278	1,001

[a] Data is subject to change due to receipt of further information related to individual reports or further case processing. Notifications for 2024-25 have been updated since the last TGA Performance Report to reflect the most recent data. Reporting an adverse event does not mean that the details of the event have been confirmed by the TGA, or that the event has been determined to be related to a medicine or a vaccine.

[b] 'Other source' includes reports received from state and territory health departments (accounting for >95% of these reports) as well as reports received from other organisations that are not pharmaceutical companies.

8. Medical devices

The medical devices regulatory framework spans the life cycle for these products, including:

Priority review of medical devices: This pathway enables us to prioritise applications for medical devices that meet specific criteria, such as being novel or offering significant health benefits beyond those of existing devices.

Medical device manufacturing: As a regulatory authority within MDSAP, the TGA assesses and recognises third party AOs to conduct audits of medical device manufacturers across multiple jurisdictions through a single audit process. We also evaluate the QMSs of manufacturers seeking TGA conformity assessment certification. This involves onsite audits, desktop reviews of third-party-reports such as MDSAP audit reports, or a combination of both. Surveillance audits are also undertaken to verify ongoing compliance.

Conformity assessment: Manufacturers must systematically examine their medical devices to confirm safety, performance, and compliance with the Essential Principles. The TGA may certify the manufacturer's conformity assessment procedures or recognise equivalent certification from comparable overseas regulators, including European notified bodies and MDSAP AOs.

Inclusion in the ARTG: Medical devices must be included in the ARTG to be lawfully imported to, supplied in, or exported from Australia, unless a valid exemption applies, such as custom-made medical devices or sample importation. Sponsors may apply for inclusion if the medical device complies with the Essential Principles and has undergone appropriate conformity assessment procedures.

Preliminary assessment: TGA staff conduct a preliminary assessment of every ARTG application to verify that the required evidence accompanies the submission. Only applications that pass this stage proceed to the next step.

Application audit: Applications that pass preliminary assessment may undergo an application audit, where we examine the evidence in greater detail to confirm compliance. Our risk-based AAF guides the selection and conduct of these audits.

Post-market monitoring: Once a medical device is included in the ARTG, it must continue to meet all regulatory, safety and performance requirements that supported its approval. Further review and investigation processes may occur in relation to reports of safety or performance concerns.

8.1 Conformity assessment of medical devices

8.1.1 Applications

In 2024-25, the number of applications for TGA conformity assessment certification declined slightly, and the backlog of applications on hand decreased by 15%.

Table 40: Number of conformity assessment applications (medical devices including IVDs)

	2023-24	2024-25
Conformity assessment applications		
Applications received	130	127
Applications on hand	90	77
Applications completed (including withdrawn or lapsed applications)	204	140

8.1.2 Outcomes

Most completed applications related to variations to existing certificates, and the number of new certificates issued remained consistent with 2023-24.

Table 41: Outcomes of conformity assessment applications

	2023-24	2024-25
New		
Approved	18	18
Refused	1	0
Withdrawn/ Lapsed	21	29
Variation (changes and re-certifications)		
Approved	152	75
Refused	0	0
Withdrawn/ Lapsed	12	18

8.1.3. Processing timeframes

The TGA completed every conformity assessment application within the legislated timeframe of 255 working days. The mean timeframe for new devices rose slightly compared to 2023-24, while the mean timeframe for variations reduced substantially. Most applications were finalised within the target timeframes introduced in 2024. However, the TGA did not achieve its goal of completing 90% of applications within those targets. All applications that exceeded the new target timeframes were received before the implementation of the new targets.

Table 42: TGA conformity assessment processing times for new devices and variations

	2023-24	2024-25* (% change)
New devices		
Mean TGA processing time (days)	147	154 (▲5%)
Median TGA processing time (days) completed in maximum target timeframe**	195	85
% of applications completed in legislated timeframe (255 working days)	100%	100%
Variations (changes and recertifications)		
Mean TGA processing time (days)	139	96 (▼37%)
Median TGA processing time (days) completed in maximum target timeframe**	144	88
% of applications completed in legislated timeframe (255 working days)	100%	100%

* To ensure processing times are accurately represented, applications that were withdrawn during the pre-assessment stage and did not proceed to assessment have been excluded from the FY 2024-25 metrics.

** Maximum target timeframes started in 2024 and 2025 are 200 business days for new or change applications, 225 business days for new or change applications requiring an onsite audit or advice from the Advisory Committee on Medical Devices, and 150 business days for recertifications. We aim to complete 90% of applications in the target timeframes.

8.2 Inclusion of medical devices (including IVDs)

8.2.1 Applications

The number of applications to include medical devices in the ARTG, including IVDs, increased by 19% in 2024-25.

The TGA completed 30% more applications for non-IVD medical devices above Class I in 2024-25, a significant increase compared to 2023-24. This contributed to reducing the backlog of applications on hand.

The implementation of the new medical device AAF supported the decrease in the backlog of Class I applications (primarily facemasks) and Class III applications (requiring clinical review). Despite a 56% increase in new Class III applications, the number of Class III applications on hand decreased by 46%.

Table 43: Applications for inclusion- medical devices (including IVDs)

	2023-24	2024-25 (% change)
Class I medical devices		
Applications received	2,089	2,334 (▲11%)
Applications completed	2,142	2,466 (▲14%)
Applications on hand	177	46 (▼118%)
Class I measuring medical devices		
Applications received	27	30 (▲11%)
Applications completed	25	31 (▲22%)
Applications on hand	2	1 (▼67%)
Class I sterile medical devices		
Applications received	266	287 (▲8%)
Applications completed	265	291 (▲9%)
Applications on hand	12	7 (▼53%)
Class IIa medical devices		
Applications received	1,237	1,515 (▲20%)
Applications completed	1,223	1,512 (▲21%)
Applications on hand	119	121 (▲2%)
Class IIb medical devices		
Applications received	610	806 (▲28%)
Applications completed	608	793 (▲26%)
Applications on hand	127	141 (▲11%)
Class III medical devices		
Applications received	381	566 (▲39%)
Applications completed	468	731 (▲44%)
Applications on hand	367	200 (▼59%)
Total medical devices (non-IVD) applications received	4,610	5,538 (▲18%)
Class 1 IVDs		
Applications received	84	68 (▲21%)
Applications completed	86	71 (▼19%)
Applications on hand	11	8 (▼32%)
Class 2 IVDs		
Applications received	72	59 (▼20%)
Applications completed	77	64 (▼18%)
Applications on hand	22	17 (▼26%)
Class 3 IVDs		
Applications received	56	83 (▲39%)
Applications completed	114	78 (▼38%)
Applications on hand	39	44 (▲12%)
Class 4 IVDs		

	2023-24	2024-25 (% change)
Applications received	25	25 (0%)
Applications completed	24	31 (▲26%)
Applications on hand	13	7 (▲60%)
Total IVD applications received [a]	237	235 (▲1%)
Grand total applications received	4,847	5,773 (▲17%)

[a] Errors in the 2023-24 IVD statistics have been corrected in this report.

In 2024-25, the number of applications for DCRs and variations to the ARTG for medical devices including IVDs increased by 14%.

Despite an increase in applications received, the TGA nearly halved the proportion of DCRs on hand at the end of 2024-25 compared to at the end of 2023-24.

Table 44: Applications for DCRs and variations to the ARTG- medical devices (including IVDs)

	2023-24	2024-25 (% change)
Device Change Request (DCR)		
Applications received	838	947 (▲12%)
Applications completed	792	1031 (▲26%)
Applications on hand	214	119 (▼57%)
Variations to Class III medical devices		
Applications received	76	96 (▲23%)
Applications completed	77	91 (▲17%)
Applications on hand	20	24 (▲18%)
Total medical device (non-IVD) applications received	914	1,043 (▲13%)
IVD DCR		
Applications received	84	112 (▲29%)
Applications completed	109	109 (0%)
Applications on hand	19	20 (▲5%)
IVD Variations		
Applications received	49	42 (▼15%)
Applications completed	56	40 (▼33%)
Applications on hand	18	20 (▼11%)
Total IVD applications received	133	154 (▲15%)
Grand total applications received	1,047	1,197 (▲13%)

8.2.2 Completion and processing times

The TGA completed 24% more applications for non-IVD medical devices in 2024-25 than in 2023-24. This included completing 11% more application audits of class I devices, made up mostly of a backlog of facemask applications from late in the COVID-19 pandemic. The process improvement implemented as part of our new AAF also helped us to reduce a longstanding backlog of clinical evidence reviews. We completed 24% more level 2 mandatory audits than in the previous year. This work also helped us significantly reduce our backlog of non-mandatory audits.

Our backlog of audits was made up of applications that had been with us for many months. In reducing our backlog, completing these applications also increased the mean and median processing times of completed applications (Table 45). This increase is most apparent for audits of Class I devices (facemasks) and level 2 mandatory and non-mandatory audits (clinical reviews). However, for shorter assessments, the impact of our AAF is reflected in shorter timeframes for level 1 audits.

Once all outstanding applications have been processed, and further process changes are implemented, we expect our processing times will improve.

We completed 19% fewer IVD applications in 2024-25 than in 2023-24. However, our new AAF meant that we completed more applications without audit and IVD audits were completed substantially quicker. IVD DCRs were also completed faster.

Previous TGA performance reports indicated target timeframes of 30 and 60 TGA workdays for level 1 and level 2 application audits, respectively. We had not met these targets for some years, and these targets were not consistent with the work needed to perform these audits. In 2024, we consulted stakeholders about establishing new target timeframes that would be realistic and reflect more efficient assessment processes. New legislative criteria for mandatory audits that started on 1 July 2024 also needed to be considered when comparing the data for 2023-24 and 2024-25.

Table 45: Processing times for medical device application audits (including IVDs)

	2023-24			2024-25		
	Total completed	Processing times (TGA working days)		Total completed	Processing times (TGA working days)	
		Mean	Median		Mean	Median
Medical devices						
Class I applications completed without audit	1,466	2	2	1,717	2	1
Class I applications completed with audit	676	17	3	749	89	7
Non class I applications completed without audit	2,061	16	16	2,612	16	17
Level 1 non-mandatory audits (Non class I) [a]	213	124	87	208	60	34
Level 2 non-mandatory audits (Non class I) [a]				211	185	167
Level 1 mandatory audits	35	98	83	33	61	48
Level 2 mandatory audits [b]	234	224	236	289	291	307
IVDs [c]						
Class 1 IVD applications completed without audit	63	11	9	60	10	10
Class 1 IVD applications completed with audit	21	123	141	11	132	132
Non class 1 IVD applications completed without audit	49	13	14	71	10	9
IVD non-mandatory audit (Non class 1)	14	208	195	19	97	86
IVD mandatory audit (Non class 1)	152	214	206	83	150	171
IVD DCR	109	78	55	109	25	15
IVD Variation	56	85	68	40	85	90

[a] The categorisation of non-mandatory audits as level 1 or level 2 started in 2024-25.
[b] All level 2 mandatory application audits completed in 2024-25 started before the AAF changed in 2024.
[c] Errors in the 2023-24 IVD statistics have been corrected in this report.

Table 46: Number of priority review determinations [a] granted

Application type	2023-24	2024-25
A: Conformity assessment (priority applicant) determinations	1	0
B: Medical devices (priority applicant) determinations	0	2

[a] Priority determination is a formal decision by the TGA to assign priority to the assessment of an application. Granting of priority determination does not guarantee approval for the application itself.

Table 47: Number of medical devices approved through the priority review pathway.

	2024-25	
Application Type	Number of applications with priority determinations approved	Median approval time (TGA working days)
A: Conformity assessment	0[a]	N/A
B: Medical devices (ARTG inclusion)	1	54
Total [a]	1	54

[a] No applications were approved in this reporting period

8.3 Post-market monitoring

8.3.1 Post-market reviews

The TGA undertakes post-market reviews of medical devices to ensure that they continue to comply with the applicable regulatory requirements and that the safety and performance of the medical devices are maintained. We also undertake targeted reviews to verify that a product is included correctly in the ARTG. We select medical devices for post-market review using information from both internal data, such as trends in adverse events, and external sources, such as industry reports of new hazards, media reports or signals identified by other regulators.

Table 48: Medical device post-market reviews

Post-market reviews	2023-24	2024-25* (% change)
Reviews commenced- number of ARTG entries	562	473 (15.8%▼)
Reviews completed- number of ARTG entries	1,300	1,750 (34.6% ▲)
Reviews on hand- number of ARTG entries	4,310	3,033 (34.8% ▼)

8.3.2 Applications for consent to supply medical devices that are non-compliant with the Essential Principles

While medical devices must comply with the Essential Principles of safety and performance, some circumstances may prevent partial compliance for a limited period. In those cases, sponsors can apply to seek consent to supply the non-compliant medical devices with an appropriate justification and risk mitigation. 'Consent to supply' applications can be for medical devices included in the ARTG, in an application for inclusion in the ARTG, or for unapproved vaping goods, including device accessories.

Table 49: Applications for consent to supply non-compliant medical devices

Consent to supply applications	2024-25
Number of consent to supply applications received	121
Number of ARTG entries in the consent to supply applications	998
Number of applications for devices in the ARTG-	3
Number of applications for unapproved devices (including vaping goods, including device accessories)	3

8.3.3 Medical device incident reports

A medical device incident is an event associated with the use or misuse of a medical device that resulted in (or could have resulted in) serious injury, illness or death to a patient, healthcare worker or other person. Australian sponsors and manufacturers of medical devices must actively monitor their devices' post-market performance and report incidents to the TGA. Mandatory reporting of medical device incidents by healthcare facilities was introduced in March 2025, commencing with a 12-month transition period of voluntary reporting. Reporting of incidents or near-incidents by users, such as healthcare providers and consumers, is voluntary.

The target timeframe for processing medical device incident reports is 90 working days.

Table 50: Number of medical device incident reports and processing times

	2023-24	2024-25
Incident report outcomes		
Device incident reports[a]		
Reports received	9,917	15,294
Reports completed	7,917	11,167
Reports still in progress	2,000	4,127

[a] Each year begins with a number of reports on hand, additional reports are received throughout the financial year and close out some of the reports on hand.

Table 51: Medical device incident report outcomes[a]

Incident report outcomes	2023-24	2024-25
Reviewed and used for trend analysis purposes	7,421	10,928
Reviewed, no further action required	234	54
Product recall	45	10
Product device correction	41	152
Hazard alert	39	6
Product alert	0	5
Safety alert	20	4
Product enhancement/improvement notice	2	0
Instructions for use amended	1	0
Referral for post-market review	3	0
Refer to another TGA branch or section	5	3
Company warned	0	0
Product suspended from ARTG	0	0

Incident report outcomes	2023-24	2024-25
Product cancelled from ARTG	0	0
Manufacturing process improvements	0	0
Quality system process improvements	0	0
Maintenance carried out by the hospital	0	0
Change to design	1	1
Not device related	1	0
TGA publication	4	0
User education	1	1
Other	2	4

[a] Outcomes are not mutually exclusive.

8.3.4 Devices manufacturing

Table 52: Outcomes of Quality Management System (QMS) audits of Australian manufacturers

	2023-24	2024-25
QMS audits (Australia)		
Number of audits completed	32	28
Satisfactory compliance (% of completed audits)	9 (28%)	8 (29%)
Marginal compliance (% of completed audits)	5 (16%)	7 (25%)
Unacceptable compliance (% of completed audits)	0 (0%)	0 (0%)
Audits pending a compliance rating (% of completed audits)	18 (56%)	13 (46%)
Processing time		
Initial audits conducted within 3 months of application	15%	55%
Re-audits conducted within 6 months of due date	12%	29%

Table 53: Outcomes of QMS audits of overseas manufacturers

	2023-24	2024-25
QMS audits (overseas)		
Number of desktop audits conducted	16	17
Number of onsite/remote audits completed	26	13
Satisfactory compliance (% of completed audits)	19 (73%)	8 (62%)
Marginal compliance (% of completed audits)	1 (4%)	3 (23%)
Unacceptable compliance (% of completed audits)	1 (4%)	0 (0%)
Audits pending a compliance rating (% of completed audits)	5 (19%)	2 (15%)
Processing time		
Initial audits conducted within 6 months of application	67%	69%
Re-audits conducted within 6 months of due date	0%	0%

Table 54: Outcomes of MDSAP (Medical Device Single Audit Program) assessments

	2023-24	2024-25
MDSAP Assessments		
Number of auditing organisation assessments	6	3
Number of witnessed manufacturing audits	4	4

9. Exports

9.1 Export only products

Table 55: Number of approved applications for export-only medicines and export certifications and relevant processing time

	2023-24	2024-25	% Change	Target processing time (days)	2023-24	2024-25	% Change
	Total approved				Average processing time (days)		
Export-only medicines							
New applications	257	199	23% ▼	30	31	22	29% ▼
Variation and grouping applications	124	231	86% ▲	30	16	13	19% ▼
Export certification							
Medicines	1,697	1,490	12% ▼	15	6	10	67% ▲
Medical devices	308	409	33% ▲	15	4	7	75% ▲

10. Access to unapproved therapeutic goods

10.1 Special Access Scheme

SAS refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis. For this reporting period, 3 pathways existed under the scheme:

- Category A is a notification pathway which can only be accessed by medical practitioners for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
- Category B is an application pathway which can be accessed by health practitioners for patients who do not fit the Category A definition. An approval letter from the TGA is required before the goods may be accessed.
- Category C is a notification pathway which allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval. The goods deemed to have an established history of use are specified in a list along with their indications and the type of health practitioner authorised to supply these products.

Any unapproved therapeutic good can potentially be supplied via the SAS although drugs listed in Schedule 9 of the Poisons Standard are forbidden from supply in most states and territories.

Table 56: SAS medicine notifications and applications

	2023-24 (% of total)	2024-25 (% of total)
Category A notifications		
Total Category A notifications	38,157 (15%)	32,168 (9%)
Category B applications		
Approved	174,333 (97%)	224,091 (98%)
Cancelled	906 (1%)	1,581 (<1%)
Withdrawn	2,096 (1%)	359 (<1%)
Rejected	3 (0%)	0 (0%)
Pending at end of reporting period	1,824 (1%)	1,327 (<1%)
Total Category B applications	179,162 (72%)	227,358 (65%)
Category C notifications		
Total Category C notifications	30,184 (12%)	91,100 (26%)
Total SAS medicine notifications/applications received (all categories)	247,503 (100%)	350,626 (100%)

Table 57: SAS medical device notifications and applications

	2023-24 (% of total)	2024-25 (% of total)
Category A notifications		
Total Category A notifications	6,701 (47%)	5,866 (39%)
Category B applications		
Approved	5,291 (92%)	6,217 (87%)
Cancelled	90 (2%)	457 (6%)
Withdrawn	45 (1%)	5 (<1%)
Rejected	25 (<1%)	2 (<1%)
Pending at end of reporting period	275 (5%)	468 (6%)
Total Category B applications	5,726 (41%)	7,149 (48%)
Category C notifications		
Total Category C notifications	1,703 (12%)	1,922 (13%)
Total SAS medical devices notifications/applications received (all categories)	14,130 (100%)	14,937 (100%)

Table 58: SAS biological notifications and applications

	2023-24 (% of total)	2024-25 (% of total)
Category A notifications		
Total Category A notifications	155 (4%)	133 (4%)
Category B applications		
Approved	359 (62%)	513 (68%)
Cancelled	163 (28%)	222 (29%)
Withdrawn	29 (5%)	1 (<1%)
Rejected	0 (0%)	0 (0%)
Pending at end of reporting period	30 (5%)	33 (4%)
Total Category B applications	581 (16%)	769 (21%)
Category C notifications		
Total Category C notifications	2,896 (80%)	2,779 (75%)
Total SAS notifications/applications received (all categories)	3,632 (100%)	3,681 (100%)

10.2 Authorised Prescribers

The AP Scheme allows approved medical practitioners authority to prescribe a specified unapproved therapeutic good(s) to a class of patients who are identified by their medical condition.

Table 59: Authorised Prescriber approvals for medicines, medical devices and biologicals

Approvals by therapeutic good type	2023-24 (% of total)	2024-25 (% of total)
Number of approvals for medicines	21,465 (99%)	22,313 (>99%)
Number of approvals for medical devices	155 (1%)	124 (<1%)
Number of approvals for biologicals	1 (<1%)	0 (0%)
Total	21,621 (100%)	22,437 (100%)

10.3 Clinical trials

The CTN scheme allows for unapproved therapeutic goods to be supplied for use solely for clinical trials. Unapproved therapeutic goods can include biologicals, devices or medicines or a combination of any of the 3 types of goods.

Table 60: Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

Therapeutic good type	2023-24 (% of total)	2024-25 (% of total)/ (% Change)
Medicine	407 (35%)	443 (35%) (▲9%)
Device	221 (19%)	228 (18%) (▲3%)
Biological	12 (1%)	12 (1%)
Medicine and device	493 (43%)	552 (44%) (▲12%)
Device and biological	6 (<1%)	8 (<1%) (▲33%)
Medicine and biological	1 (<1%)	1 (<1%)
Medicine, device and biological	12 (1%)	16 (1%) (▲33%)
Total	1,152 (100%)	1,260 (100%) (▲9%)

Note: The data shown in the above table carries a margin of error of ±1%.

Table 61: Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

Clinical trial type	2023-24 (% of total)	2024-25 (% of total)/ (% change)
Phase 0	29 (3%)	80 (6%) (▲176%)
Phase 1	378 (33%)	485 (38%) (▲28%)
Phase 2	218 (19%)	327 (26%) (▲50%)
Phase 3	296 (26%)	312 (25%) (▲5%)
Phase 4	57 (5%)	54 (4%) (▼5%)
Device	173 (15%)	NA
Bioavailability/equivalence	1 (<1%)	2 (<1%) (▲100%)
Total	1,152 (100%)	1,260 (100%) (▲9%)

Note: The data shown in the above table carries a margin of error of ±1%.

Table 62: Number of notifications for new clinical trials and variations to previously notified clinical trials, including non-fee attracting variations, involving unapproved therapeutic goods received by therapeutic good type

Therapeutic good type	2023-24 (% of total)	2024-25 (% of total)/ (% change)
Medicine	1,201 (31%)	1,299 (29%) (▲8%)
Device	379 (10%)	445 (10%) (▲17%)
Biological	19 (<1%)	31 (<1%) (▲63%)
Medicine and device	2,221 (57%)	2,567 (58%) (▲16%)
Device and biological	17 (<1%)	17 (<1%)
Medicine and biological	3 (<1%)	9 (<1%) (▲200%)
Medicine, device and biological	41 (1%)	49 (1%) (▲20%)
Total	3,881 (100%)	4,417 (100%) (▲14%)

Note: The data shown in the above table carries a margin of error of ±1%.

Table 63: Number of new clinical trials and variations to previously notified clinical trials involving unapproved therapeutic goods received by phase[a]

Phases	2023-24 (% of total)	2024-25 (% of total) (% change)
Phase 0	45 (1%)	139 (3%) (▲209%)
Phase 1	1,296 (33%)	1,587 (36%) (▲22%)
Phase 2	860 (22%)	1,080 (24%) (▲26%)
Phase 3	1,242 (32%)	1,459 (33%) (▲17%)
Phase 4	134 (3%)	145 (3%) (▲8%)
Bioavailability/equivalence	2 (<1%)	6 (<1%) (▲200%)
Total	3,579 (100%)	4,416 (100%) (▲23%)

[a] The figures here are a correction to the 2023-24 values published in the TGA Performance Report 2023-24.

Note: The data shown in the above table carries a margin of error of ±1

11. Medicines and biologicals manufacturing

11.1 Manufacturing licences issued to Australian manufacturers

Table 64: Status of manufacturing licence applications[a]

	2023-24 (% of total)	2024-25 (% of total)
New licences granted	24 (22%)	26 (21%)
Withdrawn application	54 (50%)	72 (57%)
Revoked licences- at request of licence holder	15 (14%)	17 (13%)
Revoked licences- the TGA	6 (5%)	0 (0%)
Suspended- at request of licence holder	10 (9%)	11 (9%)
Suspended- the TGA	0 (0%)	0 (0%)
Total	109 (100%)	126 (100%)

[a] As of 30 June 2025, there were 265 Australian companies holding manufacturing licences covering 422 sites.

Table 65: Outcomes of inspections of Australian manufacturers

	2023-24 (% of total)	2024-25 (%of total)/(% change)
Compliance status (Australia)		
Number of inspections conducted	179	193 (▲8%)
Satisfactory compliance (of completed inspections)	135 (75%)	122 (63%) (▼12%)
Marginal compliance (of completed inspections)	27 (15%)	26 (13%) (▼2%)
Unacceptable (of completed inspections)	7 (4%)	11 (6%) (▲2%)
Compliance under assessment	10 (6%)	34 (18%) (▲12%)

	2023-24 (% of total)	2024-25 (%of total)/(% change)
Processing time		
Initial inspections conducted within 3 months of application	17 of 34 (50%)	13 of 22 (59%) (▲9%)
Re-inspections conducted within 6 months of due date	17 of 112 (15%)	22 of 93 (24%) (▲9%)

11.2 Approval (certification) of overseas manufacturers

Table 66: Manufacturing certification application by status (overseas)

	2023-24 (% of total)	2024-25 (% of total) (% change)
Applications (overseas) [a]		
New applications received [b]	47 (36%)	49 (48%) (▲4%)
Re-inspection applications [b]	82 (64%)	54 (52%) (▼12%)
Total applications	129 (100%)	103 (100%) (▼20%)
Applications completed		
Certified	116 (60%)	97 (43%) (▼17%)
Rejected [c]	78 (40%)	131 (57% (▲17%)
Total completed	194 (100%)	228 (100%) (▲17%)

[a] As at 30 June 2025, there were 156 overseas manufacturers covering 185 manufacturing sites that are subject to TGA inspection.
[b] Refers to applications that generated an inspection, undertaken by the TGA.
[c] Rejections include withdrawn applications and applications that were submitted where an inspection was not required.

Table 67: Outcomes of inspections of overseas manufacturers

	2023-24 (% of total)	2024-25 (% of total)
Inspection status (overseas)		
Number of inspections conducted	88	86
Satisfactory compliance (of completed inspections)	72 (82%)	68 (79%)
Marginal compliance (of completed inspections)	12 (14%)	6 (7%)
Unacceptable (of completed inspections)	2 (2%)	0 (0%)
Compliance under assessment at period end	2 (2%)	12 (14%)
Processing time		
Initial certification inspections conducted within 6 months of application	22 of 41 (54%)	21 of 35 (60%)
Certification re-inspections conducted within 6 months of due date	5 of 47 (11%)	9 of 29 (31%)

11.3 Good Manufacturing Practice clearances

Table 68: GMP clearance application status

	2023-24 (% of total)	2024-25 (% of total)
Applications received		
Received	9,754	9,200
Applications completed		
Approved	8,045 (84%)	8,342 (87%)
Rejected	1,497 (16%)	1,233 (13%)
Total completed	9,542 (100%)	9,575 (100%)

Table 69: Number of GMP clearance applications received and completed by type

Application Category	Applications received	Applications completed
Cancel	7	3
Extend	4,282	4,426
New	1,696	1,719
Reactivate	77	80
Variation	3,138	3,347

Table 70: Number of GMP clearance applications actioned by pathway

Pathway	Applications received	Applications completed	Applications approved	Applications not approved
Compliance verification	1,277	1,400	1,370	30
Mutual recognition agreement	2,732	2,684	2,543	141

12. Market actions (including recalls)

12.1 Medicine market actions

Table 71: Medicine market actions by reason

Reason for market action	2023-24 (% of total)	2024-25 (% of total)
Adverse reactions	1 (1%)	0 (0%)
Foreign matter	3 (4%)	7 (8%)
GMP non-compliance	1 (1%)	0 (0%)
Impurity	5 (6%)	2 (2%)
Labelling or instructions	28 (33%)	31 (34%)
Mechanical or physical defect	23 (27%)	13 (15%)
Microbial/fungal contamination	2 (3%)	5 (6%)
Observed difference	3 (4%)	1 (1%)
Packaging or closure defect	1 (1%)	5 (6%)
Potency	1 (1%)	2 (2%)
Sterility	1 (1%)	1 (1%)
Variable content	7 (9%)	13 (15%)
Other [a]	7 (9%)	9 (10%)
Total	83 (100%)	89 (100%)

[a] 'Other' includes bioavailability, diagnostic inaccuracy, disintegration or dissolution, GMP non-compliance, preservative efficacy, therapeutic inefficiency, viral/prion contamination, wrong product, and unknown.

12.2 Medical device market actions

Table 72: Medical device (including IVDs) market actions by reason

Reason for market action	2023-24 (% of total)	2024-25 (% of total)
Adverse incidents	6 (1%)	5 (1%)
Diagnostic inaccuracy	57 (10%)	33 (5%)
Electrical defect	24 (4%)	33 (5%)
Illegal supply	0 (0%)	1 (1%)
Labelling and packaging	86 (15%)	25 (4%)
Mechanical and physical defects	251 (43%)	216 (35%)
Software defects	97 (17%)	127 (20%)
Sterility	8 (1%)	4 (1%)
Other [a]	55 (9%)	176 (28%)
Total	584 (100%)	620 (100%)

[a] 'Other' includes foreign matter, impurity, microbial contamination, observed differences, therapeutic performance, variable content, wrong product and unknown.

12.3 Blood and biological market actions

Table 73: Blood recalls

	2023-24	2024-25
Market actions to hospital level	53	68

Table 74: Biological market actions

	2023-24	2024-25
Market actions (including recalls) to hospital level	18	10

13. Laboratory testing

The TGA Laboratories take a risk-based, targeted approach to post-market monitoring and compliance testing, investigations, and reviews, and market authorisation assessment of therapeutic goods, consistent with *ISO 31000: Risk Management principals and guidelines*.

The reduction in the total samples and products tested in 2024-25 when compared to 2023-24, including the reduction in unregistered samples, reflects the completion of the TGA's 2023-24 targeted vaping goods testing project. Completing this review released resources to focus on compliance testing of other therapeutic good types as seen in the increased testing of number of prescription medicines, complementary medicines and medical device samples.

The decreased total Percentage Fail Rate from 72% in 2023-24 to 31% in 2024-25 reflects the high failure rate for unregistered nicotine vaping products tested in 2024-25. This shows the effectiveness of the TGA's risk-based approach in identifying and targeting therapeutic goods with the greatest likelihood of non-compliance.

Table 75: Samples and products tested by type of therapeutic good and percentage which failed

		2023-24	2024-25
Therapeutic good type			
Prescription medicines	Total	139	249
	% fail	0%	0%
OTC medicines	Total	84	15
	% fail	8%	13%
Complementary medicines	Total	15	65
	% fail	33%	5%
Medical devices	Total	32	138
	% fail	28%	51%
External [a]	Total	32	34
	% fail	41%	9%
Pacific Medicines Testing Program	Total	95	79
	% Fail	22%	28%
Unregistered [b]	Total	1,259	535
	% fail	90%	78%
Total samples (excluding AHQ samples)		1,656	1,115
Total samples [c]		1,902	1,662
Percentage fail		72%	31%
Total number of products tested [d]		972	758

[a] Performed on request for overseas regulators and encompasses medicines and medical devices.
[b] 'Unregistered' refers to products that meet the definition of therapeutic goods but are not included on the ARTG or otherwise specifically exempted from this requirement in the legislation. This often includes adulterated complementary medicines or counterfeit products.
[c] Includes accreditation, harmonisation and quality control (AHQ) samples.
[d] The TGA may test a number of samples of each product per reporting period.

Table 76: Samples that failed laboratory testing by reason

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Contamination	1	0	0	0	3	0	0	4 (1%)
Formulation	0	0	1	293	0	2	18	314 (60%)
Label and packaging deficiencies	20	1	0	0	0	0	0	21 (4%)
Performance [a]	49	1	0	0	0	0	0	50 (10%)
Physical or mechanical properties	0	0	0	4	0	1	4	9 (2%)
Unregistered	0	0	0	122	0	0	0	122 (23%)
Total	70	2	1	419	3	3	22	520

[a] Performance means failure of the product to meet criteria/requirements critical to its intended purpose.

Table 77: Batch release and export certification

Batch releases and certifications	2023-24	2024-25
Batch release [a]	545	525
Export certification [b]	4	9

[a] Evaluation of batch release documentation for vaccines, biotechnology and blood products.
[b] Certification of biological products being exported from Australian manufacturers to overseas markets.

The TGA provides the WHO compliant certificates for batches of biological products to be exported by Australian manufacturers to overseas markets.

Table 78: Target timeframes in working days for laboratory testing by priority and testing type

Priority of testing	Biochemical/chemical testing	Microbiological testing	Medical device testing
Urgent [a]	20 (95% of target times to be met)	40 (95% of target times to be met)	20 (95% of target times to be met)
Priority	40 (80% of target times to be met)	50 (80% of target times to be met)	40 (80% of target times to be met)
Routine	50	50	50

[a] Testing on products linked to potential public safety concerns is assigned to the 'Urgent' testing category. Urgent testing may impact the timeframes for priority and routine testing. Priority is given to testing of products with the highest risk of a quality deficiency.

Table 79: Compliance with testing timeframes[a]

Therapeutic good type[b]	Priority	Number (% of total)
Medical devices	Routine	119 (52%)
	Priority	16 (94%)
	Urgent	0 (N/A)
OTC medicines	Routine	14 (7%)
	Priority	1 (100%)
	Urgent	0 (N/A)
Prescription medicines	Routine	60 (15%)
	Priority	0 (N/A)
	Urgent	3 (100%)
Complementary medicines	Routine	59 (78%)
	Priority	6 (0%)
	Urgent	0 (N/A)
Unregistered products	Routine	503 (62%)
	Priority	18 (94%)
	Urgent	14 (0%)

[a] Samples involving complex biological assays are excluded from the target turnaround timeframes.
[b] Low numbers of samples within categories may affect compliance percentages.

14. Regulatory compliance

The TGA conducts compliance and enforcement activities against a risk-based compliance framework. The tools used to encourage compliance and address non-compliance include education and guidance, warnings, the issue of infringements, and/or product suspensions or cancellations. Investigations may also result in criminal or civil court proceedings.

14.1 Compliance Overview- all compliance priorities

Table 80: Allegations by compliance priority*

Compliance priority	Reports received	Reports finalised[a]
Nicotine vaping products- import, advertising and supply	8,270	6,451
Medicinal cannabis, psilocybine and MDMA- advertising	633	693
Wellness and beauty industries unapproved and high-risk therapeutic goods- advertising	2,436	1,897
Traditional or alternative treatments- import, advertising and supply	184	119
Substandard and falsified therapeutic goods- import	605	509
Other[b]	20,282	17,444
Total	32,410	27,113

* Reports include any alleged non-compliance report for the import, supply, manufacture or advertisement of therapeutic goods in the 2023-24 financial year. This includes referrals from the ABF.
[a] Cases may not have been received in the same financial year.
[b] Other relates to reports and cases not related to a TGA 2023-24 compliance priority. This may include cases marked as duplicate cases.

Table 81: Digital platform removal requests* by compliance priority

Compliance priority	2024-25
Nicotine vaping products- import, advertising and supply	8,706
Medicinal cannabis, psilocybine and MDMA- advertising	31
Wellness and beauty industries unapproved and high-risk therapeutic goods- advertising	3,263
Traditional or alternative treatments- import, advertising and supply	43
Substandard and falsified therapeutic goods- import	0
Other**	1,667
Total	13,710

* Removal requests include removal of advertisements, entire online profiles and proactive scanning.
** Other includes digital platform removal requests that are not directly linked to a TGA 2023-2025 Compliance Priority.

Table 82: Source of report of non-compliance

Source	2024-25
Consumer / General Public	3,782
ABF	22,714
Government/state and territory body / external agency	1,521
Company/business	491
Health practitioner	569
Regulator/legal consultant	74
Other*/**	396

* Advertising Compliance- Consumer Organisation/Body, Academia, Peak Industry Body, Publisher, and blanks
** Regulatory Compliance- Health internal, State health body, Law Enforcement, Sponsor client, Patient/practitioner

14.2 Regulatory Activity: All products (excluding nicotine/ vaping goods)

Table 83: Civil and criminal court proceedings

Criminal and civil court*	2024-25
Criminal actions commenced	2
Criminal actions finalised	0
Civil actions commenced	1
Civil actions finalised	0

*Includes any case type (i.e. import, supply, manufacture or advertising).

Table 84: Other activities

Enforceable undertakings (EUs)*	2024-25
Enforceable undertaking entered	2

*EUs can relate to alleged unlawful import, supply, manufacture or advertising of therapeutic goods, or a combination of alleged offences.

14.3 Import, Export, Manufacture and Supply of therapeutic goods

Tables below capture compliance and enforcement activities in relation to the import, export and manufacture of unapproved and counterfeit therapeutic goods and the administration of the Personal Importation (PI) Scheme (excluding nicotine/vaping goods).

Table 85: Reports of alleged import, export, manufacture and supply non-compliance

Compliance cases [a]	2024-25
Reports received	18,755
Reports finalised [b]	16,757

[a] These figures are based on case numbers and not actions taken or offence types.
[b] Cases may not have been received in the same financial year.

Table 86: Regulatory compliance referrals by special interest categories

Compliance category	2024-25	
	Referrals received	Units (% of total)
Goods on the ARTG	19	16,032 (<1%)
Goods not on the ARTG*	17,547	5,322,960 (92%)
Counterfeit products**	687	447,649 (7.7%)
Total [a]	18,253	5,786,641

* Excludes counterfeit goods.
** Excludes all goods reported as "not in the ARTG" except counterfeit goods.
[a] There can be multiple special interest categories in a single case.

Table 87: Number of offence types related to completed cases

Offence type	2024-25 (% of total)
Import	17,674 (94.8%)
Export	2 (<1%)
Counterfeit	672 (3.6%)
Manufacture	2 (<1%)
Supply	291 (1.5%)
Advertising (relating to an import, manufacture or supply case)	3 (<1%)
Total completed [a]	18,644

[a] There can be multiple offences in a single case.

Table 88: Number of compliance actions taken against completed investigations

Completed investigations	2024-25 (% of total)
No offence identified	219 (1.2%)
Goods released under PI Scheme	437 (2.3%)
Referred internally	24 (<1%)
Referred to external agency	78 (<1%)
Warning letters issued[a]	17,761 (94.4%)
Other[b]	294 (1.6%)
Infringement notice issued	5 (<1%)
Total[c]	18,818
Infringement notice value ($)	$93,900
Units of goods ref ABF for destruction[d]	5,923,338

[a] The category 'warning letters issued' can include goods destroyed as prohibited imports and goods re-exported.
[b] Other includes cases linked to existing matters, cases with insufficient information to proceed etc.
[c] There can be multiple actions per case resulting in a higher total figure than shown in finalised cases below.
[d] Units refers to single dosage unit e.g. 1 tablet, 1 capsule, 1 tub of powder or a single device.

14.4 Advertising of therapeutic goods

Tables below capture compliance and enforcement activities in relation to the advertising of approved and unapproved therapeutic goods (i.e. goods on the ARTG, and goods not on the ARTG, excluding nicotine/vaping goods).

Table 89: Reports of alleged advertising non-compliance

Compliance cases[a]	2024-25
Reports received[b]	4,143
Reports finalised[b]	3,905

[a] These figures are based on case numbers and not actions taken or offence types.
[b] Cases may not have been received in the same financial year.

Table 90: Compliance actions recorded

Action taken	2024-25
Assessed; no further action[a]	525
The TGA requested removal of advertising/profile[b]	5,004
Warning letter sent[c]	96
Infringement notice issued	25
Infringement notices value ($)	$379,356
Direction notice issued	0

[a] The term "no further action" refers to instances where we identified no appropriate avenues of action to take (e.g. no breach identified).
[b] The term "The TGA requested removal of advertising/profile" refers to the number of advertisements requested for removal from a digital platform. Removal requests include removal of advertisements, entire online profiles and proactive scanning.
[c] The term "warning letter sent" relates to correspondence advising advertisers of an alleged breach of the legislation. Other engagements with advertisers occur in addition to formal warning letters

15. Nicotine/vaping goods

Tables below capture compliance and enforcement activities in relation to the advertising, import, export and manufacture of unapproved and counterfeit nicotine/vaping goods and the administration of the PI Scheme.

Significant increase in activity in 2024-25 compared to 2023-24 is largely because vaping reform did not commence until later in the 2023-24 year.

Table 91: Reports of alleged non-compliance

Compliance cases [a]	2023-24	2024-25
Reports received	3,654	8,270
Cases finalised [b]	2,517	6,451

[a] These figures are based on case numbers and not actions taken or offence types.
[b] Cases may not have been received in the same financial year.

Table 92: Number of offence types related to completed cases

Offence type	2023-24 (% of total)	2024-25 (% of total)
Import	2,364 (91%)	5,595 (80%)
Export	0 (0 %)	0 (0%)
Counterfeit	40 (2%)	33 (<1%)
Manufacture	1 (<1%)	1 (<1%)
Supply	119 (5%)	566 (8%)
Advertising	66 (3%)	801 (11%)
Total completed [a]	2,590 (100%)	7,008 (100%)

[a] There can be multiple offences in a single case.

Table 93: Number of compliance actions taken against completed investigations

Action taken	2023-24 (% of total)	2024-25 (% of total)
Assessed- no further action [a]	151 (5%)	573 (4%)
The TGA requested removal of advertising [b]	29 (1%)	8,643 (56%)
The TGA request ISP to block access to website	23 (1%)	222 (1%)
Vaping goods released under PI Scheme	430 (15%)	415 (3%)
Referred internally	6 (<1%)	5 (<1%)
Referred to external agency	13 (<1%)	87 (<1%)
Warning letter sent [C]	2,107 (76%)	5,558 (36%)
Infringement notice issued	26 (1%) ($263,352)	60 (<1%) ($1,168,800)
Civil proceedings finalised	1 (<1%)	0
Total[d]	2,786 (100%)	15,563 (100%)

[a] The term “no further action” refers to instances where we identified no appropriate avenues of action to take (e.g. no breach identified).
[b] The term “The TGA requested removal of advertising” refers to the number of advertisements requested for removal from a digital platform. This new function was established in 2022-23 to monitor and take down unlawful advertising on digital platforms including from social media and marketplace platforms.
[c] The category ‘warning letters issued’ can include goods destroyed as prohibited imports, goods re-exported and correspondence advising of an alleged breach of the legislation.
[d] There can be multiple actions per case resulting in a higher total figure than shown in finalised cases above.

Table 94: Nicotine/vaping goods removed from the market

Action taken	2023-24	2024-25
Units of vaping goods referred to ABF for destruction[a]	885,855	1,114,607
Units of pouches referred to ABF for destruction	4,147,460	11,053,699
Units of vaping goods seized by the TGA under warrant	819,192	124,459
Units of pouches seized by the TGA under warrant	1,684	272,140
Units of vaping goods surrendered (incl business surrender)	0	238
Units of pouches surrendered	0	0

[a] Since 1 January 2024, ABF no longer required to refer disposable vaping goods to the TGA before destruction which we expect to result in a decrease in referrals over time.

Table 95: Notified Vaping Goods

Action taken	2023-24	2024-25
Number of valid sponsor notices received for nicotine vaping goods	817	2,098
Number of valid sponsor notices received for cannabis vaping goods	0	728
Number of sponsor notices withdrawn for nicotine vaping goods	2	1,023
Compliance reviews for nicotine vaping goods	0	28

16. Pharmacovigilance Inspection Program

Table 96: Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified

	2023-24	2024-25
Total inspections completed	7	7
Total inspections with deficiencies	7	7

We publish annual Pharmacovigilance Inspection Program metrics reports containing detailed de-identified information on the number of inspections held, the type of inspections, the type of findings and whether they have been resolved.

17. Good Clinical Practice Inspection Program

Table 97: Good Clinical Practice (GCP) Inspection Program inspections undertaken and deficiencies identified

	2023-24	2024-25
Total inspections completed	6	14
Total inspections with deficiencies	6	12

We publish annual GCP inspection program metrics reports containing detailed de-identified information on the number of inspections held, the type of inspections, the type of findings and whether they have been resolved.

18. Reporting of medicine shortages

Table 98: Number of medicine shortage notifications received

Notifications received	2023-24	2024-25
New	1,190	1,067
Update [a]	4,537	4,274
Total	5,727	5,341

[a] Updates of previously reported shortages, including updates to 'Resolved' status. Mandatory reporting of all shortages of prescription medicines and select OTC medicines commenced 1 January 2019.

Table 99: Number of medicine shortage reports [a] by shortage reason

	2023-24 (% of total)	2024-25 (% of total)/(% change)
Shortages Reported		
New- Commercial changes	38 (3%)	23 (2%) (▼39%)
New- Discontinuation	175 (15%)	137 (13%) (▼22%)
New- Manufacturing related	698 (59%)	704 (66%) (▲1%)
New- Product recall	5 (<1%)	0 (0%) (▼100%)
New- Unexpected increase in demand	103 (9%)	100 (9%) (▼3%)
New- Unexpected increase in demand due to other sponsors unable to supply	39 (3%)	57 (5%) (▲46%)
New-Transport / logistic issues / storage capacity issues	129 (11%)	43 (4%) (▼67%)
New- Seasonal depletion of stock	3 (<1%)	3 (<1%) (0%)
Total	1,190 (100%)	1,067 (100%) (▼10%)

[a] New reports only, does not include updates of previously reported shortages.

19. Serious Scarcity Substitution Instruments

Under Section 30EK of the Act, the Minister for Health, Disability and Ageing can make a legislative instrument to:

- Declare that there is a serious scarcity of the specified medicine across the whole or specified parts of Australia, and
- Specify the medicine (the substitutable medicine) tzhat pharmacists are permitted to dispense in substitution for the scarce medicine and specify the circumstances in which that substitution is permitted.

Serious Scarcity Substitution Instruments (SSSIs) allow community pharmacists to substitute specific medicines without prior approval from the prescriber if the permitted circumstances within the SSSI are met.

Table 100: Number of SSSIs made

	2023-24	2024-25 (% change)
Number of SSSIs made	6	4 (▼ 33%)

Table 101: SSSI's table of alerts

Issue date	Alert	Scarce medicine(s)	SSSI	Duration of SSSI
27/9/2024	Substitution allowed to address shortage of Ryzodeg 70/30 FlexTouch insulin	RYZODEG 70/30 FLEXTOUCH 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, registration number 280432	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Degludec and Insulin Aspart) Instrument 2024	27 September 2024 to 31 March 2025
19/11/2024	Substitutions approved for HRT patch shortages	(a) ESTRADERM MX 25 estradiol 25 microgram/24 hours transdermal drug delivery system sachet, registration number 67089; (b) ESTRADOT 25 estradiol 25 microgram transdermal drug delivery system sachet, registration number 338056	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Estradiol) Instrument 2024	19 November 2024 to 31 January 2026
16/12/2024	Discontinuation of Protaphane InnoLet insulin cartridges and approval of a substitute	PROTAPHANE INNOLET human insulin (rys) 100 IU/mL injection multidose cartridge, registration number 169633	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Isophane Human) Instrument 2024	16 December 2024 to 28 February 2026

Issue date	Alert	Scarce medicine(s)	SSSI	Duration of SSSI
28/5/2025	Substitutions approved for shortage of metformin immediate-release tablets	(a) FORMET 1000 metformin hydrochloride 1000 mg tablet bottle, registration number 91112; (b) FORMET 1000 metformin hydrochloride 1000 mg tablet blister pack, registration number 91113; (c) DIAFORMIN VIATRIS metformin hydrochloride 1000 mg film-coated tablet blister pack, registration number 206735; (d) METFORMIN GH metformin hydrochloride 1000 mg tablet blister pack, registration number 284975; (e) METFORMIN SANDOZ metformin hydrochloride 1000 mg tablet blister pack, registration number 292865; (f) DIAFORMIN 1000 metformin hydrochloride 1000 mg tablet blister pack, registration number 82207	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Metformin) Instrument 2025	28 May 2025 to 31 August 2025

20. Section 19A approvals

Section 19A of the Act provides the legislative basis for the Secretary of the department to approve the import or supply of an overseas registered medicine that is not included in the ARTG, to mitigate a shortage of a medicine.

Table 102: Section 19A applications

Applications processed	2023-24	2024-25 (% change)
New	117	129 (▲ 10%)
Renewals	67	89 (▲ 33%)
Total	184	218 (▲18%)

Glossary of acronyms

AAF	application audit framework
ABF	Australian Border Force
ADHD	Attention-Deficit/Hyperactivity Disorder
AHQ	accreditation, harmonisation and quality control
AI	artificial intelligence
AMR	antimicrobial resistance
ANAO	Australian National Audit Office
AO	Auditing Organisation
AP	Authorised Prescriber scheme
API	active pharmaceutical ingredient
ARCS	Association of Regulatory and Clinical Scientists
ARTG	Australian Register of Therapeutic Goods
ASEM	Australian Sunscreen Exposure Model
ASDER	Adverse Signal Detection and Event Reporting
ATN	additional trade name
BPOM	National Agency of Drug and Food Control (Indonesia)
CDPP	Commonwealth Office of the Director of Public Prosecutions
CHPWG	Complementary Health Products Working Group
CMI	Cosmetic-Medicine Interface
COR	Comparable Overseas Regulator
CTN	Clinical Trial Notification
DCR	device change request
DFAT	Australian Department of Foreign Affairs and Trade
DTx	Digital therapeutics
EU	European Union
FAQ	frequently asked question
FMI	Food-Medicine Interface
GBT	Global Benchmarking Tool
GCP	Good Clinical Practice
GLP-1 RA	glucagon-like peptide-1 (GLP-1) receptor agonist
GMP	Good Manufacturing Practice
GMWSI	Generic Medicines Work-Sharing Initiative
GSMS	Global Surveillance and Monitoring System
HBSP	Health Business Services Portal
HPRG	Health Products Regulation Group
HREC	Human Research Ethics Committee
ICMRA	International Coalition of Medicines Regulatory Authorities
IDP	institutional development plan

AAF	application audit framework
IGPRG	Inter-Governmental Policy Reform Group
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
ISP	internet service provider
IVD	in vitro diagnostic
MAWG	Medicine Availability Working Group
MDMA	3,4-methylenedioxymethamphetamine
MDSAP	Medical Device Single Audit Program
MEC	minor editorial change
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
MoU	memorandum of understanding
MTAA	Medical Technology Association of Australia
NASWG	New Active Substances Working Group
NASWSI	New Active Substances Work-Sharing Initiative
NCIRS	National Centre for Immunisation Research and Surveillance
NPRA	National Pharmaceutical Regulatory Agency (Malaysia)
NRA	National Regulatory Authority
ODC	Office of Drug Control
OTC	Over the counter
PDR	People's Democratic Republic (Lao)
PGPA Act	Public Governance, Performance and Accountability Act 2013
PI Scheme	Personal Importation Scheme
PMF	Plasma Master File
PMTP	Pacific Medicines Testing Program
PMMD	patient-matched medical device
PoC	point of care
PTA	Pathology Technology Australia
Quadripartite	The four international agencies: the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE), the UN Environment Programme (UNEP) and the World Health Organization (WHO)
QMS	quality management system
RAC	Regulatory Authority Council
RAGNA	Regulatory Agencies Network against AMR
RMP	risk management plan
RSP	Indo-Pacific Regulatory Strengthening Program
RSV	respiratory syncytial virus
SAHPRA	South African Health Products Regulatory Authority
SaMD	software as a medical device
SAP	Signal Assessment and Prioritisation
SAS	Special Access Scheme

AAF	application audit framework
SAR	self-assessable request
SCS	spinal cord stimulator
SRA	Stringent Regulatory Authority
SRR	safety-related request
SSSI	Serious Scarcity Substitution Instrument
TCM	traditional Chinese medicine
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration
TGACC	Therapeutic Goods Advertising Consultative Committee
TGO	Therapeutic Goods Order
Thailand FDA	Thailand Food and Drug Administration
The Act	*Therapeutic Goods Act 1989*
The department	Department of Health, Disability and Ageing
TMF	Technical Master File
UDI	Unique Device Identification
VPN	Vaccine Pharmacovigilance Network
WHO	World Health Organization
WLA	WHO-Listed Authority