Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Administration

Performance Report 2023-24

Acknowledgement of Country

The Therapeutic Goods Administration proudly acknowledges the Traditional Owners and Custodians of Country throughout Australia and pay respect to those who have preserved and cared for the lands on which we live, work, and benefit from each day. We recognise the inherent strengths and knowledge Aboriginal and Torres Strait Islander peoples provide to the health and aged care system and thank them for their existing and ongoing contributions to the wider community. We extend this gratitude to all health and aged care workers who contribute to improving health and wellbeing outcomes with, and for, First Nations peoples and communities. We also recognise and respect Aboriginal and Torres Strait Islander peoples' continuing connections and relationships to the lands, waters, culture, and community, and pay respect to all Elders past and present.

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Message from the Deputy Secretary

I am pleased to present the 2023-24 Performance Report for the Therapeutic Goods Administration (TGA). This report reflects our unified efforts to safeguard public health through best-practice regulation, continuous innovation and strong stakeholder engagement. It highlights how we have adapted to emerging health challenges while ensuring the safety, efficacy, performance and quality of therapeutic goods, in alignment with national and international standards.

In 2023-24, the TGA demonstrated a consistent focus on strengthening regulatory effectiveness, ensuring timely access to life-saving products, and enhancing public confidence in Australia's regulatory frameworks. Our work this year was driven by a commitment to improving compliance, advancing digital transformation, and supporting healthcare innovation. Through strong domestic and international collaboration, we maintained and strengthened Australia's reputation as a global leader in health products regulation.

Key achievements:

- **Regulation of vaping products:** The TGA took a leading role in the delivery of the Australian Government's comprehensive range of measures to reduce the harms from vaping, culminating in the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* commencing on 1 July 2024. These reforms include the prohibition of non-therapeutic vapes and the introduction of strengthened product standards and controls for therapeutic vapes. Between January and June 2024, working with the Australian Border Force (ABF) and the states and territories, we seized over 650,000 illicit nicotine vapes and the issuing of a number of fines.
- **Medicines Repurposing Program:** Launched in March 2024, this program provides incentives for exploring new therapeutic uses for existing medicines to address unmet clinical needs where commercial incentives are limited. The program has seen strong engagement from clinicians, health organisations, and pharmaceutical companies, reinforcing the TGA's leadership in driving healthcare innovation.

- **Medical device regulatory reforms:** In 2023-24, the TGA implemented significant reforms as part of the Action Plan for Medical Devices, improving pathways for device market entry, enhancing post-market monitoring, and safeguarding patient safety. These reforms, supported by updated guidance documents and the further development of the Australian Unique Device Identification Database (AusUDID), are the building blocks for a strengthened approach to safety and traceability of medical devices in Australia.
- **Recognition as a World Health Organization (WHO) Listed Authority (WLA):** As part of our commitment to global health, the TGA continues to strengthen international collaborations through the Regulatory Strengthening Program (RSP). In 2024, the TGA submitted an expression of interest to become a WLA, which will further enhance our role in upholding global regulatory standards for medicines and vaccines.
- **Digital transformation and modernisation:** The TGA advanced its digital transformation with the launch of a new business portal for sponsors and manufacturers, streamlining submission processes and enhancing regulatory transparency and efficiency. Preparatory work to implement a new Laboratory Information Management System (LIMS) also progressed, laying the groundwork for improved operational efficiency in the future.

Stakeholder engagement remains central to the TGA's strategic direction, focusing on meaningful interactions to foster trust and collaboration. Insights from the 2024 TGA Stakeholder Survey, conducted in July 2024, showed a 7% increase in public confidence, with 72% of health professionals and 62% of consumers affirming the TGA's ability to balance safety with timely access to therapeutic goods.

This year, we expanded our engagement across industry, consumer groups and government stakeholders, aligning Australia's regulatory frameworks with global best practice. Our collaborative initiatives, including public consultations, targeted forums and strategic partnerships, have strengthened transparency and inclusivity, empowering stakeholders to shape regulatory reforms and ensuring our regulatory system remains responsive to evolving healthcare challenges.

During the 2025-26 period, the TGA will focus on advancing regulatory reforms and strengthening compliance frameworks, particularly to address the use of unapproved therapeutic goods. This includes enhancing oversight of their import, export and supply, supporting industry through reform initiatives, and modernising regulatory processes to improve efficiency and transparency. Key activities will also include collaboration with domestic and international stakeholders, such as the Australian Health Practitioner Regulation Agency (Ahpra), to ensure safe and effective practices, while maintaining adaptability to emerging technologies and addressing public health priorities like vaping reforms.

The TGA remains steadfast in its mission to protect public health through regulatory excellence and foster innovation across the therapeutic goods sector. Together, through the dedication of our people and the strength of our partnerships, we'll ensure the safety, efficacy, performance and quality of therapeutic goods, thereby driving better health outcomes into the future.

Professor Anthony Lawler

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

Our purpose

The TGA, as part of the Australian Government Department of Health and Aged Care the department, is responsible under the *Therapeutic Good Act 1989* (the Act) for the evaluation, assessment and monitoring of products that are defined as therapeutic goods. We help Australians to stay safe by regulating therapeutic goods for safety, efficacy, performance and quality.

We regulate the advertising, manufacture, import, export and supply of:

- prescription medicines
- vaccines
- non-prescription medicines
- some sunscreens and complementary medicines, including vitamins, minerals, herbal and traditional medicines
- medical devices, including relevant software
- blood and blood products
- cellular therapies
- biologicals, and
- other goods defined as therapeutic goods under the Act.

Consistent with the Act, we:

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

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

Our vision

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

Our strategic intent

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

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

Our strategic focus is on a healthy culture, strong and effective internal and external engagement, and regulatory capability. We aim to enhance public health outcomes through best practice regulation, build trust through active stakeholder engagement, and foster innovation to address emerging regulatory challenges. By prioritising these areas, we ensure our regulatory environment remains contemporary and effective, contributing to the health, safety and wellbeing of all Australians.

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

We undertake our regulatory functions in alignment with 3 Best Practice Principles outlined in the Resource Management Guide 128 Regulator Performance:

Continuous improvement and building trust

We will:

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

Risk based and data driven

We will:

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

Collaboration and engagement

We will:

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

Our strategic objectives

Guided by the 3 Best Practice Principles described above, the TGA developed strategic objectives and performance indicators that reflect stakeholder expectations. Through consultation with both internal and external stakeholders, including industry representatives, the TGA established the following strategic objectives:

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

Structure of this report

Overview of performance reporting and strategic objectives

In accordance *Resource Management Guide 128*, we have measured our performance against the strategic objectives and focus areas outlined in the TGA Business Plan 2023–24.

This report highlights notable activities across 35 focus areas corresponding to our 4 strategic objectives. Each objective is supported by several performance indicators, which underpin our activities and achievements.

Given the breadth and volume of work undertaken in the 2023–24 financial year, it is not feasible to mention all of the TGA's activities and achievements within this report. However, we provide regular updates through the year via external platforms, including the TGA website, email newsletters, social media, events, webinars and stakeholder forums.

The appendices of this report include detailed performance statistics for the period from 1 July 2023 to 30 June 2024, by product themes and work programs. In addition, this report includes insights from the 2024 TGA Stakeholder Survey. These insights reflect stakeholders' opinions and perceptions of the TGA, as surveyed in July 2024.

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

- TGA Business Plan 2023–24
- The TGA Stakeholder Survey
- TGA International Engagement Strategy

Strategic objective 1

Improve public health outcomes through best practice regulation

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

Performance Indicators

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

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

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

Insights from the TGA Stakeholder Survey

The TGA conducts an annual stakeholder survey to analyse and enable improvement of how we work with our stakeholders. In 2024, we surveyed 1,050 consumers, 205 health professionals and 1,589 stakeholders with a TGA Business Services (TBS) account, many of whom have roles directly associated with the medical products industry.

In performance indicator 1.2, we assess our success at providing timely access to innovative therapies and emerging technologies that respond to public health needs. In our stakeholder survey, we asked respondents who were aware of the TGA to indicate whether they agree or disagree with the statement, 'The TGA gets the balance right between safety for consumers and timely access to products'.

In the survey, 63% respondents with a TBS account agreed and 14% disagreed with the statement. The remaining respondents said they 'neither agree nor disagree' or were 'not sure'. Agreement is down almost 3% compared with the 2023 survey, while disagreement is up by just 1%.

The majority of health professionals believe the TGA gets the balance right, with 72% agreeing and 9% disagreeing, with agreement and disagreement down 1% in this cohort compared to 2023. Among consumers, 62% agreed that the TGA gets the balance right, with 11% disagreeing. In this cohort, agreement is up 7% and disagreement is down 4% compared with the 2023 survey.

While the results are positive overall, and a level of disagreement is expected given the broad range of therapeutic goods regulated by the TGA, we will continue working to ensure stakeholders understand our risk-based approach to regulation.

Figures used – p.9 (consumers), p.15 (opt-in) and health professional (p12).

Strengthening the regulation and enforcement of vaping products

We introduced new controls on the importation, manufacture, supply and advertisement of vaping products to address the increasing health risks posed by vaping, while preserving legitimate patient access to therapeutic vapes.

During 2023-24, the TGA worked closely with multiple stakeholders to strengthen the regulation and enforcement of vaping products. This included developing significant legislative reforms introducing new controls on the importation, domestic manufacture, and supply of vaping products to better protect public health, particularly for young people. The reforms support the TGA Business Plan's objective of enhancing regulatory compliance and safeguarding Australians from harmful products.

Key reforms under the Government's vaping reforms include:

Importation controls:

As of 1 January 2024, the importation of disposable single-use vapes, irrespective of nicotine content or therapeutic claims, was prohibited, with limited exceptions. Additionally, from 1 March 2024, the importation of all other vaping products was restricted, requiring compliance with new product standards, an import licence and a permit. The personal importation scheme for all vaping products ceased to apply.

Domestic regulatory measures:

From 1 March 2024, stronger controls were applied to the manufacture and supply of therapeutic vaping goods in Australia, including enhanced requirements for pre-market notification and compliance with the new product standards.

Legislative reforms and enforcement:

Amendments to the Act, taking effect on 1 July 2024, introduced new offences related to the unlawful importation, manufacture, supply, commercial possession and advertising of vaping products. These changes will enable more robust enforcement actions with higher penalties for illicit supply, while enabling a health practitioner-led pathway for legitimate patient access.

Seizure of illicit products:

Between January and June 2024, over 650,000 suspected illicit nicotine vaping products (NVP) were seized by the TGA in collaboration with the ABF. This significant enforcement activity reflects the enhanced powers provided by the new reforms.

Establishing a medicines repurposing function

We established a dedicated function to identify and validate new therapeutic uses for existing medicines, driven by research and evidence-based approaches.

Following extensive public and targeted consultations from 2021 to 2023, the Medicines Repurposing Program commenced on 1 March 2024. This program is funded through the 2023-24 Federal Budget's Pharmaceutical Benefits Scheme reforms package and is scheduled to run until 30 June 2027.

It aims to encourage industry to explore new therapeutic uses for existing medicines by offering fee waivers for applications seeking extensions of indications.

The program has received nominations of candidate medicines from clinicians, health organisations, patient groups and pharmaceutical companies. The evaluation of these nominations focuses on unmet clinical need and access barriers, particularly where there is limited commercial incentive for sponsors to pursue regulatory approval. Discussions with sponsors of candidate medicines from the initial tranche of nominations are ongoing.

As we advance, we will continue to collaborate with stakeholders to refine and improve program processes, ensuring that our approach remains responsive to the evolving needs in the field of medicine repurposing.

Recall reforms

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

During 2023-24, we implemented several key reforms following the analysis of stakeholder responses to our public consultation, *Therapeutic Goods Recall Processes – Discussion Paper.*

Based on stakeholder feedback, we prioritised the following actions:

- reduced regulatory burden by streamlining unnecessary steps in the recall process
- ensured recall letters and notices are clear and concise, with key information prominently displayed for quick understanding by customers and end users
- enhanced transparency in our recall processes, including clearer guidelines on the timing for releasing recall information and the hazard classification process for recall actions
- updated recall document templates to reflect best practices
- transition from a Customer Acknowledgement Form to a Customer Response Form, incorporating modern tools such as QR codes and online survey links to improve customer response rates to sponsor recall letters, and
- providing sponsors with the opportunity to review Early Advice Notices before seeking feedback from stakeholders on recall actions.

In support of these recommendations, we implemented changes to recall processes and enhanced the clarity and accessibility of our guidance and resource materials. These reforms were introduced through the new version of the Uniform Recall Procedure for Therapeutic Goods (URPTG) Version 2.4, and included updates to the recall information provided through our website.

Additionally, we initiated a review to assess whether our current legislative recall powers are effectively supporting recall processes, marking the beginning of Phase 3 of our reform program.

Prioritising evaluations and monitoring of new products

We prioritised the evaluation, post-market reviews and performance monitoring of new products, with a focus on national health emergencies and other critical public health issues.

Reviewing medical device safety and performance

Throughout 2023-24, we conducted numerous post-market reviews of a range of medical devices to assess their continued safety and performance. This work included reviews of home-use foetal dopplers, ventilators, sleep apnoea devices, spinal cord stimulators, plastic syringes, HIV nucleic acid tests and neonatal incubators. Following these reviews, action was taken to remove all 9 home-use foetal dopplers from the Australian Register of Therapeutic Goods (ARTG) due to the risks associated with unsupervised use. We also identified and cancelled 12 non-compliant spinal cord stimulator (SCS) devices from the ARTG and imposed stringent conditions on 45 other (SCS) devices to improve their ongoing safety and performance.

We also continued to closely monitor emerging health threats including avian influenza, proactively assessing the suitability of in vitro diagnostic devices to detect these evolving strain variants.

Strengthening pharmacovigilance and vaccine evaluation

We expanded our pharmacovigilance efforts to include comprehensive monitoring of newly registered vaccines and other high-priority products. This included focused surveillance on Shingrix following its inclusion in the National Immunisation Program (NIP), as well as the recently approved Respiratory Syncytial Virus (RSV) vaccines, AREXVY and ABRYSVO, and the RSV monoclonal antibody Beyfortus. This coordinated approach enabled timely detection of safety signals and implementation of appropriate regulatory actions to maintain public confidence in these critical therapeutic products.

Additionally, we undertook thorough investigations into glucagon-like peptide-1 receptor agonists (GLP-1 RAs), such as Ozempic (semaglutide), resulting in product label updates and regulatory interventions to address potential risks to the community.

Priortising the evaluation and laboratory testing of new products

The TGA prioritised the evaluation and approval of COVID-19 vaccines, including those containing the new XBB.1.5 strain, as well as novel RSV vaccines, to ensure they met safety, efficacy and quality standards. To support Australia's immunisation efforts, we facilitated the timely release of over 50 shipments of the shingles vaccine Shingrix, effectively addressing supply challenges.

All testing activities adhered to ISO/IEC 17025 standards, demonstrating our commitment to robust quality assurance. In response to policy changes, we intensified our testing of vaping products, with 1,090 samples analysed during the 2023-24 financial year, including more than 280 samples tested as part of Campaign Obelia, a joint operation with the ABF.

Our efforts extended to the investigation of the *Ralstonia pickettii* contamination linked to saline devices, where targeted testing and expert analysis were crucial in ensuring that only safe products remained available to the public.

Addressing medicine and medical device supply disruptions

Recognising the urgency of medicine shortages, we worked closely with relevant teams to prioritise and expedite the evaluation and approval of critical therapeutic products. This strategic initiative aimed to ensure the continuous availability of essential therapeutic goods, addressing healthcare needs across Australia.

Commitment to continuous improvement

We remain dedicated to refining our evaluation and monitoring processes in collaboration with stakeholders. Our focus will continue to be on adapting to emerging health challenges, maintaining the highest standards of patient safety and driving innovation to strengthen public health outcomes in Australia.

Managing medicine and medical device shortages

We maintained oversight and management of medicine and medical device shortages to support continuous patient access to essential therapeutic goods.

Through the following coordinated efforts, the TGA has reinforced its commitment to facilitating continuous patient access to essential therapeutic goods. Our proactive approach to managing medicine and medical device shortages, in collaboration with key stakeholders, has strengthened our ability to respond swiftly to supply disruptions and mitigate their impact on public health

Medicine shortages

Building on the legislative amendments made in 2022-23 to provide additional access pathways to alleviate the effects of medicine shortages, the TGA continues to strategically manage medicine shortages using a range of mechanisms, including stakeholder engagement and partnerships.

Medicine shortages management:
The TGA continued to improve management actions and strategies for monitoring and addressing shortages of important medicines. This included convening multiple Medicine Shortages Action Group (MSAG) meetings to address high-impact shortages. Each MSAG is a short-term working group that brings together health professionals, consumer representatives and relevant stakeholders to provide clinical shortage management strategies.

Coordination of Medicine Availability Working Group (MAWG):
The MAWG, consisting of representatives from state and territory health departments and expert advisers, met monthly to discuss medicines of concern and provide expertise on supply and demand forecasting. This group played a key role in monitoring and managing shortages of critical medicines, ensuring ongoing availability for patients.

Dynamic Model of Medicine Availability:
We developed a new Dynamic Model of Medicine Availability to forecast the availability of hospital medicines under various scenarios. This modelling enabled us to collaborate with stakeholders in hospital settings to predict and manage medicine shortages more effectively, especially during critical supply disruptions.

Data sharing for hospital medicine shortages:
In 2023-24, we progressed a targeted consultation on a data-sharing framework to improve the management of serious hospital medicine shortages. By collaborating with supply chain groups and health authorities, we ensured that accurate data on medicine supply and demand was available to support national medicine conservation and management strategies.

Medicine Shortages Report 2024:
Our data-driven approach continued to evolve during the 2023-24 period, informed by state and territory health departments, wholesalers, sponsors and other key stakeholders. The results of this work were subsequently published in the *Medicine Shortages Report 2024 on 30 July 2024*, which includes data, case studies, and an overview of our strategies for addressing shortages.

Medical device shortages

Although medical device sponsors are not currently required to report shortages to the TGA, we continued to work closely with sponsors, states and territories, and overseas regulators to monitor emerging signals of shortages and supply disruptions. Our collaborative approach with stakeholders allowed us to manage potential risks and address supply chain issues efficiently. Several device disruptions, such as those stemming from delays due to global regulatory changes, impacted supply availability.

In the 2023-24 financial year, the TGA received 51 signals of device supply disruptions, of which 27 were successfully resolved. Through regular engagement with relevant stakeholders, including state and territory health departments, healthcare professionals and sponsors, we shared information and updates on actions to mitigate the impact of these supply issues on patient access.

Facilitating regulation of psilocybin and MDMA supply

We introduced regulatory changes to facilitate the domestic manufacture, import, prescribing, and supply of psilocybin and MDMA by authorised psychiatrists for clinical use.

Effective from 1 July 2023, the TGA rescheduled psilocybin and MDMA from Schedule 9 (prohibited substances) to Schedule 8 (controlled drugs) of the Poisons Standard, specifically for the treatment of treatment-resistant depression and post-traumatic stress disorder (PTSD). For all other uses, these substances remain classified as Schedule 9 and are restricted to use in clinical trials.

To ensure the safety and efficacy of these treatments, we also developed draft quality standards for MDMA and psilocybin, specifying the minimum quality requirements for both the active pharmaceutical ingredients (API) and the finished products. These quality standards aim to ensure consistency in the products supplied to Australian patients, supporting the known safety and therapeutic outcomes.

Quality standards development

The draft standards for MDMA and psilocybin were developed with input from companies manufacturing these substances for clinical trials, ensuring that the proposed requirements reflect current methodologies and testing limits for both the API and finished products (e.g. capsules). To gather broader stakeholder input, a public consultation was held between 8 December 2023 and 31 January 2024. Stakeholders, including manufacturers, peak health organisations, medical practitioners, pharmacists and patients, provided feedback with broad in-principle support for the proposed standards. Several minor technical changes were suggested and are now under review.

Authorised Prescriber (AP) scheme

Under the TGA's AP scheme, registered psychiatrists can prescribe MDMA and psilocybin for psychedelic-assisted psychotherapy for the treatment of treatment-resistant depression and PTSD. To become an AP, medical practitioners must receive approval from a Human Research Ethics Committee (HREC) under a defined treatment protocol. Once approved, psychiatrists are required to report biannually to the TGA on the number of patients treated with these unapproved products.

During the initial reporting period (1 July 2023 to 30 June 2024), 12 applications were authorised, allowing 9 psychiatrists to prescribe MDMA and/or psilocybin for psychedelic-assisted psychotherapy:

Medicine and indication	Number of psychiatrists authorised
MDMA	3
Psilocybin	3
Both MDMA and psilocybin	3
Total	**9**

Continuous monitoring and implementation

The TGA continues to provide regulatory oversight of these substances through the AP scheme and publication of the quality standards, with preparatory work for the quality standards completed during 2023-24 and implementation scheduled for January 2025. The TGA will work closely with stakeholders to ensure compliance and maintain stringent oversight of psilocybin and MDMA treatments, safeguarding patient safety while expanding access to innovative therapeutic options.

Enhancing laboratory testing for high-risk products

We increased the frequency and scope of laboratory testing for ARTG registered and listed products identified as higher risk, ensuring adherence to regulatory standards and protecting consumer safety.

The Laboratories Branch continued its annual risk-based testing program to identify and monitor therapeutic goods that pose the greatest risk of non-compliance with regulatory requirements. In the 2023-24 financial year, in addition to testing ARTG registered and listed products, the program also placed particular emphasis on nicotine vaping products, which, while not approved or ARTG listed, are known to carry significant risks to public health.

Additionally, the Laboratories Branch conducted extensive testing on several other high-priority products, including:

- sunscreens
- vitamin D supplements
- COVID-19 vaccines
- insulin preparations, and
- factor VIIa products.

Through this comprehensive testing program, the TGA was able to identify non-compliant products and take appropriate regulatory actions to protect consumer safety and maintain the integrity of therapeutic goods in Australia.

Commitment to consumer safety

The risk-based testing program continues to be a key tool in ensuring that products available to Australian consumers meet strict regulatory requirements. By focusing on high-risk categories, the TGA demonstrates its commitment to protecting public health and ensuring that non-compliant products are promptly identified and addressed.

Advancing the Action Plan for Medical Devices

We continued to implement the Action Plan for Medical Devices, improving pathways for device market entry, enhancing post-market monitoring, and ensuring patients have better access to information about the devices they use.

During the 2023-24 period, the TGA made significant advancements in the regulation and oversight of medical devices. Our comprehensive efforts included publishing essential guidance documents, engaging extensively with stakeholders, enhancing regulatory processes, and implementing targeted IT improvements to better identify devices incorporating software, Artificial Intelligence (AI), and machine learning (ML) technologies. The TGA continued to strengthen post-market monitoring and safety, improved consumer access to device information, and collaborated through targeted working groups. These achievements emphasise our ongoing commitment to ensuring the safety, performance and availability of medical devices in Australia.

Market entry and regulatory engagement

Over the past 12 months, we have published and updated 21 guidance documents, covering critical topics such as boundary and combination products, real-world evidence for medical devices, personalised medical devices, software as a medical device including AI, and ongoing reclassification reforms. Our regulatory engagement has been extensive, with more than 100 stakeholder interactions taking place. These included workshops, presentations, conferences, webinars and roundtable meetings with representatives from government, industry, consumer groups and healthcare organisations. Facilitating "lived experiences" discussions underpinned our reform approaches to ensure alignment with consumer and user expectations.

We completed 10 public consultations, addressing important regulatory areas such as boundary and combination products, in vitro diagnostic (IVD) devices, software as a medical device (SaMD), electronic instructions for use for medical devices, and the essential principles of medical devices. Additionally, we delivered over 70 presentations at various conferences and symposia, ensuring ongoing communication about medical device reforms and providing important regulatory updates.

Significant progress has been made in implementing a new risk based AAF. To support this, the TGA worked closely with industry to adopt this new approach for government approvals. Now, the TGA can recognise certifications from comparable overseas regulators (CoRs), such as those in Canada, Japan, Singapore, the United States and the European Union. This recognition leverages existing assessments and streamlines the market entry process for medical devices.

To support our efforts, we made improvements to our IT systems, to better equip us to identify medical devices that incorporate software, AI or ML technology. These enhancements ensure our regulatory processes remain robust and effective in overseeing emerging technologies and provides transparency to the public about devices approved for supply in Australia.

Throughout the reporting period, the AAF processed 45 requests and conducted 38 meetings to assist applicants progress their applications. These engagements contributed to improved compliance, increased transparency and stronger collaboration with industry. Additionally, legislative changes to support CoR certification were initiated, with implementation from 1 July 2024. These changes will reduce the need for full audits, thereby enhancing the efficiency of device application audit processes.

We developed guidance documents setting out the risk factors and audit selection process, as well as our new case management approach to assist sponsors selected for audit. These initiatives ensure a robust and streamlined approach to managing audits and regulatory requirements.

Post-market monitoring and safety enhancements:

The *Therapeutic Goods Act 1989* was amended in March 2023, making it mandatory for public, private and day hospitals in Australia to report certain medical device related adverse events to the TGA. Regulations that set out the implementation details are expected to be in place in March 2025.

Consumer Information and the Australian UDI Database (AusUDID)

The AusUDID has been updated to allow manufacturers and sponsors to link patient information leaflets with unique device identifiers (UDIs). This enhancement aims to improve access to essential device information for consumers. In 2023-24 the system has undergone successful testing and is on track for full implementation during 2024-25.

Specific working groups:

Throughout the reporting period, various working groups contributed to advancing regulatory initiatives and enhancing consumer engagement.

- **Breast Implant Expert Working Group (BIEWG):** This group met twice, publishing a comprehensive risk management framework for breast implants. The group concluded its work in April 2024, having achieved its goals, with the option to reconvene if necessary.
- **Medical Devices Consumer Working Group (MDCWG):** Meeting 5 times, this group made significant contributions to public consultations, consumer-focused campaigns, and the refinements of the regulation of software and AI in medical devices. Incorporating the consumer voice in our reform work was recognised in the group's nomination for an Institute of Public Administration Australia - Spirit of Service Awards.
- **Women's Health Products Working Group (WHPWG):** This group met twice, covering critical topics such as the use of AI in women's health, media classification for IVF treatments, accessibility of oral contraceptives, and the regulation of feminine hygiene products.

Progressing the Unique Device Identification system

We advanced the development and international alignment of the Unique Device Identification (UDI) system to enhance product safety and improve surveillance across the Australian supply chain.

Advancing UDI development and international alignment

Throughout the year, we made significant progress in further developing the UDI system, which will improve the traceability and identification of medical devices. The system will facilitate better pre-market assessments and more efficient post-market safety activities, including quicker identification and recall of problem devices and improved adverse event management.

In 2023-24 we continued to work closely with medical device manufacturers, sponsors and international regulators, to ensure that Australian UDI requirements are aligned internationally. This alignment will minimise the impact on the medical device industry while enhancing post-market surveillance. We expect the UDI regulations to be finalised during 2024-25 with the formal launch of the system and commencement of compliance activity.

Key policy areas and industry engagement

Our consultations with sponsors and manufacturers focused on three key policy areas:

- consistency of UDI information when a device has more than one sponsor in Australia
- labelling requirements for devices sold solely in retail and not supplied to hospitals, and
- finalising Australia's UDI implementation timetable, while ensuring, where possible, alignment with the EU's UDI and Medical Device Regulation (MDR) transition.

We received positive industry feedback during these consultations, ensuring our approach supports and balances both local and international requirements.

Testing and refining the AusUDID

AusUDID has undergone extensive testing, with more than 120 sponsors providing valuable feedback. This has helped us refine UDI data elements, data validation rules and machine-to-machine transfers, improving the overall user experience.

Collaboration with health organisations

Engagement with Queensland Health, NSW Health, and the Australian Commission on Safety and Quality in Health Care (ACSQHC) provided critical insights into hospital IT systems. This collaboration has allowed us to fine-tune our guidance and messaging to healthcare providers, leading to more effective integration of the UDI system in the future.

Supporting sponsors through regulatory processes

We provided ongoing support to sponsors, helping them to navigate regulatory and reimbursement processes, and expanding regulatory approvals for therapeutic goods in key areas of health care.

Improving access to adverse event reports

A new self-serve system was introduced enabling sponsors to access adverse event report information more efficiently. This enhancement allows sponsors to meet their regulatory requirements more rapidly without needing to request reports directly, streamlining processes and improving compliance.

Guidance for COVID-19 vaccine strain updates

Updated guidance was provided to assist sponsors in managing COVID-19 vaccine strain updates, helping to ensure the rapid availability of vaccines addressing new variants. This guidance supports the continued efficacy of vaccines during evolving pandemic conditions.

Introduction of the Promise Pilot Pathway

The Promise Pilot Pathway, a new priority review process for international workshare applications, was introduced to expedite the approval of critical prescription medicines. This initiative aims to accelerate regulatory reviews for medicines that address public health needs, improving the timeliness of regulatory decisions.

Engaging with sponsors

We engaged with sponsors through multiple industry channels, including pre-submission meetings, pipeline discussions and targeted presentations. Over the financial year, we accommodated 26 requests from sponsors for pre-submission meetings, allowing sponsors to receive tailored regulatory advice and enabling the regulator to understand the relevant issues likely to be encountered.

In addition to these meetings, we responded to over 800 email enquiries, offering timely and comprehensive guidance to sponsors on regulatory processes.

Educational webinars and resources

We delivered educational webinars designed to assist sponsors in drafting product information documents, with a particular focus on compliance with regulatory requirements for generic medicines. These webinars provided practical guidance on aligning product submissions to TGA standards.

Rapid response to sponsor enquiries

We demonstrated a commitment to supporting sponsors with fast and efficient responses to regulatory enquiries, with an average response time of four days for approximately 770 enquiries related to product approvals.

Reforming clinical trials regulation

We reviewed and reformed the regulatory framework for clinical trials, offering clearer guidance, expanding scientific advice, and enhancing oversight of high-risk trials to improve safety and regulatory compliance.

Legislative changes and oversight

In November 2023, legislative amendments expanded the TGA's capacity to gather more detailed information about certain high risk medical devices used in clinical trials. Access to this information helps us to identify any safety concerns. The changes also mean that medical device trials are incorporated into the Good Clinical Practice (GCP) inspection program, enhancing oversight of medical device trials, and empowering the TGA to intervene when necessary to protect public interest.

Updated Clinical Trial Notification (CTN) form

In April 2024, we updated the CTN form, introducing mandatory fields and a file upload function for documents such as the Investigator's Brochure. This update has improved the data quality received from sponsors and facilitated better monitoring of clinical trials.

Proactive monitoring of high-risk trials

The TGA's monitoring has focused on first-in-human trials of 8 categories of implantable and cardiac invasive devices, which pose a high risk of catastrophic consequences in the event of failure. Monitoring efforts for these high-risk trials were significantly improved through the new CTN form. The first review of a high-risk first-in-human trial commenced in June 2024, marking a key step in ensuring enhanced oversight and patient safety.

Webinars and stakeholder engagement

To support sponsors and ensure compliance with new regulatory requirements, we hosted 2 key webinars in 2024:

1. Insights from the TGA GCP inspection program (March 2024)
2. Updates to the CTN form and first-in-human high-risk implantable or cardiac invasive medical device trials (May 2024).

These webinars provided vital information on regulatory changes and offered practical guidance for stakeholders.

Updated guidance for sponsors

In addition to webinars, we published new and updated guidance documents for sponsors, including guidance on the GCP inspection program and proactive monitoring of high-risk medical device trials. These resources aim to improve the clarity of clinical trial requirements and enhance the reporting quality for sponsors.

Building robust international regulatory partnerships

We strengthened international regulatory systems and processes through improving work-sharing arrangements and harmonisation with global regulators to enhance product access and safety, particularly in response to communicable diseases.

Indo-Pacific Regulatory Strengthening Program (RSP) multilateral engagements

Globally, regulatory authorities increasingly rely on collaboration with other National Regulatory Authorities (NRAs) to reduce duplication of effort, maximise the efficient use of resources, and build trust across international borders. The TGA, through the RSP, has been actively working with Southeast Asian NRAs and regional reliance-based mechanisms, such as the Association of Southeast Asian Nations (ASEAN) Joint Assessment Procedure for Pharmaceutical Products (ASEAN JA), to support international partnerships and enhance mutual recognition and cooperation. These efforts aim to streamline market access across Southeast Asian markets, allowing products approved in one market to gain entry into multiple others.

Bilateral meetings

Throughout the reporting period, the TGA participated in several bilateral meetings aimed at reinforcing international regulatory relationships and addressing shared challenges.

- In November 2023, we hosted a delegation from Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC). Discussions focused on critical topics such as traceability, manufacturing and regulatory controls for active pharmaceutical ingredients and excipients, risk-based market authorisation processes, pharmacovigilance, and laboratory inspection practices. This engagement was aimed at supporting Nigeria's regulatory capacity-building efforts.
- In the same month, we hosted senior representatives from Health Canada's Health Products and Food Branch (HPFB), including the Assistant Deputy Minister and Chief Medical Advisor. Discussions covered shared regulatory priorities such as NVPs, medicinal cannabis, advanced therapeutic products and vaccine development for COVID-19 and RSV. These exchanges reinforced the longstanding collaboration between the TGA and Health Canada.
- In April 2024, the TGA hosted a delegation from Bangladesh's Ministry of Health and Family Welfare, Directorate-General of Health Services, and Directorate-General of Medical Education. Key topics included medical devices regulation, medicines, post-market surveillance, adverse event reporting and laboratory capabilities. This high-level engagement contributed to enhancing Bangladesh's regulatory framework.
- In May 2024, the TGA hosted a roundtable with Malaysia's Deputy Health Minister, in collaboration with the Australian Department of Foreign Affairs and Trade (DFAT). Discussions covered a broad range of regulatory topics, including Malaysia's RSP supported by DFAT, tobacco and vaping regulations, and regulation in the context of communicable and non-communicable diseases. This bilateral engagement further solidified regulatory cooperation with Malaysia.
- In June 2024, TGA representatives visited Health Canada in Ottawa for a series of bilateral meetings. Key topics included precision regulation, reliance models, collaboration on medical devices, and regulatory approaches to medicinal cannabis and psychedelic substances. These meetings also addressed mutual challenges such as medicine shortages and compounding practices. The deepening of this partnership through extensive bilateral discussions reflects our ongoing commitment to regulatory convergence.

By engaging with global regulatory counterparts, the TGA has furthered its strategic goal of enhancing international regulatory frameworks through harmonisation and collaboration. These efforts have contributed to improving the safety and availability of therapeutic products both domestically and internationally.

During this reporting period, 2 important medicinal products were successfully registered via ASEAN joint assessments supported by the RSP:

- Cabotegravir, the first long-acting injectable HIV pre-exposure prophylactic therapy, and
- Ocrelizumab, used for the treatment of relapsing Multiple Sclerosis.

Analysis of the 2022 ASEAN joint assessment of cabotegravir, conducted in collaboration with participating NRAs, the WHO and the Bill and Melinda Gates Foundation, demonstrated that this approach led to faster evaluation timeframes compared to standard regulatory pathways. It also enhanced technical capabilities and strengthened trust between participating regulators. These findings underscore the success of reliance-based mechanisms in improving the efficiency of regulatory processes while maintaining high standards.

Moving forward, the TGA will continue to expand regulator-to-regulator cooperation, fostering greater compatibility between Australian, Southeast Asian and global regulatory frameworks through initiatives such as the RSP. These efforts are expected to support improved health outcomes in the region's growing markets.

Agreements to facilitate information sharing

In addition to multilateral collaborations, the TGA has established numerous agreements with international regulatory counterparts to enable the confidential exchange of information. These agreements are vital in reducing duplication of effort and expediting certain assessments, ensuring Australia maintains timely access to safe, high-quality therapeutic goods. Currently, the TGA has over 30 such agreements in place, alongside participation in 5 treaty-level Mutual Recognition Agreements (MRA) with other countries.

During this reporting period, the TGA signed a new agreement with the South African Health Products Regulatory Authority (SAHPRA), further enhancing our international cooperative efforts. Additionally, we progressed negotiations on agreements with:

- The Central Drugs Standard Control Organisation (CDSCO) of India's Ministry of Health and Family Welfare, and
- The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea.

World Health Organization (WHO) involvement

The TGA, also through the RSP, played a significant role in regional WHO initiatives during the reporting period. Australia, represented by the TGA, was elected as a representative for the Western Pacific region and served as vice-chair of the Steering Committee of the WHO's Member State Mechanism on Substandard and Falsified Medical Products. RSP staff contributed actively to working groups under this mechanism, addressing the significant global risks posed by substandard and falsified medicines.

Australia's involvement extends further through the TGA's participation in the WHO Coalition of Interested Parties (CIP) at both global and regional levels. The RSP leverages its role in the CIP Global Steering Group (GSG) to support the high-level regulatory strengthening strategy, with a particular emphasis on improving regulatory frameworks in Southeast Asia and the Pacific.

This engagement reflects Australia's commitment to advocating for robust, harmonised regulatory systems in regions where healthcare product safety is critical.

At the regional level, the RSP contributed to the South-East Asian Regional Network (SEARN) through active participation in drafting groups focused on Capacity Building, Integrity of Excipients, and Reliance. The TGA, as a Stringent Regulatory Authority (SRA), provided expert insights into these areas, collaborating with international partners to address key regulatory challenges. The work of these drafting groups has helped to strengthen the region's ability to safeguard the quality and safety of therapeutic products.

Australia's continued leadership and participation in these international and regional initiatives reinforce the TGA's strategic objective of supporting global health by enhancing regulatory systems.

WHO-Listed Authority (WLA) process

The TGA has initiated a process to be designated as a WLA. This designation will affirm the TGA's status as meeting the highest regulatory standards for ensuring the quality, safety, and efficacy of medicines and vaccines. In June 2024, the TGA submitted an expression of interest to the WHO for WLA listing, with the formal assessment process scheduled to take place during the 2024-25 financial year. Achieving WLA status will enhance Australia's international recognition as a trusted regulatory authority on the global stage.

International initiatives and forums

Throughout the reporting period, the TGA actively contributed to various global initiatives aimed at harmonising regulatory standards and improving the quality of medicines.

- **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH):** The TGA played a key role in developing harmonised international guidance through its involvement in ICH Expert Working Groups. These efforts contribute to global alignment in regulatory standards, ensuring the quality and safety of pharmaceuticals.
- **International Pharmaceutical Regulators Programme (IPRP):** The TGA maintained active membership in the IPRP Quality and Bioequivalence Working Group for Generic Medicines, which provided a platform for surveying global regulatory approaches and proposing convergence topics to enable greater regulatory cooperation. As part of this commitment, the TGA will attend face-to-face meetings in Singapore in September 2024 to progress ongoing projects and strengthen international collaboration.
- **Generic Drug Cluster:** The TGA also participated in the Generic Drug Cluster, a forum chaired by the US Food and Drug Administration (US FDA). These quarterly meetings facilitate discussions among global regulatory agencies on technical and emerging issues related to generic medicines. The TGA's involvement in this cluster enables the exchange of knowledge and best practices, contributing to the advancement of regulatory approaches in the generic medicines space.

Medical devices authorisation and surveillance

The TGA continues to review and reform its regulatory frameworks to ensure they remain fit-for-purpose, with a focus on enhancing international harmonisation and adopting reliance and recognition processes where feasible. These efforts contribute to faster market access for medical devices, ensuring that Australian patients benefit from innovations already approved in comparable international markets.

- **Australian-United Kingdom (AUS-UK) Mutual Recognition Agreement:** Following Brexit, the operational AUS-UK MRA continues to provide streamlined regulatory pathways, allowing medical devices approved in the United Kingdom to be accessed more quickly in Australia. This ongoing collaboration ensures that Australia remains aligned with evolving global standards while also enabling Australian medical device manufacturers to export to the UK under the MRA.
- **European Union (EU) regulatory alignment:** The TGA has amended its processes and timeframes to align with recent regulatory changes in the EU, where appropriate. These amendments ensure that medical devices regulated under the EU framework can undergo a streamlined assessment process in Australia, enhancing regulatory efficiency without compromising safety.
- **International harmonisation and reliance:** The TGA has established streamlined auditing and assessment processes in collaboration with EU regulators and other comparable international authorities. These reliance-based frameworks expedite the approval process for medical devices, reducing duplication of effort while maintaining high regulatory standards.
- **Global engagement:** The TGA remains actively engaged in international medical device regulation through its participation in multilateral and bilateral forum, including the International Medical Device Regulators Forum (IMDRF) and the Medical Device Single Audit Program (MDSAP). We are members of 7 IMDRF Working Groups, including as Chair of the Personalised Medical Devices Working Group. In addition, the TGA is the current chair of the MDSAP Regulatory Authority Council, with a focus on enhancing the MDSAP to transition it from a pilot program and ensuring it has the transparency, accountability and frameworks in place for expansion and to be sustainable into the future. These engagements facilitate global regulatory convergence, enabling faster Australian access to safe and effective medical devices.

By maintaining its commitment to international collaboration and regulatory reform, the TGA ensures that its medical device regulatory framework remains responsive, efficient, and aligned with global best practices.

Enhancing international medical device safety and supply chain resilience

The TGA has been actively contributing to monthly International Medical Device Safety (IMDS) meetings alongside 11 other international medical device regulators. These meetings provide a crucial platform for:

- **Exchanging information:** Sharing intelligence on emerging health and safety risks, as well as findings from investigations and recalls.
- **Harmonisation of approaches:** Aligning regulatory actions and processes, particularly in managing global supply disruptions.
- **Administrative support:** Leading the provision of administrative support to ensure the IMDS platform remains a robust tool for information sharing among international regulators.
- **Managing supply chain disruptions:** With increasing global supply chain challenges, the IMDS meetings have allowed the TGA to exchange real-time intelligence on pending medical device or raw material shortages. This includes identifying clinical alternatives, engaging with suppliers to secure local supply, exploring import alternatives, and ensuring timely communication with healthcare providers.

A number of short-term working groups were established to focus on addressing critical safety issues to improve patient outcomes.

The TGA also plays an active role in international standard working groups related to medical devices, risk management and quality management systems. This participation contributes to international standards that are robust enough to maintain the performance and safety of medical devices worldwide.

Pacific Medicines Testing Program (PMTP)

The TGA remains actively involved in the PMTP. Between 1 July 2023 and 30 June 2024, the program tested 32 medicines for the 13 participating countries, with 21.9% of these medicines failing to meet the required testing standards.

In February 2024, the TGA hosted the Training Course in Medicines Regulation – Detect, Respond, and Prevent, which focused on enhancing regional regulatory capabilities. This course trained 26 delegates from participating countries and 2 WHO observers, and covered both regulatory and laboratory-based aspects of identifying and managing substandard medicines.

Strengthening international agreements and arrangements for Good Manufacturing Practice (GMP)

The TGA maintains several international agreements and arrangements with other countries and regulatory authorities, to enhance mutual reliance on GMP inspection programs. These agreements enable the TGA to streamline the process for GMP Clearances by recognising the inspections conducted by partner regulators, thus facilitating market access for therapeutic goods in Australia.

- **Mutual Recognition Agreements:** MRAs are legally binding international agreements designed to facilitate trade by allowing mutual recognition of GMP inspections for medicine manufacturers. Since December 2023, all European Union members have been operational under the EU-Australia MRA for GMP, enhancing collaboration and efficiency in regulating medicines between Australia and the EU. Throughout 2023-24, the TGA held regular meetings with MRA partners to review the regulatory frameworks and GMP inspection protocols, ensuring the continued effectiveness of these agreements.
- **Health Canada collaboration:** A memorandum of understanding (MoU) was signed with Health Canada in 2023-24 to further increase collaboration between the 2 regulators. This agreement facilitates greater reliance on GMP inspections conducted outside each country's borders, expanding the scope of recognised inspections and reducing the duplication of effort for manufacturers operating in multiple markets.
- **GMP Single Inspection Program Pilot:** In partnership with Health Canada and the UK's Medicines and Healthcare products Regulatory Agency (MHRA), the TGA initiated a pilot GMP Single Inspection Program. This program is designed to establish a globally coordinated approach to GMP inspections of foreign manufacturing sites of common interest. The pilot aims to improve inspection efficiency and harmonise regulatory standards across participating countries, further enhancing the safety and quality of medicines entering the Australian market.

These agreements and arrangements underscore the TGA's commitment to fostering international collaboration and ensuring that GMP standards are upheld globally, benefiting Australian consumers and supporting the safety, quality and accessibility of therapeutic goods.

Enhancing global pharmacovigilance and drug shortage mitigation efforts

At the end of 2023, the TGA took on a leadership role as chair of the Drug Shortages Global Regulatory Working Group, an international forum comprising medicine regulators from the EU, the UK, Canada, the United States, Japan and Australia, along with the WHO. This working group was established to facilitate the sharing of information on globally impactful drug shortages and the actions taken by each jurisdiction to mitigate these shortages. Meeting quarterly, the group fosters international collaboration aimed at reducing the global impact of medicine shortages and improving patient outcomes.

The TGA also continued its role as co-chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) COVID-19 Vaccine Pharmacovigilance Network (VPN), alongside the UK's MHRA. This network meets regularly to share critical knowledge and experiences related to COVID-19 vaccine

pharmacovigilance, with a focus on monitoring safety and benefit-risk profiles. These meetings ensure that global regulatory bodies remain aligned on the latest safety data and contribute to informed decision-making around vaccine safety.

The TGA was also an active participant in the International Post-Market Surveillance Teleconference, an initiative that facilitates the exchange of information regarding the safety of medicines and vaccines. This collaboration not only informs global regulators of potential safety issues but also strengthens the evidence base for safety signal investigations in Australia, ensuring that the Australian public benefits from the latest international safety data.

Moreover, the TGA participated in the Access Consortium Clinical Trials Working Group, collaborating with regulatory counterparts from Health Canada, Singapore's Health Sciences Authority, Swissmedic, and the UK's MHRA. This group focuses on harmonising clinical trial regulations and sharing knowledge to improve the regulatory oversight of clinical trials. The TGA also engages with other regulators in work-sharing evaluations for Risk Management Plans (RMPs), ensuring that Australia's pharmacovigilance efforts are informed by the latest international developments.

Strengthening regulatory systems in the Pacific and South-East Asia

We worked closely with National Regulatory Authorities in the Pacific and South-East Asia regions to fortify regulatory systems, promoting public health and improving regulatory outcomes.

TGA's International Engagement Strategy

The TGA's International Engagement Strategy 2021–2025 outlines our long-term commitment to collaborating with international regulatory counterparts through technical assistance programs. These efforts aim to strengthen regional regulatory systems and promote access to safer and more effective medical products.

Regulatory strengthening as a long-term process

Since the 1990s, the TGA has provided expert technical support to regional NRAs. Over the past 5 years, with the support of the Australian Government, we have delivered regulatory strengthening programs in the Pacific and Southeast Asia. These programs benefit NRAs individually and promote the value of collaboration. The RSP builds on these efforts, combining successful elements of previous TGA-led programs.

Indo-Pacific Regulatory Strengthening Program

The RSP is implemented by the TGA, under the Australian Government's Partnerships for a Healthy Region initiative, spanning from 1 July 2023 to 30 June 2027. This program works with NRAs and Ministries of Health from 22 countries to strengthen regulatory systems and support the availability of quality, safe and effective medical products for managing communicable diseases, |noncommunicable diseases, sexual and reproductive health, and assistive technologies.

Contributions to public health:

With RSP support, regional NRAs made assessments or decisions on 10 products addressing serious public health challenges, including malaria, COVID-19, human immunodeficiency virus (HIV), and critical medicine shortages. This reflects our strategic focus on improving product quality and safety with a real-world benefit to public health.

- **Capacity building:** Ongoing technical training was provided to 9 participating regulators, covering all aspects of the product life cycle. The training focuses on building technical capability and assisting in the development of associated policies and procedures, which will increase the availability of quality-assured medicines and help to identify and remove substandard or falsified medical products.
- **Workshops and knowledge sharing:** RSP hosted 2 large, multi-day technical assistance workshops. The first covered Bioavailability and Bioequivalence, vital for assessing generic medicines to improve availability and affordability. The second focused on Quality Controls in pre-market medicine assessments. Over 130 staff from NRAs across 10 Indo-Pacific countries participated in these workshops, highlighting the regional reach and impact of the program.
- **Advanced therapies and reliance practices:** The RSP has contributed to overarching regulatory policies, particularly in the regulation of advanced therapies and reliance-based decision-making. This included invitations to present at the Malaysian National Regulatory Conference (August 2023) and the Workshop on Reliance and Recognition in Drug Registration in Vietnam (December 2023). During the workshops, Malaysia's National Pharmaceutical Regulatory Agency (NPRA) highlighted TGA's support, which was instrumental in the development of their reliance practices.

Recognition of partnership:

On 4 February 2024, the TGA received the Award of International Partnership from Indonesia's National Agency of Drug and Food Control (BPOM), in recognition of our role in strengthening BPOM's regulatory capacity under the RSP.

National Pharmaceutical Reference Agency (NPRA) Biologics section and RSP staff at Malaysia's National Regulatory Conference, August 2023

An exchange of letters between TGA and Thai Food and Drug Administration (FDA) reaffirms the relationship between the two regulators for RSP 2023-2027, establishing a solid foundation for continued partnership.

Regional regulatory engagement

In July 2024, as part of the RSP, the TGA presented to a senior delegation from the Drug Administration of Vietnam (DAV) on the scheduling of medicines and poisons. This engagement supported the enhancement of Vietnam's regulatory systems and contributed to the broader goal of building robust regulatory frameworks across the region.

Training course in Medicines Regulation: Detect, Respond, and Prevent

In Canberra in February 2024, the TGA hosted the training course Medicines Regulation- Detect, Respond, and Prevent, attended by 26 delegates from 13 PMTP countries and 2 WHO observers. The course aimed to enhance the region's regulatory capacity to detect and prevent substandard medicines.

The training included 2 key components:

1. **Workshop-based stream:** Focused on various aspects of medicine regulation, featuring presentations and workshops delivered by TGA experts, and
2. **Laboratory-based stream:** Focused on GPHF-minilab™ training, enabling participants to detect contaminants such as diethylene glycol (DEG) and ethylene glycol (EG) in oral liquid medicines.

Twenty-seven delegates attended the 4 day course in Canberra. The overwhelmingly positive feedback highlighted the program's success in enhancing regulatory capacity within the region.

Refining frameworks for emerging technologies

We refined our regulatory frameworks to support cutting-edge technologies, including digitally enabled diagnostics, point-of-care manufacturing and genomics, ensuring they are effective and responsive to ongoing advancements in health care.

National Roundtable on Digital Therapeutics and Emerging Models of Care

In August 2023, we hosted a National Roundtable on Digital Therapeutics and Emerging Models of Care, bringing together representatives from domestic and international manufacturers of digital health technologies. The roundtable focused on identifying uncertainties and challenges within Australia's current regulatory framework, using innovative digitally enabled products and various access/delivery models as examples. This collaborative approach helped to identify focus areas for further regulatory development to keep pace with emerging health technologies.

Consultation on Clinical Decision Support System (CDSS) Software

We conducted a public consultation on CDSS software to clarify the conditional exemption for CDSS software. This consultation, held in response to concerns raised in recent years, addressed issues such as the need for consistent terminology, scope and functionality of decision supportsoftware, and the criticality that health practitioners can verify outputs provided by the software. The feedback will inform future decisions on CDSS regulation and clarify how manufacturers and software developers can comply with the regulatory framework.

Safe and Responsible AI Initiative

In May 2024, we launched a significant reform program as part of the Australian Government's Safe and Responsible AI initiative. This initiative focuses on reviewing legislation to address the impact of AI in healthcare, therapeutic goods, and other sectors. The TGA hosted 18 targeted consultation webinars, engaging over 600 stakeholders, gathering input on key regulatory issues related to our SaMD framework including AI. The outcomes from these discussions, alongside a public consultation paper, will shape a sector-specific report to the Australian Government and inform a forward program of work for the TGA.

Advancements in Point of Care (PoC) Manufacturing

We progressed work on regulatory frameworks for PoC manufacturing of patient-matched medical devices. An overarching steering committee was established to advance PoC manufacturing efforts, and comprised national regulators, state and territory governments, and Engineers Australia. This committee is supported by 3 sector-specific working groups, representing allied health, the dental sector, and complex manufacturing hubs, and which periodically provide guidance and collaborate with the TGA to develop dedicated materials that will support stakeholders in these healthcare sectors.

Technical Reference Group for SaMD and AI

To address the increasing complexity of software and AI-enabled medical devices, we established a Technical Reference Group (TRG) for SaMD and AI. This group provides the TGA with expert technical knowledge on software and AI technologies and their implications for medical device regulation. The TRG ensures that the TGA has access to the specialist expertise needed to navigate the complex technical and regulatory challenges posed by these rapidly evolving technologies.

Enhancing medical device adverse event reporting

We are introducing new processes for mandatory adverse event reporting by healthcare facilities and piloting a new vigilance program to improve the management of medical device safety.

In March 2023, the Act was amended to make it mandatory for public, private, and day hospitals in Australia to report specific medical device-related adverse events to the TGA.

To guide the strategic planning and implementation of the mandatory reporting scheme, an Interjurisdictional Steering Committee was established in February 2024. This committee includes representatives from the ACSQHC, state and territory governments, private healthcare providers, day hospitals, the Australian Medical Association, and the Royal Australasian College of Medical Administrators. Between February and June 2024, the committee held 4 meetings, focused on harmonising data fields, standardising definitions, and aligning reporting requirements to enhance data consistency and integration.

The TGA is actively collaborating with the ACSQHC in its update to the third edition of the National Safety and Quality Health Service standards, to include mandatory reporting of medical device adverse events as an accreditation requirement for healthcare facilities. Stakeholder engagement has been instrumental in shaping these regulations, ensuring a streamlined approach that strengthens the effectiveness of the reporting framework.

Launch of the Medical Devices Vigilance Program (MDVP)

In September 2023, the TGA launched the pilot MDVP with an information webinar attended by over 500 medical device sponsors. The voluntary program aims to enhance sponsors' awareness, understanding and compliance with regulatory requirements, focusing on improving adverse event reporting and surveillance.

The MDVP pilot is structured in 3 stages to progressively engage sponsors based on compliance risk and the TGA's areas of focus which are:

- sponsor self-assessment tool
- desktop audit, and
- onsite audit.

Continuous feedback from sponsors has been integral to refining the MDVP framework. The pilot will be reviewed and evaluated before providing government with advice on the potential future of the program.

Commitment to continuous improvement

These collective efforts reflect the TGA's commitment to developing a robust framework for medical device adverse event reporting and enhancing industry compliance. Through strategic partnerships and ongoing stakeholder engagement, we aim to refine our processes and ensure a proactive approach to medical device safety, aligning with our goal of protecting public health.

Increasing transparency of adverse event data

We enhanced the Database of Adverse Event Notifications (DAEN), improving public access to adverse event data and increasing transparency in therapeutic goods safety.

Increasing transparency of adverse event data

We have progressively improved transparency in reporting adverse event data, through ongoing enhancements to the DAEN. This year, we built on previous efforts to ensure that the public and healthcare professionals have easier access to critical safety information about therapeutic goods, enhancing public confidence and engagement.

Enhancements to the DAEN and Adverse Event Management System

To support our continuous improvement efforts, we have also modernised our internal Adverse Event Management System. These improvements ensure the reliability of the data underpinning the DAEN, streamlining reporting processes and enabling more effective management of adverse event information.

Expanding data sharing and accessibility

Building on the foundation of previous work, we have continued to refine our data sharing capabilities. These enhancements streamline the process of sharing adverse event information, making it easier for stakeholders to access up-to-date safety data.

Strategic objective 2

Build trust by actively engaging with our stakeholders

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

Performance Indicators

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

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

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

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

Insights from the TGA Stakeholder Survey

In performance indicator 2.1, we look to assess our success at responding to enquiries in a timely and effective manner.

In the TGA's stakeholder survey, respondents were asked if they had contacted or interacted with the TGA in the past 12 months. For respondents with a TBS account, 87% indicated they had. Overall, most were satisfied with their experience communicating with the TGA (65% - down 2% compared with last year), while 14% were dissatisfied (also down 2%) and 21% were neither satisfied nor dissatisfied.

Opt-in p.41, p43 of tables doc

Fewer health professionals and consumers indicated they had contacted or interacted with the TGA in the past 12 months. Overall, most consumers were satisfied with their experience communicating with the TGA (74% - up 3% compared with last year), while 4% were dissatisfied (down 9%) and 22% were neither satisfied nor dissatisfied. Among health professionals, 71% of those who had contacted or interacted with the TGA were satisfied (up 3%), while 9% were dissatisfied (up 1%) and 20% were neither satisfied nor dissatisfied.

Health professional p40 and consumer p81

In performance indicator 2.1, we also look to assess our success at being clear about our regulatory decisions. In the TGA stakeholder survey, stakeholders who had participated in a TGA consultation were asked to rate the various aspects of the process, including whether the TGA clearly explained the outcome. Among TBS account holders, 55% agreed that the TGA had clearly explained the outcome (down 1% compared with last year), while 16% disagreed (down 2%). While the number of health professionals and consumers who had been involved in a TGA consultation was low, 79% of consumers and 76% of health professionals believed the TGA clearly explained the reasons for the final outcome, with disagreement of 2% and 11% respectively.

Opt-in p44, health professional p41 and consumer p83

In performance indicator 2.2, we look to assess our success at actively communicating with and educating stakeholders. In the stakeholder survey, we asked respondents if they had seen or been involved in a TGA educational activity. This included seeing TGA social media advertising campaigns

or social media posts, attending TGA webinars or events such as the GMP Forum, or receiving a TGA email newsletter.

Almost 1 in 5 (19%) of consumers indicated they had seen a TGA educational activity in the past 12 months. Of this number, most had seen a social media campaign or post. Overall, 99% had found the education activity had been useful. Of these, 55% had found the educational activity 'very useful' or 'extremely useful' (up 10% compared with last year).

Consumer p94 and p96

Almost half of health professionals (49%) who were aware of the TGA indicated they had seen or been involved in a TGA educational activity. Of this number, most had seen a social media campaign or post. Overall, 98% of health professionals had found the education activity useful. Almost 3 in 5 (57%) had found the educational activity 'very useful' or 'extremely useful'.

Health professional P45, p47

Over half (59%) of TBS account holders had seen or been involved in a TGA educational activity in the past 12 months. Many of these respondents had attended a TGA webinar or received a TGA newsletter. Overall, 97% had found the education activity had been useful. Of this, 55% had found the educational activity 'very useful' or 'extremely useful' (up 3% compared with last year).

P48 p50

In performance measure 2.3, we look to assess our success at collaborating with domestic and international health system stakeholders to address regulatory issues and understand the impact of changing policies, practices and services.

Representatives from many state and territory agencies, including health departments, were asked as part of the TGA stakeholder survey whether they believed the TGA consults with state and territory governments on regulatory changes. Almost 65% of respondents agreed (up 5% compared with last year) while 14% disagreed (down 8%). State and territory representatives were also asked whether the TGA appropriately considers the impact of its regulatory actions and changes on the states and territories, with 46% agreeing (up 2%) that it does and 23% disagreeing (down by 13%).

State and territory p37

Engaging stakeholders on regulatory policy

We expanded engagement with peak industry bodies, industry start-ups, state and territory health departments and consumer groups on regulatory policy reforms to foster improved regulatory practices and more responsive oversight.

Engagement with medical device stakeholders and regulatory support

The TGA partnered with ANDHealth to offer regulatory support for digital medical software companies aiming to commercialise new products. During 2023-24, this initiative delivered 11 webinars presented to 440 attendees, and 129 one-on-one stakeholder meetings.

The TGA also continued its engagement with key medical device stakeholders through the Regulatory and Technical Forum. This forum facilitates discussions on regulatory and technical matters relevant to sponsors and manufacturers. It allows stakeholders to raise issues arising from current regulation and propose solutions, while also providing a platform to highlight concerns on both current and emerging issues faced by the TGA and the medical device sector more broadly.

This engagement aligns with the TGA's broader reform agenda to ensure that Australia's regulatory framework remains robust and adaptable in an evolving healthcare landscape. Stakeholders are actively involved in shaping reforms through public consultations, feedback and insights aimed at addressing both industry needs and public health safety.

Addressing medicine shortages and stakeholder engagement

In response to challenges posed by medicine shortages and discontinuations, a comprehensive consultation, *Medicine shortages in Australia – Challenges and opportunities*, was conducted from February to June 2024. This process aimed to better understand the impacts of these shortages on patients, health professionals and industry.

Key outcomes from this consultation included recommendations on priority areas for potential reform, which have been submitted to the Australian Government for consideration. Stakeholder engagement during the development of the reforms workplan involved:

- discussions with international regulatory counterparts, exploring comparable approaches to managing medicine shortages and lessons learned
- a public consultation that received over 200 responses
- market research surveying more than 800 consumers and health professionals, including 17 one-on-one interviews
- webinars presenting the consultation findings, and
- a series of prioritisation focus groups engaging stakeholders across the supply chain.

Findings from the public consultation, along with non-confidential submissions, are available at Medicine Shortages in Australia Consultation.

Additionally, the TGA actively contributed to the Inter-Governmental Policy Reform Group (IGPRG), which focuses on enhancing access to high-quality, ethical research for patients, researchers, industry representatives, and sponsors in Australia.

Collaboration with Medicines Australia Regulatory Affairs Working Group (RAWG)

The TGA regularly engages with the RAWG to address issues of strategic importance to the medicines industry. This collaboration provides an essential platform for industry representatives to directly discuss regulatory concerns with the TGA, and jointly explore ways to improve regulatory processes.

During the reporting period, these meetings identified possible enhancements to regulatory practices. The forum also enabled the TGA to provide updates on key regulatory reforms and other relevant initiatives impacting the medicines sector.

Advertising compliance

The TGA works through industry bodies and associations to educate their members on how to comply with legislative obligations for advertising therapeutic goods. Regular engagement with these stakeholders remains a key part of ensuring compliance with advertising regulations.

The TGA also continues to engage with industries through the Therapeutic Goods Advertising Consultative Committee (TGACC), which holds virtual and in-person meetings to discuss advertising-related issues. Informed by ongoing consultation with TGACC, state and territory regulators and other stakeholders, the TGA ensures that compliance efforts are targeted to the areas of greatest need.

Additionally, the TGA collaborated with 10 social media and digital platforms to raise awareness of compliance priorities. These engagements have allowed for a more rapid response to alleged unlawful advertising. In 2023-24, the TGA expanded this collaboration to include key internet service providers (ISPs) to further strengthen efforts in disrupting access to unlawful advertising online.

Stakeholder engagement on regulatory reforms

Using a variety of communication channels, including social media, subscription newsletters, webinars and events, the TGA raises awareness of regulatory policy reforms among stakeholder groups. Stakeholders are encouraged to engage more deeply with reforms that impact them, through consultation processes or targeted information sessions.

The TGA also seeks input from stakeholders during the planning and development of public awareness and education activities, ensuring that these efforts are informed by those they aim to support.

TGA educational programs and industry engagement

In 2023-24, the TGA continued to collaborate with universities, incubators, industry and other government organisations to develop and deliver educational programs to help businesses and individuals to understand their regulatory obligations within the therapeutic goods sector. This engagement included participation in workshops, events, and speaking sessions to share regulatory knowledge and guidance.

Public consultations on probiotics and sunscreen standards

In July 2023, the TGA conducted a public consultation on the draft *Guidelines for the Quality of Listed Probiotics Medicines*. The consultation received 14 submissions from a range of stakeholders, including industry peak bodies, sponsors, manufacturers, regulatory affairs consultants, international pharmacopoeias and individuals. Feedback from these stakeholders has helped to make the guidelines clearer and more user-friendly. The final version of the guidelines will be published in the 2024-25 period.

The TGA also developed an Australian Sunscreen Exposure Model, enhancing the ability to assess the safety of sunscreen ingredients based on local usage patterns, rather than relying solely on international assessments. This model was developed in collaboration with peak industry bodies and other government, consumer, professional and academic stakeholders. A public consultation on this model is planned before its adoption in 2025.

Additionally, the TGA conducted a public consultation on the adoption of the 2021 Australia/New Zealand Sunscreen Standard. This standard, which was incorporated into therapeutic goods legislation in mid-2024, includes updated ISO testing methods and introduces new labelling requirements for aerosol sunscreens to ensure they are used safely and effectively.

Ensuring transparency in decision-making

We enhanced transparency in our decision-making processes through the use of multiple communication channels, including the TGA Consultation Hub, ensuring stakeholder engagement and trust.

Throughout the 2023-24 financial year, the TGA used its Consultation Hub to engage stakeholders on various regulatory proposals and reforms. Public consultations were subsequently promoted through the TGA's social media channels and subscription newsletters, reaching approximately 80,000 followers, as well as through direct stakeholder contact, targeted emails and information sessions.

Key consultations on regulatory proposals

The TGA conducted consultations on a range of significant regulatory issues, including:

- clarifications on the regulation of CDSS software
- exemptions for certain medical devices, including companion diagnostic IVDs
- MDSAP, and
- point-of-care manufacture of medical devices.

These consultations were followed by webinars that provided stakeholders with additional clarity and opportunities for discussion.

Aligning regulatory frameworks with international standards

Incorporating meaningful stakeholder feedback, the TGA ensured that Australia's regulatory framework for medical devices remained aligned with international standards and adapted to emerging technological advancements. This approach balanced public safety considerations with industry perspectives, supporting both innovation and compliance.

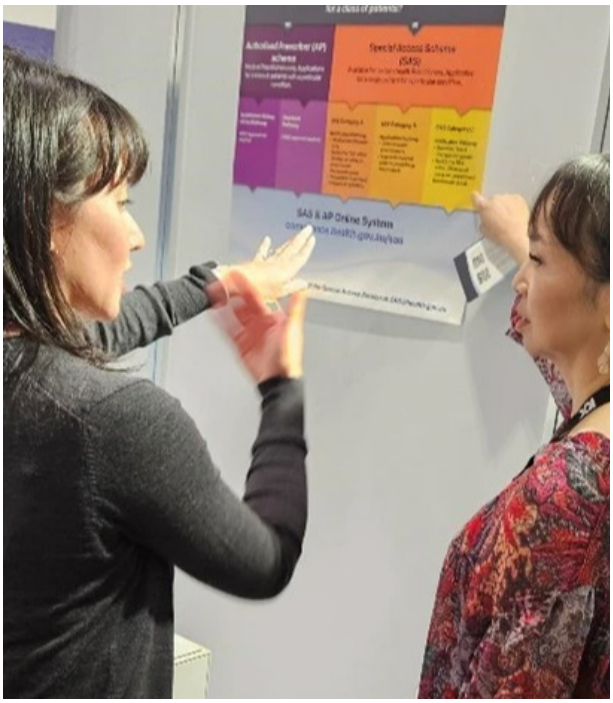
Enhancing reporting transparency

The TGA also promoted transparency in regulatory reporting by enabling sponsors to submit notifications for their CDSS software and custom-made medical device annual reports through the Consultation Hub. This initiative streamlined the reporting process, facilitating easier compliance for stakeholders and contributing to the overall goal of transparency in regulatory practices.

Participation in the General Practice Conference and Exhibition (GPCE)

The GPCE brought together healthcare professionals to discuss the latest medical innovations and approaches to patient care. The TGA delivered a keynote session on vaping reforms, outlining the regulatory changes and their implications for general practice. This session provided key insights to healthcare professionals, ensuring they were well informed about the evolving regulatory landscape.

In addition to the keynote, the TGA engaged with attendees at an exhibition booth, where discussions covered topics such as vaping, the Special Access Scheme (SAS), medicinal cannabis, and medicine shortages. The TGA's presence at the event reinforced its role in educating healthcare providers about important regulatory changes and promoting transparency in its processes.



Improving the TGA website

We invested in the TGA website, improving its consistency, clarity and reliability, ensuring that stakeholders have access to current, trusted, and user-friendly information.

Enhancing website functionality and user experience

We implemented several enhancements to improve the overall usability of the TGA website, informed by user feedback and driven by the need to provide clearer access to regulatory information:

Search functionality- We added new filter fields and refined search result display order, ensuring that more relevant items appear higher. This was complemented by the introduction of searchable data tables, providing users with faster access to key information.

- **Real-time updates-** To enhance user engagement, we introduced RSS feeds and re-established email notifications for medicine shortages, allowing users to receive timely updates.
- **Document uploads in web forms-** We added document upload functionality to web forms, streamlining interactions between users and the TGA.

Content uplift program- We continued our content uplift program, removing outdated information and improving the clarity and quality of content across various areas, including medical devices, adverse event reporting, medicinal cannabis, and vaping.

Supporting new platforms and analytics

The TGA website now supports the new Health Business Services Portal, ensuring a smooth user journey from the main website to the portal. We also prepared for the migration from Google Analytics 3 (Universal Analytics) to Google Analytics 4 (GA4), which will further enhance our ability to track and optimise user interactions on the site.

Website updates and accessibility enhancements

Over 900 updates were completed across the TGA website during the reporting period. These updates focused on improving website navigation, simplifying complex regulatory guidance, and enhancing accessibility to meet the needs of all users, including those with disabilities. Key improvements included:

- **Content simplification-** We rewrote complex regulatory guidance in plain language to ensure it is accessible to a broader audience, including sponsors, manufacturers, health professionals and the public.
- **Improved website navigation-** The structure of the website was reorganised to make it easier for users to find information related to medical devices, medicines and other therapeutic goods.
- **Accessibility enhancements-** Compliance with web accessibility standards was improved, including better text contrast, alternative text for images and enhanced navigational tools to improve usability for people with disabilities.

Focus on regulatory compliance and educational resources

The TGA progressed a series of content updates related to regulatory compliance and enforcement, ensuring that key resources are easily accessible to consumers, health professionals and industry bodies. This effort is part of the Therapeutic Goods Advertising and Compliance Education Plan, which promotes education and compliance with regulatory obligations.

Strengthening international regulatory partnerships

We built on our partnerships with international regulatory bodies through initiatives such as Project Orbis and the International Medical Devices Regulator's Forum (IMDRF), harmonising practices and strengthening regulatory systems globally.

Through IMDRF, the TGA actively contributed to global efforts to harmonise medical device regulations. During 2023-24, we participated in 4 meetings aimed at enhancing opportunities for regulators with emerging capabilities to progress towards regulatory harmonisation. Australia's contribution also included managing online collaboration platforms, such as the IMDRF.org website and the IMDRF Collaboration Hub on SharePoint, which saw significant growth in traffic and member engagement.

As part of the IMDRF internal working group, the TGA focused on strengthening governance processes to ensure the sustainability of the forum. We also supported the development and publication of several regulatory white papers to enhance global regulatory practices.

Leadership in the MDSAP

The TGA, a founding member of the MDSAP, has played a pivotal role in transitioning the program from a pilot to a fully operational model. MDSAP allows recognised Auditing Organisations (AOs) to conduct a single audit of a medical device manufacturer's quality management system (QMS) that satisfies the regulatory requirements of multiple regulatory authorities. This approach provides robust oversight while reducing the regulatory burden on manufacturers.

As Chair of the MDSAP Regulatory Authority Council (RAC) for 2024, the TGA led key enhancement projects aimed at increasing program capacity, monitoring performance, improving audit timeliness, and enhancing overall audit quality. Seven international projects are currently underway, including:

Development of an Independent MDSAP public website- This project will move MDSAP information from the US FDA's website to a new independent domain, improving utility for all stakeholders and enhancing program visibility. The TGA convened an international working group to oversee this development, including input from Affiliate Members and Auditing Organisations.

Remote and Hybrid Auditing Pilot Program- This project explores the use of remote and hybrid audits to increase audit capacity and ensure regulatory oversight in a post-pandemic environment.

The TGA also reviewed the MDSAP Audit Approach document in consultation with Australian sponsors, to ensure clarity on local regulatory requirements and improve the quality of audits conducted. We participated in eight assessments, including head office audits and witness audits of manufacturers, further supporting the program's operational activities.

Key events and collaborations

The TGA chaired the 2024 Medical Device Single Audit Program (MDSAP) Annual Forum held in Essen, Germany, marking the first time the event was hosted by a recognised MDSAP AO, TÜV NORD CERT. TÜV NORD CERT is a certification body accredited to conduct audits under the MDSAP framework. This forum provided a platform for regulatory authorities, AOs and industry stakeholders to engage in panel discussions, training sessions and workshops on the MDSAP program and enhancement initiatives.

Strengthening international partnerships through ICMRA engagement

In 2023-24, the TGA strengthened its collaboration with global regulatory bodies through the International Coalition of Medicines Regulatory Authorities (ICMRA). Established in 2013 to enhance global public health cooperation, ICMRA facilitates strategic leadership and shared solutions during public health crises.

In November 2023, the TGA hosted the annual ICMRA Summit and plenary meetings in Melbourne, bringing together representatives from global medicines regulatory authorities and the WHO. The summit focused on key regulatory challenges and emerging trends in healthcare, with participants discussing critical topics to align regulatory practices globally.

The three major scientific sessions at the summit were:

- Use of Artificial Intelligence (AI) and Machine Learning (ML) in Medicine Regulation- co-chaired by TGA and the European Medicines Agency
- Evolution of Clinical Trials- co-chaired by Health Canada and Ireland's Health Products Regulatory Authority, and
- Advanced Medical Products- co-chaired by the UK's Medicines and Healthcare products Regulatory Agency and Japan's Pharmaceuticals and Medical Devices Agency.

These sessions highlighted the growing need for collaboration between regulators, academia and industry. Discussions emphasised the importance of embracing technological advancements and the role of regulatory frameworks in improving patient access to safe, effective therapeutic goods.

Enhancing global collaboration through the Access Consortium

The TGA continued its active participation in the Access Consortium, a coalition of regulatory authorities from Australia, Canada, Singapore, Switzerland, and the United Kingdom. This medium-sized partnership aims to promote greater regulatory collaboration and alignment of requirements across member countries.

During the 2023-24 period, the heads of the 5 agencies met twice, once in November 2023 in Melbourne and again in June 2024 in San Diego. These meetings were opportunities to review the progress of ongoing working groups and approve the work program for the upcoming year, further strengthening international regulatory alignment and cooperation.

During the reporting period, the Access Consortium maintained 5 active working groups and 3 networks, driving work-sharing initiatives and streamlining regulatory processes:

- New Active Substances Working Group (NASWG)
- Generic Medicines Working Group (GMWG)
- Information Technology Working Group (ITWG)
- Clinical Trials Working Group (CTWG), and
- Advanced Therapy Medicinal Products Working Group (ATMPWG).

Prescription medicines and Access Consortium work-sharing

The TGA further advanced its partnerships through the Access Consortium's work-sharing initiatives. In 2023-24, the TGA approved 9 submissions through the Access New Active Substances Work-Sharing Initiative (NASWSI). In November 2023, the NASWG launched the Promise Pilot Pathway, an aligned process for priority review, enabling partners to adopt a common approach to priority status and work-share assessments. These collaborations streamline regulatory processes, enhance technical expertise sharing, and reduce duplication of effort across partner agencies.

The Generic Medicines Work-Sharing Initiative (GMWSI) saw further operational updates, offering sponsors greater clarity on entry criteria and comparator products. The GMWG engaged global generic medicine sponsors and manufacturers to seek feedback and drive further improvements.

Project Orbis collaboration and prescription medicines approvals

Through our ongoing involvement in Project Orbis, led by the US FDA, the TGA continues to collaborate with international regulatory partners to accelerate the review and approval of oncology products. This joint evaluation framework facilitates concurrent submissions and parallel review, contributing to faster access to novel cancer treatments. The Project Orbis partnership comprises the regulatory authorities from Australia, Canada, Switzerland, Singapore, the UK, Brazil, and Israel.

During the 2023-24 period, the TGA approved 11 submissions through Project Orbis and participated in the first Orbis-Access hybrid collaboration pilot, which involved all 5 Access partners and included the piloting of RMP work-sharing. This initiative strengthens international cooperation and advances regulatory processes to meet patient needs more efficiently.

TGA Participation in the 2024 Drug Information Association Conference

In June 2024, the TGA participated in the Drug Information Association (DIA) Global Conference in San Diego, reinforcing Australia's role as a key player in the global regulatory landscape. The conference, which attracted approximately 5,000 participants, provided a platform for world-leading experts to discuss scientific and medical innovations.

The TGA actively contributed to several sessions alongside international regulatory counterparts, leading a roundtable Q&A titled *"ICMRA Post-pandemic: Regulators Looking into the Future"*, and contributing to the session on *"International Regulatory Convergence: Regulatory Science to Address Challenges Brought by Pharmaceutical Innovation."*

As a member of the Access Consortium, the TGA co-presented a session titled "*Access Consortium: Re-imagining Regulatory Collaboration."* Key topics covered during this session included:

- **Updates and New Access Initiatives:** Highlighting the Promise Pilot Pathway and the Advanced Therapy Medicinal Products Working Group.
- **Clinical Trial Collaboration:** Emphasising opportunities to expand collaboration in pre-submission and clinical trial processes through the Access Clinical Trials Working Group.
- **Strategic Plan Renewal for 2025-2028:** Outlining the Consortium's commitment to strengthening work-sharing initiatives, supporting regulatory innovation, and expanding the lifecycle approach to regulatory practices.

The TGA's presence and active involvement demonstrated Australia's ongoing contributions to global regulatory convergence and innovation.

Pharmaceutical Inspection Cooperation Scheme (PIC/S) and Inspection Reliance

The TGA continues to play an active role in the PIC/S, working with international partners to build consistency and reliance in pharmaceutical inspection processes. As a participant in the European Inspector Working Group, the TGA serves as an observer and leads or contributes to various PIC/S initiatives. This includes the development of guidance on remote inspections, and revisions to the PIC/S Guide to Good Manufacturing Practice (GMP) for medicinal products, specifically addressing Annex 11 on computerised systems and Chapter 4 on documentation.

Raising public awareness of therapeutic goods

We undertook public awareness campaigns and educational initiatives aimed at consumers, health professionals and industry, to promote the safe and effective use of therapeutic goods.

Public awareness education campaigns

Our public awareness education campaigns, designed to address emerging regulatory issues and priority topics, consistently outperformed the Australian Government benchmark. These campaigns reached large audiences, demonstrating the relevance and effectiveness of the TGA's communication efforts. Across 11 paid campaigns, we achieved more than 70.8 million impressions and attracted over 38,000 visitors to our website.

Campaign Overview:

Campaign	Total Impressions
What the TGA regulates	3,889,110
Create content that plays by the rules	1,745,170
Travelling with medicines and medical devices – Phase 2	9,624,963
Vaping access pathways	9,706,217
Committees recruitment	703,608
Medicine shortages	5,459,324
Vaping regulation reforms	9,154,455
Monitoring medicine safety	5,827,258
Adverse event reporting – General	13,685,265
Adverse event reporting – Devices	4,867,942
Compounding medicines	6,164,663
Total	**70,827,975**

Each campaign focused on priority topics, such as vaping regulation reforms, adverse event reporting and medicine shortages, ensuring that target audiences were well-informed on critical health and safety issues.

Compliance education

In parallel with our public education campaigns, the TGA's compliance education strategy focused on maximising compliance with therapeutic goods regulations, particularly regarding advertising, import and supply. The TGA's Therapeutic Goods Import, Advertising and Supply Compliance Education Strategy, alongside the Advertising and Compliance Education Plan 2024, outline the planned education tools and activities, and provide the framework for engaging and educating stakeholders on regulatory requirements.

Key compliance education activities included the publication of safety alerts, guidance materials and consumer awareness campaigns. Compliance-focused media releases and safety alerts were pivotal in raising awareness and served as a deterrent to non-compliance.

Safety alerts and warnings:

Date	Safety Alert
11 Dec 2023	Ying Da Wang Tablets Safety Advisory
11 Dec 2023	Li Da Daidaihua Capsules Safety Advisory
11 Dec 2023	Bigger Longer More Time More Sperms Capsules Safety Advisory
11 Dec 2023	BAIWEI Maximum Powerful Tablets Safety Advisory
11 Dec 2023	Compounding Safety Information: Semaglutide-like Product
29 Jan 2024	Bullblood Tablets
29 Jan 2024	Excite for Her Tablets
29 Jan 2024	Kamasutra Herbal Jelly for Him Bottle
29 Jan 2024	Tantra Jelly
29 Jan 2024	Commander Stamina Time Tablets
29 Jan 2024	Throb Herbal Supplement Tablets
31 Jan 2024	Artri King Tablets
28 Mar 2024	Substandard Semaglutide Vials Safety Advisory
30 Apr 2024	Dark Horse Capsules

These efforts were part of the broader strategy to ensure that both consumers and industry stakeholders were aware of regulatory obligations and safety concerns, contributing to higher levels of compliance and safer therapeutic goods.

Launching TGA Learn for regulatory education

We launched TGA Learn, an education initiative providing self-paced and structured learning opportunities for enterprises, researchers and industry to better understand regulatory and legislative obligations.

To help support and educate start-ups, researchers and small-to-medium enterprises on how to navigate the regulatory pathway, we launched the TGA Learn service. TGA Learn provides a self-paced learning model for industry engagement and education through 4 pillars-self-paced online education, structured online learning events, targeted in-person events, and strategic partnerships.

Through TGA Learn, we expanded our engagement with universities, incubators, industry and other government organisations to develop and deliver education sessions for businesses and individuals to understand their regulatory obligations within the therapeutic goods landscape.

In 2023-24, this included the CSIRO's Innovate to Grow Program aimed at helping small to medium sized businesses learn about collaborative research and development, and the NSW Health Commercialisation Training Program to build foundational commercialisation knowledge and skills in those working on medtech and biotech innovations.

In November and December 2023, we worked in partnership with MTPConnect as part of their Researcher Exchange and Development within Industry (REDI) initiative to deliver the Australian Medical Device Registration Bootcamp. Twenty TGA subject matter experts delivered targeted

face-to-face education sessions to industry delegates on medical device regulations, from pre-market to post-market requirements.

Over 130 delegates attended the sessions which were held in Adelaide, Brisbane, Melbourne, Perth and Sydney. Feedback was positive, with delegates indicating that the program of content made them more confident in developing regulatory submissions.

As in previous years, we attended and contributed significantly to the ARCS Annual Conference in Sydney in June 2024. The conference brought together over 1,500 delegates from various backgrounds including health professionals, industry professionals, researchers and academics. Over 3 days, the TGA had 25 staff deliver sessions on a diverse range of topics on current and emerging regulatory environment and trends. We saw an increase of delegate interactions from previous years at our exhibition booth, with over 280 interactions recorded.

Feedback from delegates highlighted the value of the knowledge and information shared by TGA staff at the conference, and the opportunity to engage directly with subject matter experts.

Advising developers of emerging technologies

We provided targeted advice to developers of innovative technologies, including cell and gene therapies and software-based medical devices, to assist them in navigating regulatory requirements.

In 2023-24, we continued to provide targeted regulatory advice to developers of emerging technologies, including cell and gene therapies, software-based medical devices, and 3D-printed devices. This support aligned with our strategic focus on enhancing product quality and safety while fostering innovation in the medical technology sector.

Through our partnership with ANDHealth, Australia's National Digital Health Initiative, we supported over 400 participants from the digital health industry. Our regulatory and technical staff provided tailored guidance and training to assist companies in commercialising new medical device software products. This initiative played a vital role in helping digital health companies navigate regulatory requirements and advance the approval process for their innovative technologies.

We also provided expert advice to external stakeholders on the regulation of bacteriophage and medical-grade maggots, contributing to the broader dialogue on innovative therapies. Our participation in 5 national and international conferences showcased our leadership in the regulation of cell therapy products, reinforcing our commitment to supporting emerging technologies while ensuring public health and safety.

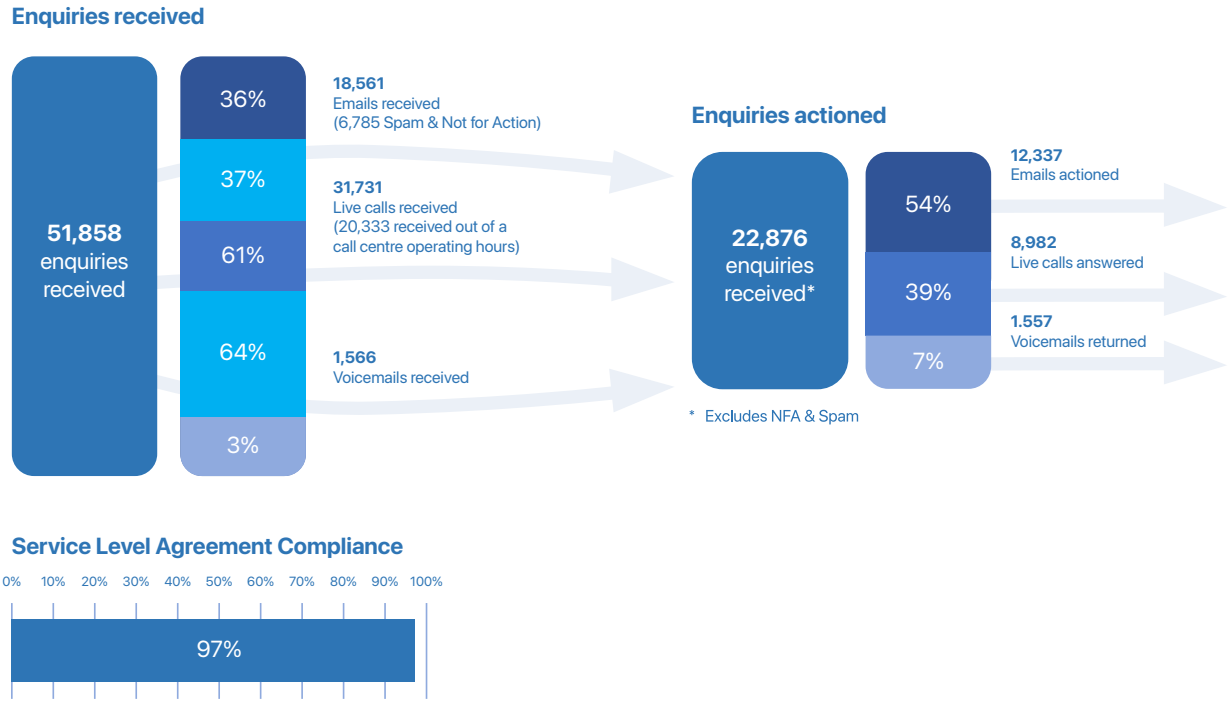
Enhancing stakeholder engagement channels

We enhanced our channels for stakeholder enquiries, improving the timeliness of responses and ensuring the consistent and accurate delivery of regulatory information.

In 2023-24 the TGA has undertaken foundational work to implement the new enquiry management model, and this will continue into 2024-25. The new model will improve the timeliness, efficiency and documentation on how the TGA responds to enquiries from sponsors, health professionals and the public.

The objectives include delivering improved customer experience and a consolidation of enquiry channels for our external stakeholders. The model will also feature improved data management, along with an uplift in staff training and TGA-wide knowledge sharing in best practice enquiry management.

Figure 2.1 TGA Contact Centre (TCC) enquiry overview in 2023-24



The TCC received almost 52,000 enquiries in 2023-24, actioning 77% of enquiries available to action while maintaining a compliance rate of 97% with our service level agreements for enquiry response times. These metrics represent an improvement from the previous financial year, with a 1% increase against compliance with our service level agreement targets.

Over the reporting period, the Medical Device Information Unit received a total of 21,520 emails and 3,719 calls, covering a wide range of queries. These primarily focused on topics such as the medical device approval process, including for personalised devices, and the impact of reclassification reforms and changes in international jurisdictions such as the EU.

Strategic objective 3

Promote and enforce compliance with regulatory requirements

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

Performance Indicators

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

3.2 Serious non-compliance is addressed.

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

Insights from the TGA Stakeholder Survey

For performance measures 3.1 and 3.2, we assess our success at promoting regulatory compliance and addressing serious, deliberate and repeated non-compliance.

Three statements were included in the TGA stakeholder survey to measure perceptions of our compliance and enforcement activities. The first related specifically to the TGA's enforcement of advertising regulations. Respondents were asked to rate their level of agreement or disagreement with the statement: 'The TGA takes strong action against illegal advertising for health products'. Agreement with this statement was 63% for consumers (the same as last year), 62% for stakeholders with a TBS account (down 4%), and 71% for health professionals.

A second statement aimed to measure perceptions of the full range of the TGA's enforcement actions- 'The TGA takes strong action against illegal behaviour'. Agreement with this statement was 63% for consumers (up 3%), 67% for TBS account holders (down 3%), and 68% for health professionals.

A third statement gauged whether respondents believe the TGA takes action against serious non-compliance and repeat offenders: 'I am confident the TGA addresses serious, deliberate and repeated non-compliance'. Stakeholders tended to be more positive to this statement, with agreement of 69% for consumers (up 2%), 73% for TBS account holders (down 2%), and 71% of health professionals.

Health professionals p12, consumers p9 and opt-in p15

For performance measure 3.2, we assess whether product safety, quality, efficacy and performance issues are identified and assessed proportionately to the risk being managed.

In the survey, stakeholders were also asked to indicate their level of agreement or disagreement with the statement- 'If a safety issue is identified, I am confident that the TGA takes appropriate action'. This statement was asked in relation to three regulated products - medicines, medical devices and complementary medicines - with a short description provided to give examples of each.

For medicines, agreement was 72% among consumers that the TGA would take appropriate action if an issue were identified (up 1% compared with last year), 78% among TBS account holders (down 3%), and 79% among health professionals. For medical devices, agreement was 74% among consumers (up 2%), 74% for TBS account holders (down 5%), and 82% for health professionals.

Stakeholders were less positive overall regarding appropriate action being taken against complementary medicines. Agreement was 66% for consumers (up 1%). 60% for TBS account holders (down 6%), and 80% for health professionals.

While many respondents across all categories answered 'unsure' or 'neither agree nor disagree', the majority of those expressing a clear opinion agreed that the TGA takes strong action in response to non-compliance with the therapeutic goods legislation. These results highlight both areas of confidence and opportunities to enhance stakeholder understanding of our compliance activities.

Improving compliance with regulatory requirements

We improved compliance with therapeutic goods regulations by delivering targeted educational programs that helped businesses and individuals understand and meet legal obligations.

In 2023-24, we launched public awareness campaigns, and implemented enforcement actions, all aimed at assisting businesses and individuals to meet their obligations under the Act.

To support regulatory changes announced in May 2024 concerning compounded GLP-1 RA products, such as semaglutide, we published updated information for consumers and health professionals. This provided essential details about the changes, along with links to further resources. A webinar was also held in August 2024, prior to the changes becoming effective on 1 October 2024, to further assist stakeholders in understanding the regulatory updates and how to comply with the new rules.

In response to increasing concerns about advertising compliance for cosmetic injectables, we published updated advertising guidance and educational materials. The new guidelines sought to achieve consistency in advertising regulations across all industries that deal with therapeutic goods. These changes were also driven by concerns over the vulnerability of Australians to the advertising of non-surgical cosmetic procedures. To support industry stakeholders a webinar was held in April 2024, explaining the rationale behind the changes, and further educational support was provided through a frequently asked questions (FAQ) page published in May 2024 to address common industry queries.

Given the rise in advertising compliance issues related to medicinal cannabis, we released further guidance to assist businesses in navigating regulatory requirements for this category of products.

In December 2023, we launched a targeted educational campaign aimed at content creators and influencers on social media, educating them on the rules around promoting therapeutic goods online. This campaign, which ran on Meta and Instagram, reached over 1 million people within a 2 week period, effectively raising awareness of the advertising rules for therapeutic goods in the digital space.

Throughout 2023-24, we responded to 591 advertising-related enquiries submitted through the advertising enquiry portal and dedicated mailbox. The majority of these enquiries came from businesses seeking clarification on advertising rules related to medicinal cannabis, cosmetic injectables, social media advertising, providing samples, and prescription-only weight-loss medications.

We published several key guidance materials to support compliance across various sectors:

- *Updated Regulation of Sport Supplements in Australia: Information for importers and sellers*
- *Updated Advertising Guidance for Businesses Involved with Medicinal Cannabis Products*
- *Advertising Guidance for Businesses Involved with IV Vitamin and Related Therapies*
- *Updated Advertising for Health Services Guidance*

- *Parallel Imports Fact Sheet: Providing details on the regulatory framework for importing and supplying cosmetic injectable products, and*
- *Cosmetic or Therapeutic Good? Interface Guidance: Clarifying the distinction between cosmetics and therapeutic goods and outlining the relevant compliance requirements for advertising.*

Through these efforts, we strengthened regulatory compliance across multiple sectors, ensuring that businesses had access to clear, accurate and comprehensive guidance to meet their legal obligations.

Public awareness education campaigns to support compliance

Throughout 2023-24, 5 of our 11 paid public awareness education campaigns included topics focused on educating businesses and individuals about their legal and regulatory obligations. These campaigns achieved a total of 32,229,829 impressions, ensuring wide reach and impact.

The compliance-related campaigns included:

Compliance-related campaigns	Impressions
Create content that plays by the rules	1,745,170
Phase 2 of travelling with medicines and medical devices	9,624,963
Vaping access pathways	9,706,217
Vaping regulation reforms	9,154,455
Compounding medicines	6,164,663

By focusing on these critical areas, we increased awareness among both regulated entities and the public, reinforcing the importance of compliance with regulatory standards and requirements. These efforts supported our broader goal of improving public health and safety through enhanced understanding and adherence to legal obligations.

Compliance monitoring of listed medicines

In 2023-24, we continued to prioritise key areas of non-compliance for listed medicines, focusing on activities that safeguard the integrity of the post-market regulatory framework and consumer safety. Our targeted compliance efforts centered on the following types of non-compliance of concern:

- insufficient evidence to support efficacy
- advertising indications not included on the ARTG
- missing mandatory warning statements
- failure to meet restrictions required by the Permissible Ingredients Determination, particularly monitoring component quantity restrictions
- obvious relisting non-compliances, and
- investigating sponsors with a history of consistent non-compliance.

These areas of non-compliance were identified as priorities due to their potential to pose significant risks to public health and the overall regulatory framework. We focused our resources on improving compliance in these high-risk areas.

As part of our compliance strategy, we conducted weekly ARTG scans during the 2023-24 period, reviewing a total of 1,854 newly listed medicines to detect potential non-compliance before sponsors began marketing the products. This early engagement allowed sponsors to address compliance issues in a timely manner, receiving positive feedback as they avoided potential commercial risks or losses.

Our targeted reviews for 2023-24 included medicines containing *Artemisia* species, molluscs, and *Bacillus coagulans*, all of which require mandatory warning statements. We also conducted efficacy assessments of medicines containing colecalciferol (Vitamin D) for bone health claims, lysine hydrochloride for managing cold sores, and listed sports supplements containing magnesium in relation to enhancing muscle or exercise performance.

We also targeted medicines where the name or indications did not align with the permissible indications listed in their ARTG entries, and we focused on sponsors with a history of non-compliance.

In 2023-24, we took a total of 483 compliance and enforcement actions, ranging from educational initiatives, such as mass email education, to higher-level actions, including infringement notices and recalls. On average, 60-70% of the medicines targeted with low-level actions were brought into compliance, reaching at least 14% of sponsors across the listed medicines sector.

Delivering risk-based compliance and enforcement activities

We implemented risk-based, intelligence-informed compliance activities to ensure that the import, manufacture, advertising, and supply of therapeutic goods met regulatory standards.

In 2023-24, the TGA conducted targeted, risk-based compliance and enforcement activities to address the unlawful importation, advertising and supply of nicotine vaping products. These actions were guided by intelligence gathering and close collaboration with health and law enforcement agencies across Australia. These efforts align with the TGA's strategic focus on maintaining compliance with regulatory standards and protecting public health.

Intelligence and collaboration

The TGA gathered intelligence to identify non-compliance and worked closely with health and law enforcement agencies. This collaboration enabled a coordinated response to the unlawful importation and supply of nicotine vaping products.

Enforcement and investigation

The TGA completed 2,726 investigations into alleged non-compliance. Enforcement measures included educational outreach to social media platforms, legal requests to ISPs to block unlawful websites, and the removal of illegal advertising posts from social media and digital marketplaces.

Seizure of unlawful products

In partnership with the ABF, over 5 million vaping products were seized at the border. Additionally, joint operations with the ABF and state and territory enforcement partners resulted in the seizure of more than 810,000 vapes in New South Wales, Victoria, and Queensland, with an estimated street value of $24.3 million. A total of 14 joint activities were conducted, reflecting increased collaboration with state and territory agencies.

Legal action

The TGA also pursued legal action, including a notable case against a supplier. The Federal Court of Australia ordered the company and its director to pay $5 million in combined penalties for unlawfully advertising nicotine vaping products, setting a strong precedent for regulatory enforcement.

These efforts reinforced the TGA's commitment to ensuring compliance with the import, manufacture, advertising and supply requirements of therapeutic goods under the Act. By focusing on intelligence-informed and risk-based activities, the TGA effectively addressed unlawful practices and protected public health.

Strengthening compliance and enforcement through multi-channel detection and collaborative efforts

Throughout the 2023-24 financial year, non-compliance was identified through many channels, including community reports/complaints, advice from other regulators and agencies, including state and territory regulators and border and law enforcement bodies. Analysis of therapeutic goods industries and observed non-compliance trends also supported the identification of further non-compliant incidences. We utilise a risk-based approach to prioritise reports of non-compliance and take appropriate action.

We have continued to work closely with domestic and international agencies to detect, intercept and investigate unlawful therapeutic goods imported into Australia. Our strong partnership with the ABF has remained critical in building an effective compliance program.

While reports and case volumes for alleged non-compliance are consistent, the TGA referred a significantly higher volume of goods to the ABF for destruction following assessment in the 2023-24 financial year. A large portion of these were nicotine products.

The TGA consistently monitors online content for unlawful advertising and/or supply of therapeutic goods via web platforms. The TGA has continued to work closely with several digital platforms, including Meta, TikTok and Amazon, to deter and address advertising of unapproved therapeutic goods. When alleged unlawful advertisements on social media are identified, we alert the social media platform, which typically takes action promptly in line with their user policies. This continued growth in digital platform monitoring has seen close to 5,000 requests for removal of content made to digital platforms in the 2023-24 financial year.

In December 2023, the TGA established a framework to enhance protection for Australians from unlawful online content. When identified, the TGA can request ISPs block specific websites containing unlawful information under Section 313 (3) of the *Telecommunications Act 1997*[7], known as disruption requests. The user is then redirected to the TGA website to a page providing information on why this has occurred. Between January and June 2024, close to 70 domains have been requested for redirection via disruption request.

Where there is suspected therapeutic good advertising, import, export or supply non-compliance, we use proportionate regulatory action to achieve compliance. Repeated, deliberate and serious non-compliance matters are dealt with proportionately and enforcement actions are taken in collaboration with local, international health and law enforcement agencies, or other regulated as required and appropriate.

Compliance priorities

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

Public promotion and unlawful advertising of medicinal cannabis, psilocybin and MDMA may inappropriately influence demand, disrupt the relationship between patients and treating health professionals, and bring disrepute to the industry. It also carries the risk of deferring appropriate care for consumers, should they not seek appropriate medical treatment.

Medicinal cannabis

The TGA has taken action against several entities regarding unlawful advertising of medicinal cannabis products, and published further guidance to promote compliance, particularly within the medicinal cannabis industry.

We have also published updated advertising guidance for businesses involved with medicinal cannabis, published in December 2023, to help promote voluntary compliance. This guidance followed targeted consultation and provides information regarding the application of the Act and related legislation.

Key outcomes

In 2023-24, the TGA

- issued over 60 infringement notices totalling over $1 million for the alleged unlawful advertising of medicinal cannabis on websites and social media platforms, and
- commenced 2 civil penalty proceedings in the Federal Court of Australia against companies and their directors for alleged unlawful advertising of medicinal cannabis on websites and social media.

Case Study

We considered that an online medicinal cannabis clinic unlawfully advertised medicinal cannabis products on its website and social media pages. The advertisements allegedly:

- promoted the use or supply of medicinal cannabis by using terms including 'medical cannabis' or 'plant medicine'
- contained unapproved references to the treatment of serious diseases or conditions
- represented medicinal cannabis to be safe or without harm or side effects, or magical or miraculous
- included endorsements from current or former health professionals.

Despite repeated warnings by the TGA regarding the alleged non-compliant advertising, the companies continued to advertise medicinal cannabis. We commenced civil penalty proceedings in the Federal Court of Australia against the companies and individual responsible for the online clinic.

Psilocybin and MDMA

Since 1 July 2023, the TGA has engaged with industry and proactively monitored compliance to ensure potential advertising issues are addressed promptly. This has included issuing several warning letters for alleged unlawful advertising, resulting in voluntary compliance by the majority of entities.

Detect and disrupt unlawful 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

Australians seeking to enhance their physical performance or appearance may be vulnerable to advertisements promoting therapeutic goods as 'health and beauty products'. These include sports supplements and weight loss medications, IV drips, cosmetic injectables and other medications or medical devices intended to alter the body's appearance.

Over the last few years, the TGA has had increasing concerns regarding trends in advertising of wellness and beautify products, including:

- the widespread use of social media to promote cosmetic procedures, supplements and treatments largely targeting young people and those most vulnerable seeking to change their appearance
- the use of acronyms, nicknames and hashtags on social media posts in a manner that promotes the use and supply of unapproved therapeutic devices or medicines used in the wellness and beauty industry, and
- the misrepresentation of unregistered or counterfeit products as being safe.

An ongoing trend in the alleged unlawful import of products such as Selective Androgen Receptor Modulators (SARMs), sports supplements, weight-loss medications and cosmetic injectables has also been observed.

Key Outcomes

In the 2023-24 financial year, the TGA:

- issued infringement notices valued at over $100,000 for alleged unlawful advertising of several types of wellness and beauty products, including weight loss medicines and devices
- conducted several investigations into unlawful activities, including carrying out multiple search warrants related to wellness and beauty products
    - one such investigation related to the unlawful manufacture, supply, export and advertising of performance and image enhancing therapeutic goods
- accepted 2 enforceable undertakings for breaches of the Act related to the alleged:
    - unlawful import and supply of medical devices not included on the ARTG
    - unlawfully advertised and supplied therapeutic goods not on the ARTG.

Case study

We considered that a pharmacy had unlawfully advertised Ozempic (semaglutide), a prescription-only medicine, through in-store signages. 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. Appropriate treatment options should be determined by a health professional in consultation with their patient.

We issued an infringement notice totaling $18,780 to the pharmacy for allegedly unlawful advertising of a prescription-only medicine.

Other compliance priorities and compliance activities

Alternative treatments

The TGA also continued to focus on unregistered therapeutic goods marketed as traditional or alternative treatments. Australians may be vulnerable to those seeking to profit from the sale of such goods, raising increased concern where the goods contain higher-risk substances including Schedule 4 and Schedule 8 poisons and heavy metals.

To support voluntary compliance by this sector, the TGA published advertising guidance for businesses involved with IV vitamin and related therapies. This guidance provides information for sponsors and advertisers about what IV products must be included in the ARTG, as well as their advertising requirements.

Key outcomes:

The TGA:

- issued several infringement notices totalling over $100,000 for the alleged unlawful import and/or advertising of alternative and complementary medicines. These included complementary medicines not listed on the ARTG, as well as Himalaya branded Ayurvedic products, including Neem tablets, which contain *Azadirachta indica*, which is prohibited in Australia due to its potential health risks.
- issued search warrants associated with the alleged unlawful supply of products containing schedule 10 prohibited substances (such as black salve and amygdalin) and Schedule 4 prescription-only medicines.
- accepted an enforceable undertaking from an entity in relation to alleged illegal manufacture, supply and advertising of unregistered therapeutic goods.

Prescription-only medicines

In addition to infringement notices issued for specific TGA compliance priorities, including medicinal cannabis and wellness and beauty industry products/devices, we also issued over 40 infringement notices valued at over $700,000 for alleged unlawful advertising of other prescription-only medicines.

Falsified and counterfeit goods

The TGA has actively monitored for any indicators of substandard, falsified or counterfeit products within Australia. We continue to work with domestic and international partner agencies to reduce the risk of counterfeit products entering Australia, in line with current compliance priorities. We consistently work in collaboration with the ABF to identify, intercept and stop counterfeit goods being imported, and issue safety alerts to the public when required.

Collaborating with co-regulators and agencies

We strengthened our relationships with co-regulators, law enforcement, and international health agencies to improve collaboration and enhance regulatory outcomes globally.

In 2023-24, the TGA continued to build and reinforce strong relationships with state and territory health departments, law enforcement agencies and international partners. This collaboration was critical in improving compliance and enforcement activities in line with the TGA's strategic focus on protecting public health and ensuring regulatory standards are upheld.

Collaborating on enforcement operations

The TGA worked closely with the Queensland Police Service, the Australian Federal Police (AFP), the ABF, the New South Wales Health Care Complaints Commission, the Victorian Department of Health, and Ahpra. This engagement included mutual assistance with executing search warrants, conducting regulatory inspections, and the lawful sharing of information relevant to ongoing investigations.

National Vaping Enforcement Framework

In November 2023, the Minister for Health and Aged Care announced the formation of the National Vaping Working Group, a multi-agency body co-chaired by the Commissioner of the ABF and the Secretary of the New South Wales Ministry of Health. In May 2024, the Working Group endorsed the National Vaping Enforcement Framework, which was supported by all state and territory health and police agencies. This framework facilitated a nationally coordinated approach to the enforcement of vape reforms.

Joint enforcement operations

The TGA led several joint enforcement operations as part of its national collaboration efforts, focusing on enhancing information sharing and improving compliance outcomes. These operations contributed to a more unified approach across the nation, particularly in regulating the unlawful importation and sale of vaping products.

International cooperation

The TGA also engaged with international partners to share information and strategies related to compliance and enforcement. Collaboration with global health agencies enabled the TGA to align its regulatory approaches with international standards and further its goal of improving global health outcomes.

Enhancing compliance activities through monitoring and data analytics

We improved the effectiveness of our compliance activities by leveraging data analytics and operational intelligence, ensuring targeted and responsive regulatory enforcement.

In 2023-24, the TGA enhanced its compliance and enforcement activities by using data analytics and operational intelligence to monitor and review regulatory priorities. These efforts align with the TGA's strategic objective to protect public health through effective compliance monitoring and targeted enforcement.

Data-driven compliance and enforcement priorities:

The TGA's compliance priorities in 2023-24, including the regulation of advertising, import and supply, were guided by intelligence and data analytics. By focusing on areas of greatest risk, the TGA ensured compliance activities were responsive to emerging threats. Factors considered when setting compliance priorities included:

- the risk of harm or injury, especially where products were promoted for inappropriate use, posing a direct or indirect risk to public health
- upcoming regulatory changes, with a focus on mitigating non-compliance risks before new regulations took effect, and
- trends of persistent non-compliance across industries, particularly in sectors where serious non-compliance was observed.

Internal training and support

The Regulatory Activity Viewer, an internal digital tool, supported staff in performing compliance activities. Ongoing training and awareness of this tool ensured that compliance teams could efficiently monitor and respond to compliance issues.

Collaboration with enforcement partners

Data provided by enforcement partners, such as the ABF, facilitated targeted enforcement actions. These actions were crucial in addressing the unlawful importation of nicotine vaping products, and the intelligence gathered helped prepare for the Australian Government's vaping reforms.

Building operational intelligence capabilities

The TGA continued to build its operational intelligence capabilities, using advanced data analytics to identify non-compliance trends and target high-risk areas. This approach ensured that compliance activities were proactive and preventative, addressing non-compliance before it could pose a significant threat to public health.

Implementing ANAO recommendations for compliance activities

We fully implemented the Australian National Audit Office (ANAO) recommendations to strengthen the TGA's regulatory compliance activities, enhancing operational effectiveness and accountability.

Over 2023-24, the TGA has successfully implemented 4 out of 6 recommendations from the ANAO audit on the *Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods*.

- **Finalising Investigation Procedures (Recommendation 2):** We finalised our investigation procedures for regulating therapeutic goods, aligning them with the Australian Government Investigations Standard 2022 (AGIS), and established controls to ensure ongoing reviews and updates.
- **Maintaining Investigator Qualifications (Recommendation 3):** We implemented measures to ensure that all investigators maintain the necessary qualifications as outlined by AGIS, with comprehensive record-keeping to track these credentials.
- **Managing Declarations of Interest (Recommendation 4):** Internal controls have been established to manage and document declarations of interest for officials involved in investigations and compliance activities, promoting transparency and integrity.
- **Developing an Investigations Quality Assurance Policy (Recommendation 6):** We developed and implemented an Investigations Quality Assurance Policy to guide compliance activities in line with AGIS standards, ensuring consistency and quality in our investigative processes.

Of the remaining 2 recommendations, recommendation 1 is on track for completion in the 2024-25 financial year, and recommendation 5 in 2025-26.

Continuous improvement and ongoing implementation

To support these achievements, the TGA has established robust internal processes, including standard operating procedures and document control measures, to ensure ongoing alignment with AGIS standards and regulatory obligations. A continuous improvement framework is in place to regularly review and refine these processes to adapt to evolving compliance requirements.

Our efforts to implement the remaining 2 ANAO recommendations are progressing as planned, with a strong focus on further enhancing the TGA's regulatory framework. These initiatives reflect our commitment to continuous improvement and operational integrity, and to maintaining the highest standards of compliance in regulating therapeutic goods.

Commitment to strengthening compliance frameworks

The TGA's implementation of the ANAO recommendations highlights our proactive approach to bolstering regulatory compliance and accountability. By adopting these best practices, we enhance our ability to manage non-compliance effectively, ultimately safeguarding public health and ensuring the credibility of our regulatory processes.

Strategic objective 4

Innovate and continuously improve

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

Performance Indicators

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

4.2 Promote an impartial, flexible, and innovative workforce.

Delivering modern digital tools for regulatory processes

We launched modern digital platforms, including a contemporary portal and case management system, allowing organisations to streamline their application processes and track progress in real-time.

In 2023-24, we delivered key components of our digital transformation program, laying the groundwork for modern digital platforms that will streamline regulatory processes and make it easier for industry to meet their obligations. These efforts directly responded to industry feedback, addressing the need to simplify applications, increase visibility into the progress of requests, and improve overall efficiency.

Key deliverables included:

- launch of the first instalment of a contemporary portal for industry users - businessservices.health.gov.au
- implementation of a configurable case management solution to support multiple regulatory processes
- onboarding of the first TGA business processes into the new case management system, enhancing internal efficiency
- comprehensive user research and stakeholder engagement to ensure the system meets the needs of both internal and external users
- establishment of an Industry Working Group to guide the design and onboarding of new digital solutions and provide industry feedback, and
- concept testing and research for the first iteration of the portal, including branding andthe underpinning design system.

With the successful delivery of the foundation of our digital transformation in 2023-24, our focus in 2024-25 will shift towards building out 4 key digital pillars:

- identity management
- service management
- case (application) management, and
- data management.

Over the next year, we will expand these services to additional user cohorts, continuing to enhance the user experience and support regulatory compliance through digital innovation.

Enhancing the Special Access Scheme and Authorised Prescriber system

We improved the Special Access Scheme and Authorised Prescriber Online system, delivering increased usability and reduced administrative burden on health professionals.

In 2023-24, we implemented the fifth phase of enhancements to the Special Access Scheme (SAS) and Authorised Prescriber (AP) Online System, as part of the TGA's broader digital transformation. These upgrades are aimed at reducing regulatory burden, improving system usability, and supporting the transition to a paperless submission model, making it easier for health professionals and patients to access unapproved therapeutic goods.

Key improvements delivered in 2023-24 included:

- **pharmacist access to SAS/AP notifications:** In December 2023, the SAS and AP validation tool was introduced allowing pharmacists to verify in real-time SAS/AP notifications and application approvals issued by the TGA. This functionality was developed in response to feedback from stakeholders such as the Royal Australian College of General Practitioners (RACGP) and has seen a significant uptake by pharmacists and a reduction in validations requests to the TGA's support team.
- **updated submission guidance:** Additional guidance and supporting information were added to the SAS submission form to assist health professionals in selecting the correct pathway, reducing submission errors and associated burdens and delays.
- **account registration improvements:** Enhancements to the account registration process have significantly reduced the number of errors encountered by health professionals. As a result, monthly enquiries regarding account creation dropped from approximately 100 to around 30.
- **user experience research and design:** In-depth user experience analysis was conducted to redesign how health professionals and organisations such as hospital pharmacies can collaborate and manage applications. This work resulted in a series of designs and workflows that are ready for future implementation.
- **exploring system security enhancements:** We investigated options for strengthening system security by automatically validating health practitioner registration status through the Ahpra database of registered practitioners.

Looking ahead, the TGA will continue to explore options to further enhance system security and build on the user experience research conducted in 2023-24.

Newly formed Business Improvement and Compliance Section (BICS)

On 15 January 2024, the Special Access Section was restructured to create the BICS. BICS focuses on supporting the Special Access Section through business improvements, IT enhancements, data reporting, and active monitoring of compliance activities. This new section plays a critical role in improving the efficiency of the SAS and AP frameworks.

Improvements to support sponsor reporting

A new sponsor reporting form was launched on 20 June 2024 to reduce the administrative burden and expedite the processing of 6-monthly sponsor reports required under section 47B of the Therapeutic Goods Regulations 1990. This new form includes tabs specific to individual types of unapproved therapeutic goods, reducing confusion for external stakeholders and minimising the number of manual adjustments required by TGA staff.

SAS and AP submissions transition from paper to online only

In 2023-24, BICS collaborated with external stakeholders to transition all SAS and AP submissions from paper-based processes to fully online submissions. By 1 July 2024, most stakeholders had completed the transition, with a small number of hospitals granted extensions until 30 September 2024. The move to online submissions provided stakeholders with greater control and visibility over their applications, resulting in faster approval times. Internally, the TGA have cleared a backlog of over 14,000 SAS A and SAS C paper submissions, improving data quality and enabling a shift in focus to improving submission quality and active compliance monitoring.

Modernising TGA Laboratories

We upgraded the technology and business processes of TGA Laboratories by implementing a unified software solution, improving efficiency and compliance in laboratory operations.

During 2023-24, the Laboratories Branch continued to build and prepare for the transition to a new Laboratory Information Management System (LIMS). Full implementation of the system is expected in 2024-25. This system aims to improve the efficiency and accuracy of data recording and reporting laboratory testing results, ultimately enhancing overall operational efficiency. These efforts align with the TGA Business Plan's focus on improving technological systems and business processes within the Laboratories Branch, ensuring more streamlined and accurate operations moving forward.

Driving a user centred TGA website experience

We focused on continuous improvement of the TGA website, ensuring a user-centered and evidence-based digital experience that meets the evolving needs of our stakeholders.

In 2023-24, we focused on continuously improving the TGA website to provide a modern, user-centered and evidence-based digital experience to meet the evolving needs of our stakeholders and support the Australian Government's 'digital first' content principles.

Key Achievements:

- **Website feedback analysis system:** A new feedback analysis system was implemented to provide dynamic insights based on text and sentiment analysis of stakeholder feedback. This system has enabled us to prioritise website improvements effectively, responding to user needs with greater agility.
- **User research and engagement:** Over 250 industry and TGA users participated in user research as part of our TGA website guidance initiative. This extensive engagement in 2023-24 will drive the considerable uplift of website guidance content in 2024-25.
- **Template enhancements:** In 2023-24, we developed new website templates for presenting guidance, services and scientific guidelines. These templates include several key features:
    - consistent presentation of legislative information related to guidance
    - a clear title pattern, helping users understand the purpose of the guidance
    - a new guidance content type that enables users to search and filter guidance more effectively
    - improved navigation for long guidance pages, including sticky navigation and bookmarkable headings, and
    - visual indicators for newly added or updated guidance content.
- **Business services portal development:** Targeted user research supported the development of the new businessservices.health.gov.au portal, ensuring the platform meets user requirements effectively.
- **Search Engine Optimisation (SEO) and content research:** User interviews and SEO research were conducted to improve vaping and compliance-related content on the website. These efforts align with our goal of ensuring stakeholders can easily find the information they need.
- **Increased user research activities:** In 2023-24, we conducted more user research activities than in previous years, marking an area of continuous growth for the TGA.

These initiatives have strengthened the user-centered approach of the TGA website, ensuring a more intuitive and accessible experience for both industry professionals and consumers. By focusing on continuous improvement and engaging with users directly, we have been able to address key pain points and align with the TGA's digital transformation strategy.

Improving safety management of medicines and devices through improved information sharing

We enhanced the management of safety data for medicines, vaccines, medical devices and other therapeutic goods by improving transparency and facilitating streamlined sharing of adverse event information with state and territory health departments and professionals.

In 2023-24, the TGA made significant improvements in managing adverse event data for medicines, vaccines and medical devices, in line with the TGA Business Plan's objective of improving public health outcomes and ensuring product safety. These efforts focused on increasing transparency and enabling more effective sharing of adverse event data with state and territory health departments, healthcare professionals and other key stakeholders.

Collaboration on adverse event data sharing

The TGA actively participated in working groups under IMDRF to explore methods for extracting, formatting and securely sharing adverse event data for medical devices. This collaboration led to new strategies for data sharing under confidentiality agreements, and laid the groundwork for a pilot program to test these elements.

Post-market surveillance and rapid response

The TGA worked closely with state and territory health departments through regularly sharing updates on post-market surveillance. Notably, this collaboration proved critical during the investigation of the *Ralstonia pickettii* contamination of select saline solutions. The TGA, along with health departments and relevant industry stakeholders, quickly traced the contaminated products, resulting in timely and effective product recalls and suspension from the ARTG.

Improving access to medical device information

The TGA worked with medical device sponsors and manufacturers to enhance patient access to information leaflets for medical devices. A new online repository for patient information was developed, making it easier for patients to access critical healthcare information. This initiative also included revising patient information leaflets for spinal cord stimulators, as part of a post-market review, to help patients make informed healthcare decisions.

Streamlined access to adverse event data for sponsors

A new system was implemented that allows sponsors to access adverse event reports for their medicines using their existing login credentials. This change, enabled by 2 newly created legislative instruments in November 2023, significantly improves the speed and efficiency with which sponsors can access safety data, reducing the reliance on manual report requests.

Regular stakeholder engagement

The TGA held regular meetings with Jurisdictional Immunisation Coordinators (JICs) and the National Centre for Immunisation Research and Surveillance (NCIRS) to ensure that key stakeholders had the most up-to-date information on adverse events following immunisation. For broader medicine safety surveillance, the TGA regularly engaged with the Centre for Research Excellence in Medicines Intelligence (MI-CRE) and the Drug Utilisation Sub-Committee (DUSC) Secretariat.

Enhancing capacity for evaluation functions

We strategically increased staff capacity in key evaluation functions to address evolving priorities.

In 2023-24, we strengthened staff capacity in key evaluation functions that had previously been redirected to support COVID-19 activities. By reallocating resources effectively, we enhanced the quality and timeliness of assessments for medical devices, IVDs, biologicals and new ingredients for sunscreens and complementary medicines, directly supporting our goal of reducing evaluation timeframes and improving regulatory outcomes.

Restructuring and workload adjustments

To optimise post-pandemic operations, we restructured our evaluation processes and reallocated resources to manage workloads. These adjustments to the distribution of resources helped to prioritise evaluations based on statutory timeframes, enhancing the efficiency of our regulatory assessments.

Enhancing evaluation capacity

To address an increased demand for clinical reviews, we expanded staffing levels by adding medical officers and evaluation staff specialising in IVDs and medical devices. This allowed for more timely reviews of high-priority applications. Further efficiencies were achieved through the Application Audit Framework reform and updates to the TGA's conformity assessment procedures, streamlining application handling and reducing duplication.

Process improvements and taskforce initiatives

An Australian Sunscreen Exposure Model (ASEM) was developed by the TGA, incorporating the latest scientific data and accounting for Australian usage of sunscreens. The ASEM is planned for implementation in 2025 and will allow us to consistently assess the safety of sunscreen ingredients, which will provide more regulatory certainty for industry applicants, support innovation of sunscreen products, and support consumer confidence in a key public health measure for one of Australia's most significant potentially preventable diseases.

Supporting compliance and sponsor engagement

In 2023-24, we proactively engaged with sponsors to address potential non-compliance in new listings. This early communication helped sponsors to resolve issues before products entered the market, reducing compliance risks and facilitating smoother regulatory processes. Additionally, we developed core Product Information and Consumer Medicine Information documents for paracetamol products, assisting sponsors in preparing for the 2024-25 scheduling change.

Through these initiatives, we strengthened our evaluation processes, improved submission quality, and increased regulatory compliance, ensuring timely and effective delivery of therapeutic goods assessments.

Appendices

The appendices provide detailed statistical information on our performance during 2023-24.

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:

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 un-redacted 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 (PI) and where required, the Risk Management Plan (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: TGA processes as soon as possible.
Safety-related request	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: 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	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 1: Number of completed prescription medicine submissions by type and outcome for July 2023 to June 2024

Application Type	Number Approved	Number Withdrawn	Number Rejected	Total (% Approved)
Category 1				
A: New chemical entity/New biological entity/Biosimilar [a]	37	3	2	42 (88.1%)
B: New fixed-dose combination	2	0	0	2 (100%)
C: Extension of indication	40	3	0	43 (93%)
D: New generic medicine	90	8	0	98 (91.8%)
F: Major variation	36	6	1	43 (83.7%)
G: Minor variation [b]	4	0	0	4 (100%)
H: Minor variation [c]	20	3	0	23 (87.0%)
J: Changes to Product Information	124	10	0	134 (92.5%)
S: Provisional registration to full registration	6	0	0	6 (100%)
T: Provisional registration extension [T]	11	0	0	11 (100%)
Comparable Overseas Regulator (COR) – A				
A: New chemical entity/ New biological entity/Biosimilar	2	0	0	2(100%)
C: Extension of indication	1	0	0	1 (100%)
D: New generic medicine	3	0	0	3 (100%)
F: Major variation	1	0	0	1 (100%)
J: Changes to Product Information	0	0	0	(%)
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/Biosimilar	5	0	0	5 (100%)
B: New fixed-dose combination	0	0	0	(%)
D: New generic medicine	6	2	0	8 (75%)
F: Major variation	2	0	0	2 (100%)

Minor Variations				
Category 3				
G: Minor variation [b]	192	3	0	195 (98.5%)
H: Minor variation [c]	1,440	39	0	1,479(97.4%)
Correction [9D(1)]	205	5	0	210 (97.6%)
Additional trade name [ATN]	97	0	0	97 (100%)
Extension of Indications - Generic	9	0	0	9 (100%)
Internal Review	1	0	0	1 (100%)
Minor editorial change [MEC]	178	7	0	185 (96.2%)
Self-assessable request [SAR]	751	12	0	763 (99.1%)
Safety-related request [SRR]	845	10	0	855 (98.4%)
Total	**4112**	**111**	**3**	**4226 (97.3%)**

[a] Includes submissions processed via the priority review.

[b] The type G minor variations differ from type H minor variations in that they 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.

[c] The type H minor variations refer to applications that vary the existing good. As with type G applications, 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 2: Number of other prescription medicine applications – Consent to supply/import /export when not conforming to a standard (s14 and s14A)

Consent to supply/import/export when not conforming to a standard [S.14 and S.14A]	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
Approved	72 (100%)	74 (100%)
Rejected	0 (0%)	0 (0%)
Total (excluding withdrawals)	72 (100%)	74 (100%)

1.2. Approval times

Table 3: Prescription medicine application approval time for July 2023 to June 2024

				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]	36	255	199	201	126-254
B: New fixed-dose combination	2	255	228	228	224-232
C: Extension of indication [b]	37	255	197	197	119-243
D: New generic medicine	90	255	132	129	48-206
F: Major variation	36	255	168	172	32-253
G: Minor variation	4	255	160	171	99-199
H: Minor variation	20	255	169	177	23-253
J: Changes to Product Information requiring the evaluation of data	124	255	164	186	3-251
S: Provisional registration to full registration	5	255	144	123	69-234
T: Provisional registration extension	11	255	32	25	8-66
Comparable Overseas Regulator (COR-A)					
A: New chemical entity/ New biological entity/Biosimilar	2	120	107	107	104-110
C: Extension of indication [b]	1	120	108	108	108-108
D: New generic medicine	3	120	92	85	84-107
F: Major variation	1	120	89	89	89-89
J: Changes to Product Information requiring the evaluation of data	0	120		0	-
Comparable Overseas Regulator (COR-B)					
A: New chemical entity/ New biological entity/Biosimilar	5	175	148	154	134-159
B: New fixed-dose combination	0	175	0	0	0
D: New generic medicine	6	175	123	121	101-150
F: Major variation	2	175	138	138	117-158

[a] Application type A figures do not include 1 submission processed via the priority review pathway.

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

Table 4: Prescription medicine median approval time comparisons between 2022-23 and 2023-24

Application type	Legislated timeframe	Median approval time (TGA working days) 2022-23	2023-24 (% Change)
Category 1			
A: New chemical entity/New biological entity/Biosimilar [a]	255	199	201 (▲▼0%)
B: New fixed-dose combination	255	221	228 (▲3%)
C: Extension of indication [b]	255	197	197 (▲▼0%)
D: New generic medicine	255	133	129 (▼3%)
F: Major variation	255	184	172 (▼7%)
G: Minor variation	255	188	171 (▼9%)
H: Minor variation	255	171	177 (▲4%)
J: Changes to Product Information requiring the evaluation of data	255	173	186 (▲7%)
Comparable Overseas Regulator (COR) – A			
C: Extension of indication	120	87	108 (▲24%)
Comparable Overseas Regulator (COR) – B			
A: New chemical entity/New biological entity/Biosimilar	175	0	154 (▼2%)
D: New generic medicine	175	128	121 (▼8%)
Minor Variations			
Category 3			
G: Minor variation [c]	45	40	42 (▲5%)
H: Minor variation [d]	45	38	39 (▲3%)
Additional trade name [ATN]	45	40	42 (▲5%)
Extension of Indications - Generic	45	35	34 (▼3%)
Safety-related request [SRR]	N/A	39	29 (▼26%)
Self-assessable request [SAR]	45	31	38 (▲23%)
Minor editorial change [MEC]	45	35	23 (▼34%)
Correction [9D(1)]	N/A	41	42 (▲4%)

[a] Application type A figures do not include submissions processed via the priority review pathway. For new chemical entities, new combinations, extension of indications, new generic medicines and major variations. During these periods, volumes of submission approvals for 2021-22 and 2022-23 were: standard - 201 and 197, priority review - 8 and 9, provisional approval - 28 and 28, COR-A - 5 and 7 and COR-B - 12 and 17, respectively.

[b] Application type C figures do not include submissions processed via the priority review pathway.

[c] The type G minor variations differ from type H minor variations in that they 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] Applications that vary the existing good. As with type G applications, 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.

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 us to ascertain 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 5: Number of orphan drug registrations

	FY 2022-23	FY 2023-24	
Application Type	**Number Approved (% of Total)**	**Number Approved (% of Total)**	**Median approval time (TGA working days)**
A: New chemical entity/ New biological entity/ Biosimilar	10 (48%)	13 (68%)	189
C: Extension of indications	8 (38%)	4 (21%)	162
D: New generic medicine	2 (10%)	0 (0%)	0
F: Major variation	1 (4%)	0 (0%)	0
Total	**21 (100%)**	**17 (100%)**	**175.5**

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 involves the same amount and type of evidence as the standard review process. The same standards for quality, safety and efficacy apply as under the standard process. We take on priority applications is much more resource intensive than the standard pathway. The pathway 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 necessarily mean that the medicine will be approved after evaluation and registered on the ARTG.

Table 6: Number of medicines approved through the priority review pathway [a]

	FY 2022-23	FY 2023-24	
Application Type	**Number Approved (% of Total)**	**Number Approved (% of Total)**	**Median approval time (TGA working days)**
A: New chemical entity/New biological entity/Biosimilar	3 (37%)	1 (25%)	141
C: Extension of indications	5 (63%)	3 (75%)	125
Total	**8 (100%)**	**4 (100%)**	**133**

[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 of these medicines 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 risk inherent in the fact that additional data are still required.

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

Table 7: Number of provisional determinations granted

	FY 2022-23		FY 2023-24	
Application Type	**Number Approved**	**Total Applications**	**Number Approved**	**Total Applications**
Provisional Determination	15	15	6	7

Table 8: Provisional registration approvals

	FY 2022-23		FY 2023-24	
	Number Approved (% of total)	**Median approval time (TGA working days)**	**Number Approved (% of total)**	**Median approval time (TGA working days)**
Application type				
A: New chemical entity/ New biological entity/ Fixed dose combination	14 (47%)	197	5 (38%)	195
C: Extension of indications	6 (20%)	127	3 (23%)	180
F: Major variation	4 (13%)	81	2 (15%)	181
H: Minor variation	1 (3%)	171	0 (0%)	0
J: Changes to Product Information requiring the evaluation of data	5 (17%)	175	3 (23%)	140
Total	**30 (100%)**	**171**	**13 (100%)**	**180**

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 outlined on the following page 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 9: Categorisation of OTC medicine applications

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
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. Approval times

Table 10: Median approval time for OTC medicine applications

	FY 2022-23	FY 2023-24
New medicine applications (days)		
N1	17	39
N2	31	63
N3	108	130
N4	132	207
N5	186	231
Change applications (days)		
C1	23	14
C2	26	20
C3	96	14
C4	0	111

Table 11: OTC medicine approval time against target time by application category – July 2023 to June 2024

Application type	Number completed (% of Total)	Range	Mean	Median	% within target
New medicines					
N1	46 (45%)	0-181	47	39	59
N2	3 (3%)	52-182	79	63	33
N3	32 (31%)	1-358	144	130	66
N4	19 (19%)	94-250	179	207	42
N5	2 (2%)	188-273	231	231	50
Total	**102 (100%)**				
Change applications					
C1	242 (46%)	0-122	20	14	59
C2	277 (53%)	0-244	32	20	88
C3	1 (0.2%)	14	14	14	100
C4	1 (0.2%)	111	111	111	100
Total	**521 (100%)**				

2.2. Applications

2.2.1 New OTC medicine applications

Table 12: Applications received for new OTC medicines and changes to existing medicines

	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
New medicine applications		
N1	97 (45%)	91 (43%)
N2	16 (8%)	8 (4%)
N3	66 (31%)	56 (26%)
N4	32 (15%)	30 (14%)
N5	3 (1%)	28 (13%)
Total	**214 (100%)**	**213 (100%)**
Change applications		
CN	141 (20%)	149 (20%)
C1	293 (41%)	263 (35%)
C2	270 (38%)	320 (42%)
C3	7 (1%)	12 (2%)
C4	0 (0%)	9 (1%)
Total	**711 (100%)**	**753 (100%)**

2.2.2 Completed applications

Table 13: Outcomes of completed new OTC medicine applications

	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
N1		
Approved	85 (89%)	46 (92%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	11 (11%)	4 (9%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**96 (100%)**	**50 (100%)**
N2		
Approved	24 (89%)	3 (50%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	3 (11%)	3 (50%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**27 (100%)**	**6 (100%)**
N3		
Approved	40 (85%)	32 (91%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	6 (13%)	3 (9%)
Returned/failed screening	1 (2%)	0 (0%)
Total	**47 (100%)**	**35 (100%)**
N4		
Approved	13 (81%)	19 (86%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	1 (6%)	3 (14%)
Returned/failed screening	2 (13%)	0 (0%)
Total	**16 (100%)**	**22 (100%)**
N5		
Approved	1 (100%)	2 (100%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	0 (0%)	0 (0%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**1 (100%)**	**2 (100%)**

Table 14: Outcomes of completed OTC change applications

	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
C1		
Approved	288 (97%)	242 (96%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	8 (3%)	9 (4%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**296 (100%)**	**251 (100%)**
C2		
Approved	237 (96%)	277 (98%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	11 (4%)	7 (2%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**248 (100%)**	**284 (100%)**
C3		
Approved	8 (80%)	1 (100%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	2 (20%)	2 (67%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**10 (100%)**	**3 (100%)**
C4		
Approved	0 (0%)	1 (100%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	0 (0%)	0 (0%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**0 (0%)**	**1 (100%)**

2.2.3 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 15: Number of other OTC medicine applications

	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
Total	1	4
Requests for consent under section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard		
Approved [a]	16 (100%)	14 (100%)
Rejected	0 (0%)	0 (0%)
Total	**16 (100%)**	**14 (100%)**

[a] This includes 49 requests for consent to supply products that do not comply with TGO92 only that was established as a temporary expedited process for sponsors adversely impacted by the COVID-19 pandemic.

3. Registered complementary medicines

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

Table 16: Categorisation of registered complementary medicine applications

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 changes 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
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 17: Registered complementary medicine applications by outcome

	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
New medicines		
Approved	2 (28.6%)	8 (53%)
Rejected	4 (57.1%)	0 (0%)
Withdrawn	1 (14.3%)	7 (47%)
Returned/failed screening	0 (0%)	0 (0%)
Total	**7 (100%)**	**15 (100%)**
Variations		
Approved	25 (100%)	18 (72%)
Rejected	0 (0%)	0 (0%)
Withdrawn	0 (0%)	7 (28%)
Returned/failed screening	0 (0%)	0 (0%)
Total variations completed	**25 (100%)**	**25 (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	6 (100%)	0 (0%)
Rejected	0 (0%)	0 (0%)
Withdrawn	0 (0%)	0 (0%)
Total	**6 (100%)**	**0 (0%)**

4. Assessed listed medicines

Assessed listed medicines have intermediate risk indicators-higher then listed medicines but lower than registered medicines. To ensure safety and efficacy, these medicines undergo a full evaluation before being included 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 18: 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 19: Assessed listed medicine applications by outcome

New medicines	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
Approved	0 (0%)	1 (100%)
Refused	1 (100%)	0 (0%)
Withdrawn	0 (0%)	0 (0%)
Failed screening	0 (0%)	0 (0%)
Total	**1 (100%)**	**1 (100%)**

Table 20: Applications received for new assessed listed medicines and changes to existing medicines

	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
New medicine applications		
L(A)1	0 (0%)	0 (0%)
L(A)2	0 (0%)	0 (0%)
L(A)3	0 (0%)	1 (100%)
Total	**0 (0%)**	**1 (100%)**
Change applications		
CN	0 (0%)	0 (0%)
C1	1 (100%)	0 (0%)
C2	0 (0%)	0 (0%)
Total	**1 (100%)**	**0 (0%)**

5. Listed medicines

Listed medicines are considered to be of relatively lower risk than other medicines on the basis that they can only contain pre-approved ingredients and indications in the Therapeutic Goods (Permissible Ingredients) Determination and Therapeutic Goods (Permissible Indications) Determination respectively. If an ingredient or indication is not included in the Determinations, an application for a new ingredient or indication needs to be made. Unlike registered medicines, we do not assess each listed medicine before it goes onto the market. However, we do require sponsors to certify that the medicine complies with all relevant legislation, and that they hold evidence at the time of listing (and at all times) that their medicine does what it says it will.

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 with applicable regulatory requirements, enforcement actions may be taken on the medicine's listing and the sponsor. This can include cancellation of the product from the ARTG and infringement notices.

5.1. New ingredients permitted for use in listed medicines

Table 21: New listed medicine ingredient applications by outcome

Application outcome	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
Approved	8 (50%)	9 (82%)
Rejected	0 (0%)	1 (9%)
Withdrawn	8 (50%)	0 (0%)
Returned/failed screening	0 (0%)	1 (9%)
Lapsed	0 (0%)	0 (0%)
Total completed	**16 (100%)**	**11 (100%)**

5.2. Indications permitted for use in listed medicines

Table 22: Permitted indication applications by outcome

Application outcome	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
Approved	0 (0%)	0 (0%)
Rejected	1 (100%)	5 (100%)
Withdrawn	0 (0%)	0 (0%)
Total completed	**1 (100%)**	**5 (100%)**

5.3. New listed medicines

Table 23: New listed medicines

	FY 2022-23	FY 2023-24
New listed medicines	1,722	1,854

5.4. Variations

Table 24: Listed medicine variations under subsection 9D(1) of the Act

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

Medicine variation	2022-23 (% of total)	2023-24 (% of total)
Approved	101 (85%)	99 (77%)
Rejected	0 (0%)	18 (14%)
Withdrawn	17 (15%)	11 (9%)
Total	**118 (100%)**	**128 (100%)**

5.5. Post-market applications

Listed medicine post-market applications

After listing, it may be necessary for us 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 (which is 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 24: Applications assessed

	FY 2022-23	FY 2022-24
Applications Assessed		
Aristolochic Acid clearances		
Approved	28	13
Rejected	2	0
Total number of clearances	**30**	**13**
Consents under section 14/14A of the Act		
Approved	8	7
Extensions [a]	2	0
Rejected	5	4
Withdrawn	1	2
Total number of consents	**16**	**13**
Section 7 declaration		
Approved	0	0
Rejected	0	0
Withdrawn	0	0
Total number of declarations	0	0
Total completed	**46**	**26**

[a] Section 14 extensions were given to products that already held a consent to supply goods that did not comply with Section 9(2) of the Therapeutic Goods Order 92 – Labelling that was due to expire in September 2021.

Table 25: Conditions of listing

We may impose additional conditions of listing on products after listing. Some of these apply to all listed medicines and are automatically applied at the time of listing, while some only apply to certain products and these sponsors are notified after their products are listed in the ARTG.

On 13 December 2022, we published the Therapeutic Goods (Listed Medicines—Conditions of Listing) Determination 2022, which sets out the standard conditions that will automatically apply to the listing of certain medicines that are listed in the ARTG under section 26A or 26AE of the Act. The conditions of listing relating to aristolochic acids and testing of sunscreens by AMA laboratories are now automatically applied by the Determination. From 13 December 2022, we are no longer required to impose these conditions in writing, so these statistics are therefore not reported for the FY 2023-24.

Product specific conditions of listing	FY 2022-23	FY 2023-24
Chewing Gum	1	0
HICC (4-(4-hydroxy-4-methylpentyl)-3-cyclohexene carboxaldehyde)	0	2
Total	**1**	**2**

5.6. Enquiries and education activities

We respond to stakeholder enquiries related to the regulation of listed medicines, including Food-Medicine Interface (FMI) and Cosmetic-Medicine Interface (CMI) enquires. To help address frequently asked questions, or areas where consistent compliance issues are observed in listed medicines, we provide educational presentations for external stakeholders (e.g. at conferences and seminars) and fact sheets for FMI/CMI issues. We also respond to listed medicine-related enquiries related to educational information sent to stakeholders.

Table 26: Enquiries and education

Enquiries and education actions	FY 2022-23	FY 2023-24
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines) – emails	3,085	3,024
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines) – emails – phone calls	429	277
FMI/CMI related enquires	35	25
Guidelines, media releases, factsheets, educational web content, social media posts	16	20
FMI/CMI educational correspondences (e.g. follow up on fact-sheet) [a]	3	6

[a] data unavailable or process was not in existence.

5.7. Food/Cosmetic-Medicine Interface activities

FMI/CMI referrals may come from internal and external stakeholders. External stakeholders include Food Standards Australia New Zealand and the state and territory food regulators, the ABF, and the AFP. Referrals are also received through consumers and industry members. All referrals are triaged based on risk to consumers.

Table 27: Food-Medicine Interface (FMI) and Cosmetic-Medicine Interface (CMI) assessments

FMI/CMI assessments	FY 2022-23	FY 2023-24
FMI/CMI referrals triaged and queued	55	38
FMI/CMI referrals triaged and closed via factsheet [a] [b]	9	3
Completed FMI/CMI assessments	17	29
Referral to another TGA area or government organisation	54	17

[a] Using factsheet developed in Table 25.

[b] Data unavailable or process was not in existence.

5.8. Compliance and enforcement

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

Signals of potential non-compliances, which include those captured by ARTG scanning, as well as those gathered from complaints and referrals from external or internal stakeholders, are triaged and assessed for the level of risk they pose. Based on these assessments, the appropriate actions are meted to each signal of non-compliance. Low risk signals may be addressed with education correspondence, whereas signals which may pose a higher risk may result in an in-depth investigation being conducted. Depending on the risks, some signals may result in medium to high level compliance or enforcement actions such as a warning letter, a compliance review or infringement notices.

Targeted compliance reviews may be initiated as a result of signals investigations or from intel/data that is available regarding a compliance topic.

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

- the review is concluded, and the medicine remains on the ARTG (e.g. if no compliance breaches are identified against selected listing requirements, or if identified compliance breaches are addressed)
- the review leads to additional regulatory actions, such as cancellation from the ARTG, recall, or infringement notices being issued, and
- The review is closed due to the unavailability of information in determining its compliance status (e.g. if the medicine is yet to be manufactured).

Outcomes of all listed medicine compliance reviews, cancellations by the TGA, recall actions, infringement notices issued and advertising directions and prevention notices are published on the TGA website.

The 2023-24 compliance strategy for listed medicines only included targeted compliance activities based on intelligence and data.

Table 28: Signals triaging and investigations

Signals monitored	FY 2022-23	FY 2023-24
Newly listed medicines monitored	1,722	1,854
Intel signals of non-compliance (complaints and referrals)	110	131
ARTG signals of non-compliance (ARTG scanning)	294	262
Signals of non-compliance investigated and completed	345	307
Signals of non-compliance resolved with low to medium level compliance actions [a] (% success [b])	202 (65% [c])	126 (69% [c])
Signals of non-compliance transitioned to a compliance review	118	21
Medicines with potential non-compliance addressed via mass email education [d] (no. of topics)	539 (2)	63 (1)

[a] Educational email, obligations notice, cease and desist notice, warning notice, and any other educational correspondence.

[b] Success is measured as a percentage of medicines brought into compliance by sponsors after receiving a low to medium level compliance action.

[c] Based on available data. Assurance has been conducted for all correspondence sent in December 2024.

[d] Educational emails targeted at all listed medicines which could be at risk of the same non-compliance.

Table 29: Listed medicine compliance reviews by type

	FY 2022-23	FY 2023-24
Initiated reviews		
Compliance reviews	130	37
Compliance reviews transitioned from signal investigations	118	21
Total number of initiated reviews	**248**	**58**
Completed reviews		
Compliance reviews	133	52
Compliance reviews transitioned from signal investigations	70	50
Total number of completed reviews	**203**	**102**

Table 30: Compliance and enforcement actions

Compliance and enforcement actions [a]	FY 2022-23	FY 2023-24
Warning notices (cease and desist)	4	21
Educational correspondence (e.g. obligations notices, educational emails, other)	108	58
Mass email education [b]	192	27
Cease review notices	19	9
Conclusion notices	149	83
Deficiencies notices	36	17
Proposal to cancel notices	140	48
Cancellation notices	8	7
Directions/Prevention notice	2	1
Infringement notices	8	6
Published outcomes of compliance reviews	175	153
Referral to another TGA area or government organisation	43	40
Recall actions [c]	21	13
Total actions undertaken [a]	**905**	**483 [d]**

[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.

[c] Includes recalls, product defect corrections, hazard alerts and product defect alerts.

[d] The lower numbers are largely due to loss of staff and resources diverted to recruitment and training of new recruits.

Table 31: All compliance review [a] outcomes

	FY 2022-23	FY 2023-24
Medicines no compliance and verified compliance breaches	**185**	**96**
Medicines with no compliance breaches	57	27
Medicines with verified compliance breaches	128	69
Medicine no longer in the ARTG	**63**	**36**
Cancelled by the TGA	12	9
Cancelled by the sponsor after being notified of the compliance breaches	51	27
Medicine remains on the ARTG	**17**	**33**
Compliance breaches addressed after low level compliance action [b]	11	7
Compliance breaches addressed after proposal to cancel	6	26
Compliance status unable to be determined	**17**	**6**
Medicines cancelled by sponsors after request for information	11	2
Medicines not yet manufactured	6	4
I Product is not a therapeutic good	**1**	**0**
Total completed	**203**	**102**

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

[b] E.g., deficiencies/obligations/warning notices.

[c] The lower numbers are largely due to loss of staff and resources diverted to recruitment and training of new recruits.

In this table, compliance interactions include letters such as obligations notices, deficiency notices as well as other educational correspondences such as targeted educational email campaigns and direct email communications with sponsors. Compliance interactions includes all activities conducted for listed medicines, from applications and applying conditions of listing, through to signal investigations and compliance reviews.

Indirect reach of our compliance activities such as through reading media releases, publication of compliance review outcomes, infringement/prevention notices and recalls have not been captured here.

Table 32: Reach of compliance activities for listed medicines

Sponsors reached	FY 2022-23	FY 2023-24
Sponsors who received any compliance interactions	294 (22%)	206 (14%)
Listings covered by any compliance interactions	1,000 (7%)	399 (3%)

Table 33: Outcomes of completed compliance reviews

Outcomes of completed compliance reviews	Count	Percentage (% of Total)
Cancelled by Sponsors after TGA contact	29	30%
Cancelled by TGA after proposal to cancel	9	9%
Compliant after proposal to cancel	26	27%
Compliant after education	7	7%
Compliant	27	28%
Total	**98**	**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 *Therapeutic Goods Act 1989* 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 34: Applications for biologicals and blood received and on hand

	FY 2022-23 Number (% of total)	FY 2023-24 Number (% of total)
Applications received		
Technical Master File (TMF) [b] new	0 (0%)	0 (0%)
TMF annual updates	5 (5%)	4 (4%)
TMF variations	9 (8%)	6 (6%)
TMF notifications	10 (9%)	11 (11%)
Plasma Master File [c] annual updates	9 (8%)	12 (12%)
Biological Class 1 – new applications	0 (0%)	1 (1%)
Biological Class 2 – new applications	2 (2%)	2 (2%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	0 (0%)	3 (3%)
Biological Class 2 – variations	53 (48%)	34 (33%)
Biological Class 3 – variations	7 (6%)	0 (0%)
Biological Class 4 – variations	15 (14%)	29 (28%)
Total received	**110 (100%)**	**102 (100%)**
Applications on hand		
TMF new	0 (0%)	0 (0%)
TMF annual updates	2 (10%)	1 (4%)
TMF variations	3 (14%)	2 (9%)
TMF notifications	2 (10%)	1 (4%)
Plasma Master File annual updates	3 (14%)	0 (0%)
Biological Class 1 – new applications	0 (0%)	0 (0%)
Biological Class 2 – new applications	2 (10%)	3 (13%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	0 (0%)	3 (13%)
Biological Class 2 – variations	5 (24%)	7 (30%)
Biological Class 3 – variations	0 (0%)	0 (0%)
Biological Class 4 – variations	4 (19%)	6 (26%)
Total on hand	**21 (100%)**	**23 (100%)**

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

[b] Technical Master Files (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] Plasma Master Files 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.

Table 35: Completed applications for biologicals and blood

Biologicals applications	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Technical Master File (TMF) new	0 (0%)	0 (0%)
TMF annual updates	3 (3%)	4 (4%)
TMF variations	7 (7%)	5 (5%)
TMF notifications	10 (10%)	10 (10%)
Plasma Master File annual updates	6 (6%)	12 (12%)
Biological Class 1 – new applications	0 (0%)	1 (1%)
Biological Class 2 – new applications	2 (2%)	1 (1%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	3 (3%)	1 (1%)
Biological Class 2 – variations	50 (48%)	34 (37%)
Biological Class 3 – variations	7 (7%)	0 (0%)
Biological Class 4 – variations	17 (16%)	26 (28%)
Total completed	**105 (100%)**	**94 (100%)**

7. Medicine and Vaccine Adverse Event Reports

7.1. Adverse medicine and vaccine event notifications

Table 36: Source of notifications of medicine and vaccine adverse events [a]

	FY 2022-23	FY 2023-24
Received		
Mean number of reports received weekly	530	588
Vaccine reports	10,183	13,085
Total	**27,568**	**30,566**
Accepted cases		
Reports by health professionals	4,083	4,431
Patients/consumers	2,490	1,532
Pharmaceutical companies	13,469	18,311
Other source [b]	6,135	5,085
Total	**26,177**	**29,359**
Rejected/withdrawn cases	**1,391**	**1,207**

[a] Data is subject to change due to receipt of further information related to individual reports or further case processing. 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 medical devices, including:

Priority review of medical devices: This pathway allows faster processing of applications for devices that meet certain criteria such as being a novel device and delivering significant health benefits above those devices already on the market.

Medical device manufacturing: We assess the quality management systems of medical device manufacturers seeking TGA conformity assessment certification. This may be through onsite inspections or desktop assessment of third-party inspection reports, or a combination of these methods. Surveillance inspections are also undertaken to assess continuing compliance. In addition, we are a Regulatory Authority of the Medical Devices Single Audit Program (MDSAP) that assesses and recognises third party Auditing Organisations for the purposes of certifying medical device manufacturers. We also conduct 'for-cause' audits of some manufacturers, regardless of what type of certification they use to support approval in Australia, if we have strong postmarket concerns.

Conformity assessment: This is the systematic examination by the manufacturer to determine that a medical device is safe and performs as intended and therefore, conforms to the Essential Principles. The TGA may certify the manufacturer's conformity assessment procedure, or we may recognise certification from a comparable overseas regulator such as a European notified body.

Inclusion in the ARTG: Medical devices cannot be imported, supplied in, or exported from Australia unless they are included in the ARTG or a valid exemption applies, for example custom made medical devices, importation of samples, etc. A sponsor can apply to include a medical device in the ARTG if the device complies with the Essential Principles and appropriate conformity assessment procedures have been applied to the device.

Post-market monitoring: Once a medical device has been included in the ARTG the device must continue to meet all regulatory, quality, safety and performance requirements throughout the claimed lifespan.

8.1 Conformity assessment

Applications

Table 37: Number of conformity assessment applications (medical devices including IVDs)

	FY 2022-23	FY 2023-24
Conformity assessment applications		
Applications received	202	96
Applications on hand	119	161
Applications completed (including withdrawn or lapsed applications).	204	204

Outcomes

Table 38: Outcomes of conformity assessment applications

	FY 2022-23	FY 2023-24
New		
Approved	22	18
Refused	0	1
Withdrawn/ Lapsed	28	21
Variation (changes and re-certifications)		
Approved	136	152
Refused	0	0
Withdrawn/ Lapsed	18	12

Processing timeframes

We are required to complete our review of conformity assessment applications within 255 working days.

Table 39: TGA conformity assessment processing times for new devices and variations

	FY 2022-23	FY 2023-24
New devices		
Mean TGA processing time (days)	148	147
Median TGA processing time (days)	213	195
% of applications completed within legislated timeframe (255 working days)	100%	100%
Variations (changes and recertifications)		
Mean TGA processing time (days)	142	139
Median TGA processing time (days)	145	144
% of applications completed within legislated timeframe (255 working days)	100%	100%

8.2. Inclusion of medical devices (including IVDs)

8.2.1 Applications

Table 40: Applications for inclusion – medical devices (including IVDs)

	FY 2022-23	FY 2023-24
Class I medical devices		
Applications received	1,492	2,089
Applications completed	1,459	2,142
Applications on hand	197	177
Class I measuring medical devices		
Applications received	33	27
Applications completed	36	25
Applications on hand	0	2
Class I sterile medical devices		
Applications received	264	266
Applications completed	262	265
Applications on hand	2	12
Class IIa medical devices		
Applications received	1,179	1,237
Applications completed	1,162	1,223
Applications on hand	109	119
Class IIb medical devices		
Applications received	648	610
Applications completed	602	608
Applications on hand	72	127
Class III medical devices		
Applications received	668	381
Applications completed	572	468
Applications on hand	448	367
Active Implantable Medical Devices (AIMD)*		
Applications received	18	0
Applications completed	27	0
Applications on hand	14	0
Class 1 IVDs [a]		
Applications received	83	98
Applications completed	86	101
Applications on hand	14	5

	FY 2022-23	FY 2023-24
Class 2 IVDs		
Applications received	101	109
Applications completed	83	123
Applications on hand	27	14
Class 3 IVDs		
Applications received	157	97
Applications completed	361	151
Applications on hand	92	28
Class 4 IVDs		
Applications received	17	36
Applications completed	12	79
Applications on hand	12	4

* From 25 November 2021 active implantable medical devices (AIMD) were reclassified to Class III. All previous AIMD applications were completed in the 2022-2023 FY.

Table 41: Applications for device change requests and variations to the ARTG – medical devices (including IVDs)

	FY 2022-23	FY 2023-24
Device Change Request (DCR)		
Applications received	857	838
Applications completed	742	792
Applications on hand	209	214
Variations to Class III medical devices		
Applications received	108	76
Applications completed	110	77
Applications on hand	6	20
IVD Device Change Request (DCR)		
Applications received	107	84
Applications completed	99	109
Applications on hand	46	19
IVD Variations		
Applications received	52	49
Applications completed	58	56
Applications on hand	27	18

Between 1 July 2023 and 30 June 2024, the Medical Device Information Unit received a total of 21,520 emails and 3,719 calls, covering a wide range of queries. These queries primarily focused on topics such as the medical device approval process (including for personalised devices), and the impact of reclassification reforms and changes in International jurisdictions (such as the European Union.)

8.2.2 Processing times

A Level 1 audit may include clarification of the device classification, the conformity assessment procedure, or a review of packaging and labelling to ensure it meets requirements.

A Level 2 audit requires the information for a Level 1 audit plus clinical evidence, risk management reports, or efficacy and performance data. The target timeframe for Level 1 application audits was 30 TGA workdays and for Level 2 application audits it was 60 TGA workdays ('TGA days').

Table 42: Processing times for medical device application audits (including IVDs)

	2022-23			2023-24		
	Total completed	Processing times (TGA days)		Total completed	Processing times (TGA days)	
		Mean	Median		Mean	Median
Medical devices						
Class I applications completed without audit	1,459	2	2	1,466	2	2
Class I applications completed with audit	709	33	8	676	17	3
Non class I applications completed without audit	2,094	12	12	2,061	16	16
Non-mandatory audits (Non class I)	142	109	78	213	124	87
Level 1 mandatory audits	38	89	91	35	98	83
Level 2 mandatory audits	208	179	172	234	224	236
IVDs						
Class 1IVD applications completed without audit	58	4	2	63	12	10
Class 1 IVD applications completed with audit	23	99	56	16	91	101
Non class 1 IVD applications completed without audit	56	5	4	49	13	13
IVD non-mandatory audit	6	46	40	14	163	166
IVD mandatory audit	358	156	154	146	164	153
IVD Device Change Request	99	99	94	109	78	55
IVD Variation	58	115	68	56	85	68

Table 43: Number of priority review determinations [a] granted

Application type	FY 2022-23	FY 2023-24
A: Conformity Assessment (priority applicant) determinations [b]	0	1
B: Medical Devices (priority applicant) determinations [b]	0	0

[a] Priority determination is a formal decision by the TGA to assign priority to the assessment of an application. Priority determination does not guarantee the application will be approved.

[b] No determinations were granted in 2022-23.

Table 44: Number of medical devices approved through the priority review pathway.

	FY 2023-24	
Application Type	**Number of applications with Priority determinations Approved (% of Total)**	**Median approval time (TGA working days)**
A: Conformity Assessment	0	0
B: Medical Devices (ARTG inclusion)	0	0
Total [a]	0	0

[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 of a kind, to ensure that medical devices continue to comply with the applicable regulatory requirements and that the safety and performance of the medical devices (including IVDs) are maintained. In addition, we undertake targeted reviews to verify that a product is included correctly in the ARTG. We use information from both internal (for example, increase trend in adverse events) and external sources (for example, reports of new hazards) to select medical devices for post-market review.

Table 45: Medical device post-market reviews

Post market reviews	FY 2022-23	FY 2023-24
Reviews commenced – number of ARTG entries	899	562
Reviews completed – number of ARTG entries	1,592	1,300
Reviews on hand – number of ARTG entries	5,048	4,310

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

Medical devices are required to comply with the Essential Principles; however, there may be extenuating circumstances preventing compliance to one or more parts of an Essential Principle for a limited period of time. In those cases, sponsors of the medical devices can apply to the TGA to seek a consent to supply (CtS) the non-compliant medical devices. The CtS applications can include multiple active ARTG entries, as well as medical devices that are included in an application for inclusion in the ARTG.

Table 46: Applications for consent to supply (CtS) non-compliant medical devices

Consent to supply applications	2023-24
Total number of CtS applications received	116
Number of ARTG entries included in the CtS applications	696
Number of Applications for Inclusion in the ARTG included in the CtS applications	13

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 (near-incident): serious injury, illness or death to a patient, healthcare worker or other person. Australian sponsors of medical devices must actively monitor their devices' post market performance and report incidents to the TGA. Reporting of incidents, or near-incidents, by users is voluntary.

Table 47: Number of medical device incident reports

	FY 2022-23	FY 2023-24
Incident report outcomes		
Device incident reports [a]		
Reports received	8,403	9,917
Reports completed	6,893	7,917
Reports still in progress	1,509	2,000

[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 48: Medical device incident report outcomes [a]

Incident report outcome	FY 2022-23	FY 2023-24
Reviewed, for Trending Purposes Only	6,613	7,421
Reviewed, No Further Action Required	173	234
Field Safety Corrective Action Product recall	9	45
Field Safety Corrective Action Product correction	14	41
Field Safety Corrective Action Hazard alert	5	39
Field Safety Corrective Action Safety alert	0	20
Field Safety Corrective Action Product alert	17	6
Referral to other TGA Office	2	5
TGA Publication	2	4
Referral for Post-Market Review	9	3
Product enhancement/improvement notice	0	2
Change to design	0	1
Instructions for use amended	3	1
Not device related	5	1
User Education	3	1
Other	54	2

[a] Outcomes are not mutually exclusive. Some of the 2022-23 numbers have been updated due to the ongoing nature of investigations.

8.3.4 Devices manufacturing

Table 49: Outcomes of Quality Management System (QMS) audits of Australian manufacturers

	FY 2022-23	FY 2023-24
QMS audits (Australia)		
Number of audits conducted	14	32
Satisfactory compliance (of completed audits)	13 (93%)	18
Marginal compliance (of completed audits)	1 (7%)	9 (64%)
Unacceptable compliance (of completed audits)	0 (0%)	0 (0%)
Processing time		
Initial audits conducted within 3 months of application	100%	15%
Re-audits conducted within 6 months of due date	7%	12

Table 49: Outcomes of QMS audits of overseas manufacturers

	FY 2022-23	FY 2023-24
QMS audits (overseas)		
Number of desktop audits conducted	32	16
Number of onsite/remote audits conducted	11	26
Satisfactory compliance (of completed audits)	9 (82%)	19 (90%)
Marginal compliance (of completed audits)	2 (18%)	1 (5%)
Unacceptable compliance (of completed audits)	0 (0%)	1 (5%)
Processing time		
Initial certification audits conducted within 6 months of application	39%	67%
Certification re-audits conducted within 6 months of due date	14%	0%

9. Exports

9.1. Export only products

Table 50: Number of approved applications for export-only medicines and export certifications and relevant processing time for July 2023 to June 2024

	2022-2023	2023-2024	Target processing time (days)	2022-23	2023-2024
	Total approved			Average processing time (days)	
Export-only medicines					
New applications	308	257	30	26	31
Variation and grouping applications	129	124	30	19	16
Export certification					
Medicines	1,958	1,697	15	10	6
Medical devices	393 [a]	308	10	5	4

[a] Accurate data available with more professional data collection procedures.

10. Access to unapproved therapeutic goods

10.1. Special Access Scheme

The 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. There are currently 3 pathways under the scheme which are categorised as follows:

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 51: SAS medicine notifications and applications

	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Category A notifications		
Total Category A notifications	**32,962 (16%)**	**38,157 (15%)**
Category B applications		
Approved	131,585 (98%)	174,333 (97%)
Cancelled	305 (<1%)	906 (1%)
Withdrawn	1,480 (1%)	2,096 (1%)
Rejected	13 (<1%)	3 (0%)
Pending at end of reporting period	1,088 (1%)	1,824 (1%)
Total Category B applications	**134,471 (67%)**	**179,162 (72%)**
Category C notifications		
Total Category C notifications	**32,646 (16%)**	**30,184 (12%)**
Total SAS notifications/applications received (all categories)	**200,079 (100%)**	**247,503 (100%)**

Table 52: SAS medical device notifications and applications

	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Category A notifications		
Total Category A notifications	**4,999 (40%)**	**6,701 (47%)**
Category B applications		
Approved	5,471 (90%)	5,291 (92%)
Cancelled	64 (1%)	90 (2%)
Withdrawn	81 (1%)	45 (1%)
Rejected	9 (<1%)	25 (<1%)
Pending at end of reporting period	441 (7%)	275 (5%)
Total Category B applications	**6,066 (48%)**	**5,726 (41%)**
Total Category C notifications	**1,540 (12%)**	**1,703 (12%)**
Total SAS notifications/applications received (all categories)	**12,605 (100%)**	**14,130 (100%)**

Table 53: SAS biological notifications and applications

	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Category A notifications		
Total Category A notifications	**132 (5%)**	**155 (4%)**
Category B applications		
Approved	339 (75%)	359 (62%)
Cancelled	43 (10%)	163 (28%)
Withdrawn	58 (13%)	29 (5%)
Rejected	0 (0%)	0 (0%)
Pending at end of reporting period	12 (3%)	30 (5%)
Total Category B applications	**452 (16%)**	**581 (16%)**
Category C notifications		
Total Category C notifications	**2,219 (79%)**	**2,896 (80%)**
Total SAS notifications/applications received (all categories)	**2,803 (100%)**	**3,632 (100%)**

10.2. Clinical trials

The Clinical Trial Notifications scheme provides an avenue through which unapproved therapeutic goods may 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 54: Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

Therapeutic good type	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Medicine	390 (37%)	407 (35%)
Device	161 (15%)	221 (19%)
Biological	9 (1%)	12 (1%)
Medicine and device	477 (45%)	493 (43%)
Device and biological	5 (<1%)	6 (<1%)
Medicine and biological	2 (<1%)	1 (<1%)
Medicine, device and biological	6 (<1%)	12 (1%)
Total	**1,050 (100%)**	**1,152 (100%)**

Table 55: Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

Clinical trial type	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Phase 0	N/A	29 (2%)
Phase 1	346 (33%)	378 (33%)
Phase 2	263 (25%)	218 (19%)
Phase 3	229 (22%)	296 (26%)
Phase 4	37 (4%)	57 (5%)
Device	164 (16%)	173 (15%)
Bioavailability/equivalence	11 (1%)	1 (<1%)
Total	**1,050 (100%)**	**1,152 (100%)**

Table 56: 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	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Medicine	1,159 (32%)	1201 (31%)
Device	323 (9%)	379 (10%)
Biological	24 (<1%)	19 (<1%)
Medicine and device	2,117 (58%)	2221 (57%)
Device and biological	16 (<1%)	17 (<1%)
Medicine and biological	6 (<1%)	3 (<1%)
Medicine, device and biological	22 (<1%)	41 (1%)
Total	**3,667 (100%)**	**3,881 (100%)**

Table 57: Number of new clinical trials and variations to previously notified clinical trials involving unapproved therapeutic goods received by phase

Phases	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Phase 1	1,069 (29%)	45 (1%)
Phase 2	954 (26%)	1,296 (33%)
Phase 3	1,167 (32%)	860 (22%)
Phase 4	120 (3%)	1,242 (32%)
Device	341 (9%)	134 (3%)
Bioavailability/equivalence	16 (<10%)	302 (8%)
Total	**3,667 (100%)**	**2 (<1%)**

10.3 Authorised Prescribers

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

Table 58: Authorised Prescriber approvals for medicines, medical devices and biologicals

Approvals by therapeutic good type	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Number of approvals for medicines	13,641 (98%)	21,465 (99%)
Number of approvals for medical devices	235 (2%)	155 (1%)
Number of approvals for biologicals	0 (0%)	1 (<1%)
Total	**13,876 (100%)**	**21,621 (100%)**

11. Medicines and biologicals manufacturing

11.1 Manufacturing licences issued to Australian manufacturers

Table 59: Status of manufacturing licence applications

	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
New licences granted	13 (14%)	24 (22%)
Withdrawn application	68 (69%)	54 (50%)
Revoked licences – at request of licence holder	13 (14%)	15 (14%)
Revoked licences – TGA	0 (0%)	6 (5%)
Suspended – at request of licence holder	3 (3%)	10 (9%)
Suspended – TGA	0 (0%)	0 (0%)
Total	**97 (100%)**	**109 (100%)**

[a] As at 30 June 2024, there were 261 Australian companies holding manufacturing licences covering 416 sites.

Table 60: Outcomes of inspections of Australian manufacturers

	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
	Number (% of Total)	
Compliance status (Australia)		
Number of inspections conducted	132	179
Satisfactory compliance (of completed inspections)	98 (74%)	135 (75%)
Marginal compliance (of completed inspections)	21 (16%)	27 (15%)
Unacceptable (of completed inspections)	2 (2%)	7 (4%)
Compliance under assessment	11 (8%)	10 (6%)
Processing time		
Initial inspections conducted within 3 months of application	10 of 15 (67%) [b]	17 of 34 (50%) [c]
Re-inspections conducted within 6 months of due date	16 of 90 (18%)	17 of 112 (15%)

[b] The 2022-23 data do not include inspections that were delayed at the request of the manufacturer.

[c] Twenty-six of the delayed re-inspections were blood and biological manufacturers.

11.2 Approval (certification) of overseas manufacturers

Table 61: Manufacturing certification application by status (overseas)

	FY 2022-23	FY 2023-24
	Number (% of Total)	
Applications (overseas) [a]		
New applications received [b]	52 (48%)	47 (36%)
Re-inspection applications [b]	57 (52%)	82 (64%)
Total applications	**109 (100%)**	**129 (100%)**
Applications completed		
Certified	124 (65%)	116 (60%)
Rejected [c]	68 (35%)	78 (40%)
Total completed	**192 (100%)**	**194 (100%)**

[a] As at 30 June 2024, there were 166 overseas manufacturers covering 206 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 62: Outcomes of inspections of overseas manufacturers

	FY 2022-23	FY 2023-24
	Number (% of Total)	
Inspection status (overseas)		
Number of inspections conducted	118	88
Satisfactory compliance (of completed inspections)	85 (72%)	72 (82%)
Marginal compliance (of completed inspections)	20 (17%)	12 (14%)
Unacceptable (of completed inspections)	0 (0%)	2 (2%)
Compliance under assessment at period end	13 (11%)	2 (2%)
Processing time		
Initial certification inspections conducted within 6 months of application	9 of 33 (27%) [a]	22 of 41 (54%) [b]
Certification re-inspections conducted within 6 months of due date	4 of 66 (6%)	5 of 47 (11%)

[a] Twenty-nine overseas initial inspections did not achieve the six-month processing timeframe due to manufacturers not being ready for inspection.

[b] The 2022-23 data do not include inspections that were delayed at the request of the manufacturer.

11.3. Good Manufacturing Practice (GMP) clearances

Table 63: GMP clearance application status

	FY 2022-23	FY 2023-24
	Number (% of Total completed)	
Applications received		
Received	11,511	9,754
Applications completed		
Approved	8,714 (90%)	8,045 (84%)
Rejected	996 (10%)	1,497 (16%)
Total completed	**9,710 (100%)**	**9,542 (100%)**

Table 64: Number of GMP clearance applications received and completed by type from 1 July 2023 to 30 June 2024

Application Category	Applications received	Applications completed
Cancel	2	4
Extend	4,589	4,893
New	1,813	1,570
Reactivate	93	100
Variation	3,257	2,975

Table 65: Number of GMP clearance applications actioned by pathway from 1 July 2023 to 30 June 2024

Pathway	Applications received	Applications completed	Applications Approved	Applications not approved
Compliance Verification	1,472	685	650	35
Mutual Recognition Agreement	2,910	3,137	2,948	189

12. Recalls

12.1. Medicine recalls

Table 66: Medicine recalls by reason for recall

Reason for recall	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Adverse reactions	11 (10%)	1 (1%)
Foreign matter	3 (3%)	3 (4%)
GMP non-compliance	0 (0%)	1 (1%)
Impurity	7 (7%)	5 (6%)
Labelling or Instructions	29 (27%)	28 (33%)
Mechanical or Physical defect	15 (14%)	23 (27%)
Microbial/Fungal contamination	2 (2%)	2 (3%)
Observed difference	3 (3%)	3 (4%)
Packaging or closure defect	9 (8%)	1 (1%)
Potency	3 (3%)	1 (1%)
Sterility	1 (1%)	1 (1%)
Variable content	14 (13%)	7 (9%)
Other [a]	9(9%)	7 (9%)
Total	**106 (100%)**	**83 (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 recalls

Table 67: Medical device (including IVDs) recalls by reason for recall

Reason for recall	FY 2022-23 Number (% of Total)	FY 2023-24 Number (% of Total)
Adverse incidents	3 (<1%)	6 (1%)
Diagnostic inaccuracy	23(4%)	57 (10%)
Electrical defect	14(3%)	24 (4%)
Illegal supply	0 (0%)	0 (0%)
Labelling and packaging	89 (17%)	86 (15%)
Mechanical and physical defects	271 (51%)	251 (43%)
Software defects	87 (16%)	97 (17%)
Sterility	4 (1%)	8 (1%)
Other [a]	45 (8%)	55 (9%)
Total	**536 (100%)**	**584 (100%)**

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

12.3. Blood and Biological recalls

Table 68: Blood recalls

	FY 2022-23	FY 2023-24
Recalls to hospital level	54	53

Table 69: Biological recalls

	FY 2022-23	FY 2023-24
Recalls to hospital level	18	18

13. Laboratory testing

Our laboratories conduct post-market monitoring and compliance testing, investigations, and reviews, as well as market authorisation assessment of therapeutic goods.

A risk management approach, consistent with ISO 31000: Risk Management principles and guidelines, is used to prioritise products with a higher risk of not complying with the required quality standards. This risk-based, targeted approach to testing is reflected in the failure rates reported in the table below.

During the 2023-24 period the TGA Laboratories worked with the Regulatory Compliance Branch and ABF to test nicotine vape products being imported into Australia. The outcomes of this compliance project are reflected in the significant increase in numbers, and failure rates, for unregistered products (Table 71).

The TGA Laboratories finalised testing for the post market review of face masks in 2022-23. This resulted in the significant decrease in medical device testing in 2023-24. Further information regarding this testing can be found on the testing of face masks and respirators webpage.

Table 70: Samples and products tested by type of therapeutic good and percentage which failed

		FY 2022-23	FY 2023-24
Therapeutic good type			
Prescription medicines	Total	125	139
	% fail	2%	0%
OTC medicines	Total	34	84
	% fail	50%	8%
Complementary medicines [a]	Total	32	15
	% fail	6%	33%
Medical devices	Total	409	32
	% fail	20%	28%
External [a]	Total	7	32
	% fail	0%	41%
Pacific Medicines Testing Program	Total	66	95
	% Fail	23%	22%
Unregistered [b]	Total	401	1,259
	% fail	75%	90%
Total samples (excluding AHQ samples)		**1,074**	**1,656**
Total samples [c]		**1,230**	**1,902**
Percentage fail		39%	72%
Total number of products tested [d]		**621**	**972**

[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] We may test a number of samples of each product per reporting period.

Table 71: Samples that failed laboratory testing by reason for July 2023 to June 2024

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Contamination	0	1	0	2	0	5	1	9 (0.8%)
Formulation	1	0	0	1,071	5	6	14	1,097 (92.3%)
Label and packaging deficiencies	4	6	0	0	0	0	0	10 (0.8%)
Performance [a]	4	0	0	0	0	0	0	4 (0.3%)
Physical or mechanical properties	0	0	0	0	0	2	6	8 (0.7%)
Unregistered	0	0	0	60	0	0	0	60 (5.1%)
Total	**9**	**7**	**0**	**1,133**	**5**	**13**	**21**	**1,188**

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

Table 72: Batch release and export certification

Batch releases and certifications	FY 2022-23	FY 2023-24
Batch release [a]	649	545
Export certification [b]	18	4

[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 World Health Organisation compliant certificates for batches of biological products to be exported by Australian manufacturers to overseas markets.

Table 73: 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 are assigned to the 'Urgent' testing category. Urgent testing may impact on the timeframes for priority and routine testing. Priority is given to testing of products with the highest risk of a quality deficiency.

Table 74: Compliance with testing timeframesa for July 2023 to June 2024

Therapeutic good type [b]	Priority	Number (% of Total)
Medical devices	Routine	39 (95%)
	Priority	2 (100%)
	Urgent	No Urgent Samples
OTC medicines	Routine	8 (88%)
	Priority	76 (29%)
	Urgent	No Urgent Samples
Prescription medicines	Routine	22 (68%)
	Priority	No Priority Samples
	Urgent	No Urgent Samples
Complementary Medicines	Routine	12 (100%)
	Priority	3 (0%)
	Urgent	No Urgent Samples
Unregistered products	Routine	1,112 (85%)
	Priority	142 (56%)
	Urgent	5 (40%)

[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

We conduct compliance and enforcement activities against a risk-based compliance framework. A range of tools are used to encourage compliance and address non-compliance including 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 75: Allegations by compliance priority – FY 2023-24

Compliance priority	Reports received	Reports Finalised [a]
Medicinal cannabis, psilocybin and MDMA - advertising	721	432
Nicotine vaping products – import, advertising and supply	4,170	2,194
Substandard and falsified therapeutic goods – import	147	103
Traditional or alternative treatments – import, advertising and supply	92	26
Wellness and beauty industries unapproved and high-risk therapeutic goods – advertising	1,321	484
Other*	9,743	7,724
Total	**16,194**	**11,495**

Reports includes 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.

* *Other relates to reports and cases not related to a TGA 2023-24 compliance priority. This may include cases marked as duplicate cases.*

Table 76: Digital platform removal requests by compliance priority – FY 2023-24

Compliance priority	FY 2023-24
Medicinal cannabis, psilocybin and MDMA - advertising	149
Nicotine vaping products – import, advertising and supply	29
Substandard and falsified therapeutic goods – import	0
Traditional or alternative treatments – import, advertising and supply	611
Wellness and beauty industries unapproved and high-risk therapeutic goods – advertising	3,030
Other *	1,016
Total	**4,835**

* *Other includes digital platform removal requests that are not directly linked to a TGA 2023-24 compliance priority.*

Table 77: Source of report of non-compliance

Source	FY 2023-24
Consumer/General Public	2,168
Australian Border Force	11,700
Government/State and Territory body/External Agency	576
Company/business	436
Health practitioner	427
Regulator/legal consultant	80
Other*/**	261

* *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 (excl. nicotine/ vaping products)

Table 78: Civil and criminal court proceedings

Criminal and civil court *	FY 2023-24
Criminal actions commenced	1
Criminal actions finalised	0
Civil actions commenced	3
Civil actions finalised	0

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

Table 79: Other activities

Enforceable undertakings *	FY 2023-24
Enforceable undertaking entered	2

* *Enforceable undertakings 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 Import Scheme.

Table 80: Reports of alleged import, export, manufacture and supply non-compliance

Compliance cases [a]	FY 2023-24
Reports received	8,051
Reports finalised [b]	6,750

[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 81: Regulatory compliance referrals by special interest categories

Compliance category	FY 2023-24	
	Referrals received	Units(% of total)
Goods on the ARTG	19	6,241 (0.1%)
Goods not on the ARTG *	7,922	5,714,462 (96.8%)
Counterfeit products **	133	180,942 (3.1%)
Total [a]	8,074	5,901,645 (100%)

* 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 82: Number of offence types related to completed cases

Offence type	FY 2023-24 Number (% of total)
Import	7,153 (96%)
Export	2 (<1%)
Counterfeit	131 (1 %)
Manufacture	4 (<1%)
Supply	158 (2%)
Advertising (relating to an import, manufacture or supply case)	14 (<1%)
Total completed [a]	**7,432 (100%)**

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

Table 83: Number of compliance actions taken against completed investigations

Completed investigations	FY 2023-24 Number (% of total)
No offence identified	219 (3%)
Goods released under Personal Import Scheme	337 (4.6%)
Referred internally	6 (<1%)
Referred to external agency	52 (<1%)
Warning letters issued [a]	6,635 (91.3%)
Infringement notice issued	15 (<1%)
Total [c]	**7,264 (100%)**
Infringement notice value ($)	$146,490
Units of goods referred to ABF for destruction [d]	2,988,461

[a] The category 'warning letters issued' can include goods destroyed as prohibited imports and goods re-exported.

[b] Criminal prosecution for import, export, manufacture and supply may also include advertising offences. Where criminal prosecution has related to advertising offences only it is not included in this table. Refer to the next section on advertising.

[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.

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).

Table 84: Reports of alleged advertising non-compliance

Compliance cases [a]	FY 2023-24
Reports received [b]	3,370
Reports finalised [b]	1,430

[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 85: Compliance actions recorded

Action taken	FY 2023-24
Assessed - no further action [a]	1,036
TGA requested removal of advertising [b]	4,806
Warning letter sent [C]	168
Infringement notice issued	147
Infringement notices value ($)	$2.20 million
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 "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 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.

14.4. Nicotine/vaping products

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

Table 86: Reports of alleged non-compliance

Compliance cases [a]	FY 2023-24
Reports received	3,654
Reports finalised [b]	2,517

[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 87: Number of offence types related to completed cases

Offence type	FY 2023-24 Number (% of total)
Import	2,364 (91%)
Export	0 (0 %)
Counterfeit	40 (2%)
Manufacture	1 (<1%)
Supply	119 (5%)
Advertising	66 (3%)
Total completed [a]	**2,590 (100%)**

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

Table 88: Number of compliance actions taken against completed investigations

Action	FY 2023-24 Number (% of total)
Assessed - no action taken [a]	151 (5%)
TGA requested removal of advertising [b]	29 (1%)
TGA request ISP to block access to website	23 (1%)
Goods released under Personal Import Scheme	430 (15%)
Referred internally	6 (<1%)
Referred to external agency	13 (<1%)
Warning letters issued [c]	2,107 (76%)
Infringement notices	26 (1%)
Civil proceedings finalised	1 (<1%)
Total [d]	**2,786 (100%)**
Infringement notices value ($)	$263,352
Units of goods referred to ABF for destruction [e]	5,053,976
Units of goods seized under warrant [f]	811, 669

[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 "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.

[e] Units refers to single dosage unit e.g. 1 tablet, 1 capsule, 1 tub of powder or a single device.

[f] Includes therapeutic goods seized that are not nicotine vaping goods, but seized in operations targeting nicotine vaping goods.

14.5. 2023-24 financial year – data changes

2023-24 financial year – data changes

In previous years, the TGA has reported a financial year comparison between the current and previous financial year performance. We have also historically provided a single view of all data for regulatory and advertising compliance work.

In the 2023-24 financial year, TGA compliance priorities were updated and will remain in effect until the end of the 2024-25 financial year. These priorities include a specific focus on nicotine product compliance, in line with legislative and regulatory updates. We have therefore provided a breakdown of data for "non-nicotine" and "nicotine" products to provide transparency and clarity around these areas of work.

Due to these reasons, a direct comparison between the 2022-23 and 2023-24 financial year performance is not possible. The 2024-25 Performance Report will provide a financial year comparison for the 2023-24 and 2024-25 period.

15. Pharmacovigilance inspection program

Table 89: Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified

	FY 2022-23	FY 2023-24
Total inspections completed	9	7
Total inspections with deficiencies	9	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.

16. Good Clinical Practice (GCP) Inspection Program

Table 90: GCP Inspection Program inspections undertaken and deficiencies identified

	FY 2022-23	FY 2023-24
Total inspections completed	7	6
Total inspections with deficiencies	7	6

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.

17. Reporting of medicine shortage

Table 91: Number of medicine shortage reports [a] by shortage reason

	FY 2022-23	FY 2023-24
	Number (% of Total)	
Shortages Reported		
New – Commercial changes	46 (3%)	38 (3%)
New – Discontinuation	168 (12%)	175 (15%)
New – Manufacturing related	827 (59%)	698 (59%)
New – Product recall	6 (<1%)	5 (<1%)
New – Unexpected increase in demand	180 (13%)	103 (9%)
New – Unexpected increase in demand due to other sponsors unable to supply	55 (4%)	39 (3%)
New – Transport / Logistic issues / Storage capacity issues	110 (8%)	129 (11%)
New – Seasonal depletion of stock	6 (<1%)	3 (<1%)
Total	**1,398 (100%)**	**1,190 (100%)**

[a] New reports only, does not include updates of previously reported shortages. From this report onwards, the TGA has amended how figures for 'New' and 'Update' notifications are captured to improve accuracy. Under the new methodology, only the first report of a shortage or a discontinuation is considered a new notification. Subsequent revisions to the first report will be captured as an 'Update' rather than a 'New' notification as previously captured. Additionally, new shortage notifications reported in error will no longer be captured.

Applying these changes to the figures for the FY 2022-23 result in 5,196 'Total' shortage notifications received: 1,282 'New' shortage notifications and 3,914 'Update' shortage notifications.

Table 92: Number of medicine shortage notifications received

Notifications received	FY 2022-23	FY 2023-24
New	1,398	1,190
Update [a]	3,807	4,537
Total	**5,205**	**5,727**

[a] Updates of previously reported shortages, including updates to 'Resolved' status. Mandatory reporting of all shortages of prescription medicines and select over-the-counter medicines commenced 1 January 2019. From this report onwards, the TGA has amended how figures for 'New' and 'Update' notifications are captured to improve accuracy. Under the new methodology, only the first report of a shortage or a discontinuation is considered a new notification. Subsequent revisions to the first report will be captured as an 'Update' rather than a 'New' notification as previously captured. Additionally, new shortage notifications reported in error will no longer be captured.

Applying these changes to the figures for the FY 2022-23 result in 5,196 'Total' shortage notifications received: 1,282 'New' shortage notifications and 3,914 'Update' shortage notifications.

18. Serious Scarcity Substitution Instruments (SSSIs)

Under section 30EK of the Act, the Minister for Health and Aged Care 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) that pharmacists are permitted to dispense in substitution for the scarce medicine and specify the circumstances in which that substitution is permitted.

SSSIs allow community pharmacists to substitute specific medicines without prior approval from the prescriber if the permitted circumstances within the SSSI are met.

Table 93: Number of SSSIs made

	FY 2022-23	FY 2023-24
Number of SSSIs made	5	6

Table 88: Serious Scarcity SSSI's table of Alerts

Issue date	Alert	Scarce Medicine(s)	Serious Scarcity Substitution Instrument	Duration of SSSI
05/07/2023	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 (AUST R 280432)	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Degludec and Insulin Aspart) Instrument 2023	6 July 2023 to 5 June 2024
07/09/2023	Substitute approved for vigabatrin (Sabril) shortage	SABRIL vigabatrin 500 mg tablet blister pack (AUST R 150021)	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Vigabatrin) Instrument 2023	12 September 2023 to 31 January 2024
31/10/2023	Extension to oral cefalexin substitution instrument	A registered medicine that contains: • cefalexin 125 mg/5 mL in a 100 mL syrup or suspension • cefalexin 250 mg/5 mL in a 100 mL syrup or suspension	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) Instrument 2023 and Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) Amendment Instrument 2023	31 October 2023 to 30 April 2024

Issue date	Alert	Scarce Medicine(s)	Serious Scarcity Substitution Instrument	Duration of SSSI
11/12/2023	Substitution approved for fluoxetine 20 mg dispersible tablets (Zactin Tabs)	ZACTIN TABS fluoxetine hydrochloride 20mg dispersible tablet blister pack (AUST R 90913)	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Fluoxetine) Instrument 2023 and Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Fluoxetine) Amendment Instrument 2024	11 December 2023 to 30 September 2024
09/02/2024	Substitute approved for gliclazide 30 mg tablets	APO-GLICLAZIDE MR 30mg tablets blister pack (AUST R 151303) GLICLAZIDE MR VIATRIS gliclazide 30mg modified release tablet blister pack (AUST R 295541) PHARMACOR GLICLAZIDE MR gliclazide 30mg modified release tablet blister pack (AUST R 316934)	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Gliclazide) Instrument 2024	29 February 2024 to 31 July 2024
15/05/2024	Substitution approved for Orencia (abatacept) shortages	ORENCIA (abatacept) 125 mg single dose syringe subcutaneous injection ORENCIA (abatacept) 125 mg single dose ClickJect prefilled autoinjector	Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Instrument 2024	15 May 2024 to 31 October 2024

18.1. Section 19A approvals

Section 19A of the Act provides the legislative basis for the Secretary of the Department of Health and Aged Care 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 89: Section 19A applications

Applications processed	FY 2022-23	FY 2023-24
New	75	117
Renewals	65	67
Total	**140**	**184**

Glossary of acronyms

AAF	Application Audit Framework
ABF	Australian Border Force
ACSQHC	Australian Commission on Safety and Quality in Health Care
AFP	Australian Federal Police
AGIS	Australian Government Investigations Standard 2022
Ahpra	Australian Health Practitioner Regulation Agency
AHQ	accreditation, harmonisation and quality control
AI	artificial intelligence
ANAO	Australian National Audit Office
AO	Auditing Organisation
AP	Authorised Prescriber scheme
API	active pharmaceutical ingredient
ARTG	Australian Register of Therapeutic Goods
ASEAN	Association of Southeast Asian Nations
ASEAN JA	Joint Assessment Procedure for Pharmaceutical Products-ASEAN
ASEM	Australian Sunscreen Exposure Model
ATMPWG	Advanced Therapy Medicinal Products Working Group
ATN	additional trade name
AusUDID	Australian Unique Device Identification Database
AUS-UK MRA	Australia-United Kingdom Mutual Recognition Agreement
BICS	Business Improvement and Compliance Section
BIEWG	Breast Implant Expert Working Group
BPOM	National Agency of Drug and Food Control (Indonesia)
CDSCO	Central Drugs Standard Control Organisation (India)
CDSS	clinical decision support system
CIP	Coalition of Interested Parties (WHO)
CMI	Cosmetic-Medicine Interface
COR	Comparable Overseas Regulator (pathway)
CoR	comparable overseas regulator (agency)
CTN	Clinical Trial Notification
CtS	consent to supply
CTWG	Clinical Trials Working Group
DAEN	Database of Adverse Event Notifications
DAV	Drug Administration of Vietnam
DCR	device change request

DEG	diethylene glycol
DFAT	Australian Department of Foreign Affairs and Trade
DIA	Drug Information Association
DUSC	Drug Utilisation Sub-Committee
EG	ethylene glycol
EU	European Union
FAQ	frequently asked question
FDA	Food and Drug Administration (Thailand)
FMI	Food-Medicine Interface
GCP	Good Clinical Practice
GLP-1 RA	glucagon-like peptide-1 (GLP-1) receptor agonist
GMP	Good Manufacturing Practice
GMWG	Generic Medicines Working Group
GMWSI	Generic Medicines Work-Sharing Initiative
GPCE	General Practice Conference and Exhibition
GSG	CIP Global Steering Group
HIV	human immunodeficiency virus
HPFB	Health Products and Food Branch (Health Canada)
HREC	Human Research Ethics Committee
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
IGPRG	Inter-Governmental Policy Reform Group
IMDRF	International Medical Device Regulators Forum
IMDS	International Medical Device Safety
IPMST	International Post-Market Surveillance Teleconference
IPRP	International Pharmaceutical Regulators Programme
ISP	internet service provider
ITWG	Information Technology Working Group
IVD	in vitro diagnostic
JIC	Jurisdictional Immunisation Coordinator
LIMS	Laboratory Information Management System
MAWG	Medicine Availability Working Group
MDCWG	Medical Devices Consumer Working Group
MDMA	3,4-methylenedioxymethamphetamine
MEDR	Medical Device Regulation (EU)
MDSAP	Medical Device Single Audit Program

MDVP	Medical Devices Vigilance Program
MEC	minor editorial change
MFDS	Ministry of Food and Drug Safety (Republic of Korea)
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MI-CRE	Centre for Research Excellence in Medicines Intelligence
ML	machine learning
MoU	memorandum of understanding
MRA	mutual recognition agreement
MSAG	Medicine Shortages Action Group
NAFDAC	National Agency for Food and Drug Administration and Control (Nigeria)
NAS	New Active Substance
NASWG	New Active Substances Working Group
NASWSI	New Active Substances Work-Sharing Initiative
NCIRS	National Centre for Immunisation Research and Surveillance
NIP	National Immunisation Program
NPRA	National Pharmaceutical Regulatory Agency (Malaysia)
NRA	National Regulatory Authority
NVP	nicotine vaping product
OTC	over-the-counter
PBS	Pharmaceutical Benefits Scheme
PGPA Act	Public Governance, Performance and Accountability Act 2013
PI	product information
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PMTP	Pacific Medicines Testing Program
PoC	point of care
PTSD	post-traumatic stress disorder
QMS	quality management system
RAC	Regulatory Authority Council
RACGP	Royal Australian College of General Practitioners
RAWG	Medicines Australia Regulatory Affairs Working Group
REDI	Researcher Exchange and Development within Industry
RMP	risk management plan
RSP	Regulatory Strengthening Program
RSV	respiratory syncytial virus
SAHPRA	South African Health Products Regulatory Authority
SaMD	software as a medical device
SAS	Special Access Scheme

SARMs	Selective Androgen Receptor Modulators
SCS	spinal cord stimulator
SEARN	South-East Asian Regional Network
SEO	search engine optimisation
SRA	Stringent Regulatory Authority
SRR	safety-related request
SSSI	Serious Scarcity Substitution Instrument
TBS	TGA Business Services
TCC	TGA Contact Centre
TGA	Therapeutic Goods Administration
TGACC	Therapeutic Goods Advertising Consultative Committee
TGO	Therapeutic Goods Order
the Act	Therapeutic Goods Act 1989
the department	Department of Health and Aged Care
TMF	technical master file
TRG	Technical Reference Group
UDI	unique device identifier
URPTG	Uniform Recall Procedure for Therapeutic Goods
US FDA	Food and Drug Administration (United States of America)
VPN	COVID-19 Vaccine Pharmacovigilance Network
WHPWG	Women's Health Products Working Group
WHO	World Health Organization
WLA	WHO-Listed Authority
SAR	self-assessable request