Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Administration

Performance Report 2022–23

Message from the Deputy Secretary

I'm pleased to present the 2022-23 Performance Report of the Therapeutic Goods Administration (the TGA).

In April, Adjunct Professor John Skerritt retired as Deputy Secretary for the Health Products Regulation Group of the Department of Health and Aged Care. Professor Skerritt led the TGA for more than a decade, and I take this opportunity to acknowledge the legacy and contribution he made during his tenure, which is also reflected in this report.

The TGA continues to modernise the way in which we work. In 2022-23, we spent our first full year in our purpose-built facilities in Fairbairn Canberra – the Gulgana office building, and the Yarwan Gawar laboratory building. The site includes modern laboratories and equipment that supports us to deliver a world-class medical products regulatory system. The site also provides flexible working arrangements for staff, with shared workspaces and tailored meeting spaces that encourage collaboration.

The TGA's Digital Transformation Program is making progress to address longstanding barriers encountered by our stakeholders when interacting with us, including by improving several of our systems and upgrading and enhancing our website. Further improvements can be expected as we progressively digitise more of our processes. This includes work on our new digital business portal for sponsors, their agents, and manufacturers seeking to submit applications. Feedback from stakeholders is informing this work, which aims to streamline the application process and provide more transparency.

The COVID-19 response has continued to be a major focus for the TGA in 2022-23. We shifted our focus to multiplex and combination rapid antigen test kits to address the need to distinguish influenza and COVID-19 during the flu season. Over 1000 COVID-19 test applications were processed and finalised and more than 100 COVID-19 (self-test and point-of-care) tests were included in the Australian Register of Therapeutic Goods (ARTG).

In 2022-23, there has been an increase in use of some of our regulatory services. Unapproved medicine approvals have significantly increased by 9.3% for Special Access Scheme B (SAS B) and 14% for Authorised Prescriber (AP) applications, primarily due to the sustained growth in medicinal cannabis products.

Medicine shortages continue to be a high priority for the TGA. In 2022-23, we expanded our data analytics capabilities to identify at risk medicines earlier and continued to use our global networks to receive early signals and share information. Refinements to legislation clarify requirements for medicine sponsors to notify us of changes to the length of shortages and provide a new pathway for allowing supply of overseas-registered medicines when a clinically important medicine has been discontinued in Australia. Following extensive stakeholder consultation, we commenced implementing a Medicines Repurposing Program, which aims to improve patient access to medicines by supporting registration of new indications for existing medicines on the ARTG.

Progress on medical devices reforms continues, with the implementation of a risk-based strategy for handling flow-on implications for medical devices affected by changes in medical device regulations in Europe. Several guidance papers have been published and consultations continue to ensure continued safety and supply of medical devices during the medical device reforms and European medical device regulation transition period. In March 2023, the Government passed legislation making it mandatory for health care facilities to

report medical device related adverse events to the TGA. This will improve our post-market surveillance of medical devices and help to safeguard patient safety.

Our compliance and enforcement actions on listed medicines has increased significantly from last year, and we have incorporated new intelligence approaches. Internal and external information is used to target investigations and reviews of listed medicines and maximise regulatory impact. A range of tools is used to encourage compliance, address contraventions, and prevent breaches of the Act. This includes education, working closely with stakeholder and other agencies, and product cancellations and issuing of infringement notices where necessary.

We have developed a formal advertising compliance function for digital platforms, including social media and e-commerce platforms, and made significant impacts on the unlawful advertising of nicotine-containing vapes and other therapeutic goods.

Looking ahead, the regulation of vapes will be an important focus for the TGA in 2023-24 and beyond. On 2 May 2023, following TGA consultation on the issue, the Minister for Health and Aged Care announced significant proposed reforms to the regulation of all vapes. These reforms will be implemented over the course of 2024 and aim to prohibit the importation, manufacture, advertising and supply of non-therapeutic and disposable vapes, increase regulatory requirements for unapproved therapeutic vapes, and maintain legitimate patient access to therapeutic vapes for smoking cessation and the treatment of nicotine dependence.

2023-24 will be an exciting and challenging time for therapeutic goods regulation, with some prominent advancements in many areas. We will continue to closely monitor and respond to all new developments and work with the medical products sector, the community and other stakeholders to make informed regulatory decisions that ensure therapeutic goods have a positive impact on the health of Australians.

Professor Anthony Lawler

Deputy Secretary

Health Products Regulation Group

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Our purpose

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

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

Consistent with the *Therapeutic Goods Act 1989* (the Act), we:

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

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

Our vision

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

Our strategic framework

By regulating therapeutic goods in accordance with the Act and the supporting *Therapeutic Goods Regulations 1990* (the Regulations), we contribute to the department's strategic priorities by providing better health and ageing outcomes for all Australians and an affordable, quality health and aged care system.

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. This applies to goods exported, imported, supplied, and manufactured in Australia.

Introduction

Each year we provide information about our regulatory performance through the TGA Performance Report. We measure our performance in line with Commonwealth best practice principles, as a platform for the strategic objectives and focus areas outlined in the TGA Business Plan. The principles are as follows:

Continuous improvement and building trust

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

Risk-based and data driven

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

Collaboration and engagement

- We seek opportunities to inform, engage and consult with our stakeholders and the Australian community.
- We are receptive to feedback and diverse stakeholder views.

Using these principles as a foundation, we have measured our performance against the strategic objectives and focus areas outlined in our 2022-23 TGA Business Plan. Our strategic objectives are as follows:

1. Improve public health outcomes through regulation
2. Actively engage with our stakeholders
3. Promote compliance with regulatory requirements
4. Innovate and continuously improve

Structure of this report

We have outlined notable activities in this report, across 41 focus areas corresponding to the four strategic objectives. Each strategic objective has several performance indicators against which we report our activities.

Due to the breadth and volume of work, it is not possible to mention all activities and achievements during the 2022-23 financial year. We regularly provide updates on our activities and achievements through various external mechanisms including the TGA website, email newsletters, social media, events, webinars and various stakeholder forums.

This report contains performance statistics in the appendices covering the period 1 July 2022 to 30 June 2023. These statistics are arranged into product themes and work programs and may include outcomes associated with key performance indicators and other performance targets.

Several useful documents can be read in conjunction with this report. These include the annual TGA Stakeholder Survey, Therapeutic goods advertising compliance: 2022-23 Annual Report, TGA international engagement strategy, the Regulatory science strategy 2020-2025, the Budget Paper No. 2: Budget Measures and the TGA Business Plan 2022-23.

Strategic objective 1 – Improve public health outcomes through regulation

As the national regulator for therapeutic goods, we strive to maintain Australia's highly regarded reputation for improving public health outcomes through risk-based regulation. We achieve this by delivering timely product approvals and regulatory assessments and work to quickly establish the safety of existing and emerging technologies and innovative therapies to respond to public health needs. To encompass this whole process, we monitor and improve our regulatory system as new information emerges, and ensure regulatory issues and risks are resolved through policy responses and process improvements.

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 improve the way we work with our stakeholders and to assist reporting on our key performance indicators. In 2023, we surveyed about 1,000 consumers, 186 health professionals and 1,759 stakeholders with a TGA Business Services 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 access to products'.

In the survey, 66% respondents from the medical products industry agreed with the statement and 13% disagreed. The remaining respondents said they 'neither agree nor disagree' or were 'not sure'. This is consistent with the 2022 survey.

The majority of health professionals believe the TGA gets the balance right, with 71% agreeing and 9% disagreeing. Among consumers, 55% agreed that the TGA gets the balance right, with 15% disagreeing.

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 to work to ensure stakeholders understand our risk-based approach to regulation.

Prioritising evaluations and post market safety and performance monitoring of COVID-19 related products

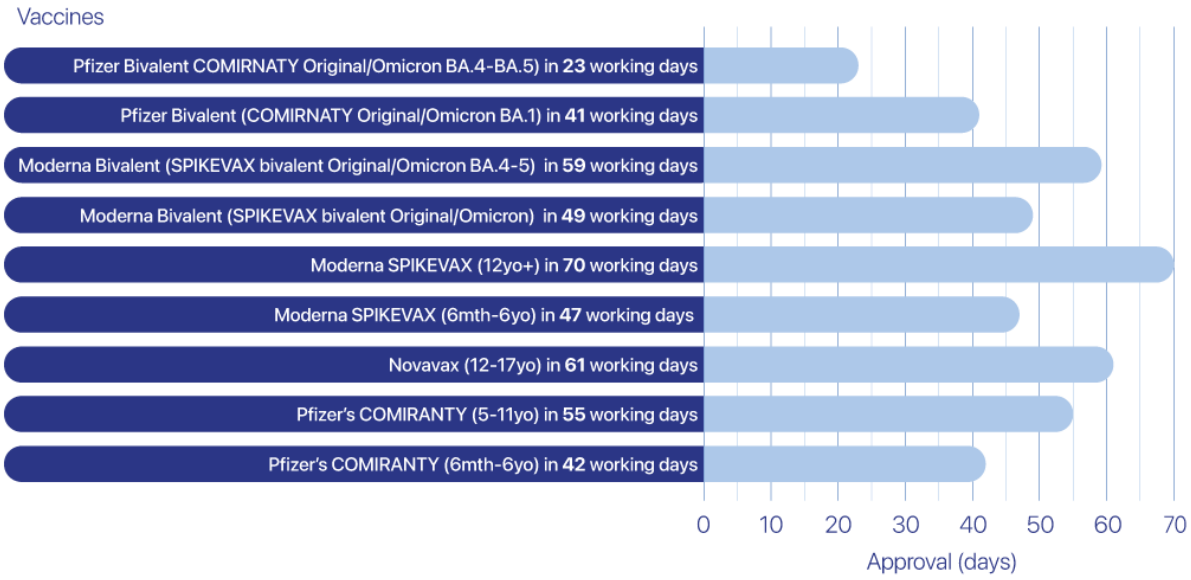
We continued to prioritise evaluations and post-market safety and performance monitoring of COVID-19 related products, including new medicines and vaccines (and medicines and vaccines for new populations), face masks, and tests for detecting

COVID-19 (including multiplex tests that also detect influenza and other respiratory viruses).

The TGA remained at the forefront of the Australian Government's response to the COVID-19 pandemic. We continue to evaluate applications for COVID-19 vaccines and treatments, including transitions to full registration, extension of indications to younger age groups, strain change vaccines, and extensions to product shelf life.

Between July 2022 and June 2023, we investigated more than 40 potential safety signals for COVID-19 vaccines, resulting in over 21 regulatory actions, which included 12 safety-related Product Information updates. We also prioritised the provisional approval of COVID-19 therapeutic goods within the timeframes stipulated in Figure 1.1.

Figure 1.1: 2022-23 Vaccines provisional approval times



In 63 working days, we approved the first transition from provisional to full registration for Moderna's Elasomeran (SPIKEVAX), noting that use in children under 6 years of age remains provisionally approved.

We reviewed 33 post-market safety reports for COVID-19 vaccines and treatments. This included 6-monthly periodic safety update reports and the additional monthly summary safety reports that were requested for COVID-19 products to closely monitor their safety.

COVID-19 test applications continued to be prioritised to meet public health need during 2023-23, with the focus shifting to multiplex tests and combination test kits to address the need to distinguish influenza and COVID-19 during the seasonal flu season. Over 1000 COVID-19 test applications were processed and finalised and more than 100 self-test and point-of-care COVID-19 tests were included in the Australian Register of Therapeutic Goods (ARTG).

A post-market review of all COVID-19-specific tests including nucleic acid, laboratory antigen and rapid antigen tests (RATs) was completed, including point-of-care and self-tests. All RATs were laboratory tested to validate the performance in detecting Delta and Omicron variants. In total, 79 RATs were found compliant with all the requirements, as they had acceptable product quality and met the requirements for analytical sensitivity and quality. Only 6 of 92 tests kits were found to be non-compliant and these kits were cancelled from

the ARTG, initiated either by the sponsor or the TGA, and are no longer supplied in Australia.[1]

We continued our post-market review of face masks and respirators, which included a total of 2,276 ARTG entries. The review included a desktop review and laboratory testing and resulted in over 85% of ARTG entries being cancelled by the TGA or the sponsor.

Reforms of medicinal cannabis products

We implemented reforms to the supply, manufacture, labelling, packaging, and compounding of medicinal cannabis products to help provide quality assurance and consistency in the products supplied.

Medicinal cannabis products, whether imported, supplied, or manufactured in Australia, must comply with quality requirements included in Therapeutic Goods Order (Standard for Medicinal Cannabis) 93 (TGO 93). The order was amended in December 2022, incorporating new manufacturing requirements for medicines manufactured overseas and released for supply on or after 1 July 2023.

The changes to the medicinal cannabis manufacturing, labelling, and packaging requirements, which include overseas medicinal cannabis manufacturing sites having to hold evidence of Good Manufacturing Practice (GMP) compliance, are now in force. We undertook GMP inspections of medicinal cannabis manufacturing sites[2], monitored signals of non-compliance, and used a risk-based approach to guide regulatory responses.

Improving access and international engagement

We continued to engage, both domestically and internationally, to build flexible and robust regulatory evaluation processes, ensuring expedited access for Australian patients and health care professionals, without compromising our regulatory standards.

Medicine shortages

We have implemented legislative amendments to help patients to access important discontinued medicines and help us improve the accuracy of our published shortage information. In response to our consultation on '*Building a more robust medicine supply*', we made amendments to the *Therapeutic Goods Act 1989* (the Act). The amendments provide additional access pathways to alleviate the effects of medicine shortages and maintain accurate, up-to-date information for patients and health professionals on our Medicine Shortage Reports Database.

These amendments include:

- new pathways under section 19A of the Act, allowing the importation and supply of overseas medicines when a medicine was previously registered and is cancelled or suspended from the ARTG, but is still clinically important and in the interest of public health

[1] Please refer Table 40 Appendix 8.2.1

[2] Please refer Table 63 Appendix 11.2

- strengthening our mandatory reporting scheme by obligating sponsors to confirm the resolution date of medicine shortages and make timely updates to any changes to the duration of a shortage.

These new tools allow health professionals to make informed decisions regarding continuity of care in the event of medicine shortages and discontinuations.

Agreements to facilitate information sharing

We have established agreements with our international regulatory counterparts to enable sharing of confidential information, which can reduce duplication and expedite some assessments to facilitate Australia's access to high quality, safe and effective therapeutic goods. Currently, we:

- have 31 agreements for confidential information sharing in place with regulatory authorities in 26 countries
- are a party to 5 treaty-level country mutual recognition agreements
- have progressed negotiations on 3 new agreements during this reporting period, pending finalisation. These include agreements with:
    - Central Drugs Standard Control Organisation (CDSCO), Ministry of Health and Family Welfare, Government of India
    - Ministry of Food and Drug Safety (MFDS), Republic of Korea
    - South African Health Products Regulatory Authority (SAHPRA)
- signed an agreement with Brunei's Darussalam Medicines Control Authority (BDMCA) to cooperate on therapeutic products to aid work-sharing, staff training and international collaboration on future medicines for Australian patients and consumers.

Interactions with our international regulatory counterparts

In August 2022, we collaborated with a delegation from Singapore, including representatives from the Consortium for Clinical Research & Innovation Singapore (CRIS), the Singapore Clinical Research Institute (SCRI), and the Advance Cell Therapy and Research Institute Singapore (ACTRIS). We shared information about the clinical trials process and role of different stakeholders in Australia, and the function of our Human Research Ethics Committees (HRECs).

We strengthened our bilateral health dialogue, broader health cooperation and strategic partnership with the Republic of Korea following a visit from the Korean Health Industry Development Institute (KIHDI) and KoNECT (Korea National Enterprise for Clinical Trials) in October 2022. We discussed the Australian clinical trials[3] regulatory framework and scope for potential cooperation between Australia and Korea in the event of a public health crisis, such as COVID-19.

We presented on Australia's regulation of therapeutic goods to Thailand's Ministry of Public Health Senior Executive Development program in June 2023. We shared details regarding recent regulatory challenges in Australia, including medicine shortages and emerging

[3] Please refer Table 55-57 Appendix 10.2

therapeutic technologies such as faecal microbiota transplant, medicinal cannabis, MDMA and psilocybin.

We worked with several counterpart national medicines regulatory authorities across the Indo-Pacific to share regulatory information and help support their determination of the suitability of Australian donated COVID-19 vaccines for their populations. This work was funded by the Australian Department of Foreign Affairs and Trade (DFAT) under the Australian Expert Technical Assistance Program – Regulatory Support and Safety Monitoring (AETAP-RSSM). The AETAP-RSSM development goal is '*to support Pacific and Southeast Asian countries' efforts to deliver safe, effective and equitable COVID-19 immunisation programs, based on a health and regulatory systems strengthening approach in line with best practices*'.

Under the AETAP-RSSM in 2022-23, the TGA facilitated expedited COVID-19 therapy registrations through developing and sharing factsheets on the TGA-approved therapies Actemra, Paxlovid and Lagevrio with all AETAP-RSSM countries. This work culminated in assisting the Tuvalu Ministry of Health to make an urgent sovereign decision to authorise these therapies for use in managing a COVID-19 outbreak. The TGA also responded to a request from the Thai Food and Drug Administration to provide expert assistance in evaluating the safety of Paxlovid in paediatric populations.

During the 2022-23 period we also delivered work under the DFAT-funded Indo-Pacific Regulatory Strengthening Program (RSP). This program aimed to strengthen the capability of Indo-Pacific National Regulatory Authorities (NRAs) and increase the availability of safe and effective medicines and medical devices through improved regulatory practice and regional collaboration.

Engagement with the National Pharmaceutical Regulatory Authority (NPRA) of Malaysia was an example of a successful partnership, resulting in many virtual interactions and discussions, as well as an NPRA visit to the TGA from 5 to 9 September 2022. These interactions, including experiential exchanges, regulatory insights on many valuable topics, and a deeper understanding of the regulatory framework in each country, are foundational steps that foster long-term collaboration.

A key achievement of the RSP during this period was collaborating with the Thai Food and Drug Administration to facilitate the successful registration of Zolgensma via reliance on our evaluation reports and expert advice. This achievement represents the first advanced therapeutic medical product evaluated by a partner NRA. It demonstrates development and

application of the skills required to evaluate products at the cutting edge of pharmaceutical science.

Another significant RSP achievement across 2022-23 was participation in the ASEAN Joint Assessment (ASEAN JA) of the HIV prophylactic product Apretude by the Philippines, Myanmar, Vietnam, and Malaysia. The TGA's role as the Stringent Regulatory Authority in the ASEAN JA led to a request to also participate in the WHO Collaborative Registration Procedure for the same product, demonstrating the TGA's reputation as a trusted reference agency for supporting collaborative registration pathways.

Further information about the AETAP-RSSM and RSP and other achievements for these programs across 2022-23 is described in greater detail in the Indo-Pacific Regulatory Strengthening Program section below.

World Health Organization (WHO)

At the World Health Organization Global Model Regulatory Framework consultative meetings, we contributed to a range of international standard setting processes to improve how standards can support patient safety and promote consistent adoption in regulatory requirements, such as medical device identification and breast implants and respiratory devices.

We also participated in a working group to provide expertise in developing WHO recommendations on good practices for implementing international guidelines.

As an Essential Regulatory Laboratory for influenza, we participated in workshops and meetings to support the WHO Pandemic Influenza Vaccine Response Operational Plan, which aims to address technical regulatory considerations and support global responsiveness in the event of an influenza pandemic.

Our laboratories now form part of an international collaborative network to support WHO programs, having been re-designated as WHO Collaborating Centres for Medicines Quality Assurance and Quality Assurance of Vaccines and Other Biologicals.

In October 2012, the World Health Assembly established the WHO's Member State Mechanism on Substandard and Falsified Medical Products (the Mechanism), which is a global forum bringing together 194 WHO member states to develop strategies to mitigate the public health risk and harm caused by substandard or falsified medical products.

Australia is an elected representative of the Western Pacific Region and Chair of the Steering Committee of the Mechanism for the 2022/23 biennium. During this period of leadership, we have driven continual improvement in the mechanism's operations, including through:

- implementing longer-term strategic planning
- introducing metrics and indicators to enhance the output of working groups
- revising the scope of existing working groups and the establishment of new working groups, allowing the Mechanism to be more flexible and responsive to emerging substandard and Falsified Medical Product issues of concern
- building support for and stewarding a proposal for an independent review of the Mechanism through the plenary meeting in 2022, the WHO Executive Board and the World Health Assembly in 2023.

In addition to our leadership role, we represented the TGA on the Mechanism's working group on 'Impact and Awareness'.

International initiatives and forums

We have contributed to the development of international harmonised guidance on bioequivalence requirements through our involvement in the Expert Working Group of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

Active membership of the International Pharmaceutical Regulators Programme Quality and Bioequivalence Working Groups has allowed us to survey different approaches to regulation, and to propose and develop topics for convergence to enable regulatory cooperation.

We actively contribute to monthly international medical device safety meetings (IMDS) in collaboration with 11 international medical device regulators, to:

- exchange information on emerging health and safety risks
- communicate findings from investigations and recalls
- discuss harmonisation of approaches and actions
- play a leading role in provision of administrative support to maintain a platform for information sharing
- manage a high volume of enquiries from international regulators.

The meetings could lead to short-term working groups to exchange information and approaches on a critical safety issue to improve patient and user outcomes. With emerging and increasing global supply chain disruptions, the IMDS meetings enable timely exchange of intelligence and impacts on pending medical device or raw material shortages, including identifying clinical alternatives and availability. They also allow closer engagement with suppliers to secure local supply, seek import alternatives where available, and ensure timely information to users on possible shortages.

World Trade Organization Technical Barriers to Trade

We continue to advocate on medical device-specific matters through the exchange of statements on specific trade concerns. We have highlighted issues around working towards harmonisation of components that support compatible systems, such as data linkages and nomenclature.

International Medical Device Regulators Forum

As 2022 Chair of the International Medical Device Regulators Forum (IMDRF), we assisted in the acceleration of international medical device regulatory harmonisation and convergence, to promote an efficient and effective medical devices sector. The TGA led work to redevelop and modernise the forum's website, procedures, memberships and strategic plan. We successfully hosted the forum in Sydney, the first face-to-face/hybrid meeting of the IMDRF since the COVID-19 pandemic. It involved 21 regulators and included joint workshops and open forums on the topic of medical device software and artificial intelligence, with more than 600 global and domestic industry stakeholders.

We actively participated in the IMDRF Management Committee and various working groups to develop and publish 6 global guidance documents to harmonise medical devices regulation internationally, addressing:

- Adverse Event Terminology
- Good Regulatory Review Practices
- Medical Device Cybersecurity Guide
- Regulated Product Submission
- Artificial Intelligence Medical Devices
- Personalised Medical Devices

We also fully or partially implemented a number of IMDRF guidance documents during the year. The TGA will continue its work collaborating with IMDRF members to reduce regulatory burden.

Pacific and Southeast Asia Programs

We worked with National Regulatory Authorities within the Pacific and Southeast Asia to strengthen regulatory systems, resulting in faster access to products for communicable diseases and minimising supply of products that are of poor quality or present health risks.

Pacific Medicines Testing Program

We continued Phase Two of the DFAT-funded Pacific Medicines Testing Program (PMTP), which assists the 12 participating Pacific Island Countries and Timor-Leste by providing advice and access to Australian laboratory testing for therapeutic goods quality assurance.

The 2022-23 PMTP testing campaign:

- received 116 samples from 13 participating countries
- focussed on ethylene glycol/diethylene glycol (EG/DEG) contamination of 25 samples syrup samples
- detected high levels of EG/DEG in one sample, which resulted in the release of a Global WHO Medical Product Alert.

The PMTP has been expanded into instances of medical device technical advice and procurement guidance. Through the PMTP, participating countries have access to the TGA laboratories for quality assurance testing, including problem and complaint investigations.

The Indo-Pacific Regulatory Strengthening Program

The Indo-Pacific Regulatory Strengthening Program (RSP) was launched in October 2018, with the goal of increasing the availability of safe and effective medical products through improved regulatory practice and regional collaboration. The program included 7 countries:

- Thailand
- Vietnam
- Laos
- Cambodia
- Papua New Guinea
- Myanmar
- Indonesia

Following delivery of the first phase on 30 June 2023, RSP was able to expand its programs until 30 June 2027, with all countries in Southeast Asia and the Pacific now eligible for technical assistance with regulatory system strengthening or regulator support. This is supported by funding by DFAT under the Partnerships for a Healthy Region program.

The RSP is a regulatory system strengthening program aimed at helping to build the regulatory capacities and capabilities of partner National Regulatory Authorities (NRAs). Additional key activities delivered during 2022-2023 included:

- the delivery of RSP regulatory practice workshops, including on reliance and different areas of technical or product expertise
- partnering with the Cambodian Department of Drugs and Food (DDF) to help to improve its ability to regulate irrational Fixed-Dose Combination products, a class of substandard medicine. We did this by developing several reliance activities, such as creating a risk management strategy and supporting business process changes that would allow the DDF to determine the suitability of a product to their country context
- assisting the Laos Food and Drug Department with capability building for GMP inspections and issuing appropriate regulatory decisions. In-country visits in June and December 2022, as well as the TGA/WHO Joint Workshop in February-March 2023, provided peer-to-peer quality and GMP technical assistance. These sessions were entirely in Thai, a language similar to Lao which Lao speakers can generally understand. This helped to overcome the Lao-English language barrier that had previously made collaboration difficult
- taking active steps to improve coordination and communication with partner organisations. Collaboration has occurred over a wider set of fora in 2022-23 than was possible during the COVID-19 pandemic. A key collaboration event was the in-person 2023 Indo-Pacific Regulatory Practice Workshop, where participating partners included United State Pharmacopeia, Duke-NUS Centre of Regulatory Excellence, WHO and the National Centre for Immunisation Research and Surveillance, who were able to engage with the program and NRAs.

Case Study – Indo-Pacific Regulatory Practice Workshop

Between 20 to 23 February 2023, a 4-day face-to-face workshop was held at the TGA offices in Canberra. The workshop aimed to strengthen regulatory knowledge, technical skills and information sharing between partner NRAs.

The workshop was collaborative and interactive, with participants sharing discussions and participating in technical workshops. The primary aim was to reiterate the importance of the regulator's role in ensuring access to quality, safe and effective medicines. It also highlighted different techniques that can be used in relation to reliance and information sharing through hands-on, interactive problem-centric learning. These techniques complemented ongoing virtual activities and in-country engagements.

Participants included regulatory staff from participating country NRAs, as well as presenters from key program partners such as the United States Pharmacopeia, the Centre for Regulatory Excellence, National Centre for Immunisation Research and Surveillance, and DFAT.

The workshop covered the following themes:

- risk-based approaches to pre-market quality evaluation, bioequivalence studies, GMP and laboratory testing
- safety monitoring and the Quality Use of Medicines
- opportunities for regulatory collaboration and reliance.

Participants had opportunities to access a broad range of technical experts from the TGA for hands-on, interactive problem-centric learning. They also toured our new TGA laboratory facilities and heard from other NRAs about their experiences across a range of regulatory subjects.

The workshop was fortunate to hear Dr. Penny Lukito, Chairperson of the Indonesian FDA, share her agency's experience in dealing with ethylene glycol and diethylene glycol contaminants in paediatric oral liquid medicine. This session was very well received, as the incident is current and directly relevant to the work of many of the participants. It generated further conversations and information sharing about this critical issue throughout the workshop.

The workshop received positive feedback from participating NRAs and program partners. Participants found the experience valuable, with many indicating that they felt their skills and knowledge had been strengthened. They also expressed continued interest in working with the TGA on topics such as regulatory cooperation, risk management and risk assessment, GMP inspection, post-marketing surveillance, critical quality attributes, and reliance.

The Australian Expert Technical Assistance Program for Regional COVID-19 Vaccine Access – Regulatory Support and Safety Monitoring (AETAP-RSSM)

The AETAP-RSSM was launched in April 2021 to support access to high quality, safe and effective COVID-19 vaccines. It aims to provide coordinated and holistic Australian policy and regulatory expertise to national COVID-19 immunisation programs in Southeast Asia and the Pacific. The program was delivered on 30 June 2023, and has incorporated the following 18 countries:

- Cambodia
- Fiji
- Indonesia
- Kiribati
- Laos
- Thailand
- Malaysia
- Myanmar
- Nauru
- Papua New Guinea
- Philippines
- Samoa
- Solomon Islands
- Timor-Leste
- Tonga
- Tuvalu
- Vanuatu
- Vietnam

We facilitated the expedited registration of COVID-19 therapies in the Indo-Pacific region by sharing technical information on their use in vulnerable groups, particularly in cases of severe COVID-19. This included sharing assessment reports for TGA-approved COVID-19

therapies with counterpart regulatory agencies in the region. As noted above, in response to requests from partners, we also developed and shared clinical factsheets for Lagevrio, Actemra, and Paxlovid, highlighting recommendations on their use in vulnerable populations such as pregnant women, women of reproductive age, and paediatric age groups.

In addition, through a series of virtual training workshops, we strengthened safety monitoring systems and post-market monitoring capabilities in Lao PDR, Malaysia, Thailand, and the Philippines. We also collaborated with WHO and NCIRS to provide joint workshops on signal detection and adverse event following immunisation identification in the Pacific Islands to strengthen post-market safety frameworks for COVID-19 vaccines. Additionally, considerable focus has been given to Fiji's pharmacovigilance capability building through mentorship of its first pharmacovigilance officer (funded by the WHO) and development of guidelines and policies.

Action Plan for Medical Devices

We are continuing to implement the Action Plan for Medical Devices, to improve how devices get on the market, strengthen monitoring and follow-up of devices already in use, and provide more information to patients about the devices they use.

As part of implementing the Action Plan for Medical Devices, numerous activities have been undertaken to improve the application and evaluation processes for market approval of devices. These include:

- holding webinars and stakeholder workshops about managing the transitioning and assessment of medical devices approved under the European (EU) Medical Devices Directive to the new EU Medical Device Regulations
- extending transition timelines for introduction of companion diagnostics regulations to 26 May 2026, to align with EU In Vitro Diagnostic Regulation (IVDR) timelines
- amending the Therapeutic Goods (Excluded Purposes) Specification 2020 to allow for legal supply of COVID-19 self-tests to meet the public health need during COVID-19 pandemic management
- reclassification of certain medical devices:
    - active medical devices for therapy with diagnostic function
    - spinal implantable medical devices (motion preserving)
    - devices used in direct contact with the heart, central circulatory system, or central nervous system
    - medical devices that administer medicines or biologicals by inhalation
    - active implantable medical devices
    - medical devices that are substances introduced into the body via body orifice or applied to the skin
- review of fees and charges to align cost-recovery activities with reform measures.

We have published guidance for industry relating to regulatory amendments for first aid kits and system or procedure packs, and updated guidance relating to personalised medical devices. Guidance materials were also published on performance requirements and risk mitigation strategies for COVID-19 tests including combination test kits, on requirements for Patient Information Leaflets and Patient Information Cards, and on regulations relating to software and applications which meet the legislative definition of a medical device in Australia. Sponsor notification forms for reclassified medical devices were developed and, to

assist with the European IVDR transition, guidance was published on transition of manufacturer evidence for IVD medical devices.

Five working groups with consumer representation have been established and have been meeting regularly during the reporting period, including the:

- Breast Implant Expert Working Group
- Medical Device Consumer Working Group
- Women's Health Products Working Group
- Ventilator Expert Working Group
- Surgical Mesh Expert Working Group.

Each of the device-specific expert working groups – Surgical Mesh, Breast Implant and Ventilator working groups – comprises experts in the field and a consumer representative. The Medical Devices Consumer Working Group met four times during the year, and gives consumer insights into medical devices reforms projects. This working group was integral in ensuring consumers' needs were considered as part of the TGA's social media campaigns on 'Travelling with medicines and medical devices' and 'Five questions to ask your health professional before you get a medical implant', as well as in the creation of factsheets for health care professionals and consumers on the patient implant card and patient information leaflet.

On 21 March 2023, legislation was passed making it mandatory for Australian public hospitals, private hospitals, and any other health care facility (as prescribed by regulations) to report serious medical device-related adverse events to the TGA. Regulation to support the implementation of this new legislative requirement is due by 22 March 2025. We are working with the Australian Commission on Safety and Quality in Health Care (ACSQHC) and state and territory jurisdictions on implementing the mandatory reporting of adverse events by health care facilities.

To assist consumers and health care professionals, we have published factsheets on medical implants for consumers and health professionals. We also undertook a public consultation on proposed regulatory changes strengthening safety oversight of clinical trials for medical devices.

We regularly met with state and territory health departments to discuss matters including COVID-19 RATs, personal protective equipment, and other regulatory actions relating to medical devices. A suite of measures has commenced to enhance the post-market adverse event reporting and surveillance of medical devices, including establishing a national supply disruption monitoring role.

Reforms to regulate new technologies

We are implementing reforms to better accommodate new technologies such as medical device software, medical apps and personalised medical devices.

Australia's healthcare system is seeing an increasing role and demand for sophisticated, innovative, and easily accessible software solutions that are regulated as medical devices.

We have developed a close partnership with digital health commercialisation organisation ANDHealth, which provides training, support and assistance to industry in understanding how medical device regulation applies to software-based medical devices. We have also

published guidance to support manufacturers and software developers, many of whom are new to medical device regulation. Some topics include:

- digital mental health
- baby movement apps
- generative artificial intelligence (AI
- clinical decision support system software
- advertising factsheets specific to the software sector.

We have responded to feedback from stakeholders impacted by the introduction of the personalised medical devices framework, conducting 4 point-of-care manufacturing surveys across the allied health, dental and complex manufacturing sectors. These surveys sought to obtain more information about medical device manufacturing activities undertaken at the point-of-care by, or on behalf of, health practitioners and professionals.

In June 2023, we convened a National Symposium with representatives from other regulators and state and territory governments to discuss issues and risks with medical devices manufactured at the point-of-care, and the need for a streamlined approach to regulating these activities. Participants agreed to form an overarching steering committee, informed by sector-specific working groups, to:

- identify circumstances where medical devices are manufactured at the point-of-care either by, or on behalf of, health practitioners and professionals
- identify the risks associated with these devices and document the measures already in place to mitigate them
- map existing regulatory frameworks to identify gaps and potential refinements that will reduce burdens without introducing additional risks
- make refinements where appropriate to ensure regulation of point-of-care manufacturing activities is seamless and appropriately addresses risks associated with these devices
- communicate and educate stakeholders about their regulatory obligations by providing information through the most appropriate channels available.

Unique Device Identification improvements to product safety and surveillance of products

We are progressing the development and international alignment of the Unique Device Identification (UDI) system, to improve product safety and surveillance of products in the Australian supply chain.

When implemented across supply chains and the healthcare system, the UDI system will enable improved identification and traceability of medical devices. It will help to improve the effectiveness of pre-market assessments of medical devices, enable improved information on the application of devices, and help the management of post-market safety-related activities, including faster identification and recall of problem devices and management of adverse events.

The UDI can assist by providing:

- easier and faster identification of patients who have been implanted with a device of concern, such as a device with a safety incident or recall related to that device
- easier identification and removal of those devices from stocks, storage, and distribution, helping to prevent any further devices of that model being implanted or used.

Throughout this year we have engaged with public and private hospitals and healthcare organisations, peak bodies and other experts, including Queensland Health, Western Health in Victoria, and the ACSQHC. This engagement is aimed at improving our knowledge and understanding to develop guidance documents specifically for healthcare organisations to adopt the UDI.

We have been working closely with international regulators and the International Medical Device Regulators Forum to maximise alignment of Australian UDI regulations with the UDI implementations of other international regulators. This alignment will help to minimise the regulatory burden on industry and enhance post-market surveillance activities and our ability to respond to international signals regarding device performance.

A focus this year has been consulting closely with sponsors and manufacturers to help us to understand the EU's UDI timetable, areas of difference and any potential consequences arising from Australia's implementation. Two face-to-face national workshops were held to discuss the challenges identified by stakeholders, and a number of webinars were held with participation from global attendees.

Additionally, a test version of the Australian UDI database (AusUDID) has been used by sponsors and manufacturers to help identify and align our UDI data elements, data validation rules, machine-to-machine data transfers and system implementation. Sponsors have provided detailed feedback, enabling refinements of the AusUDID.

We are actively working to ensure understanding and adoption of the UDI across the healthcare system and continue to actively engage with many stakeholders, seeking feedback through consultation papers, working groups, fora, and webinars. Extensive feedback has informed considerations for the Australian UDI system, including:

- global alignment
- Global Medical Device Nomenclature and other data integrity considerations
- Data elements and implementation impacts
- communicating the benefits of UDI and any implementation considerations for hospitals and other health care facilities, and health care practitioners and professionals.

Following ministerial approval of the key UDI policy elements in April 2023, we have engaged with industry to finalise the proposed implementation timetable, understand any transition considerations and finalise the design and implementation of the AusUDID. Finalisation of the UDI regulations and transition arrangements are anticipated during 2024.

Repurposing of medicines

We have progressed process and policy reforms to facilitate repurposing of existing medicines to address unmet medical needs.

Following extensive public and targeted consultation in 2021-22 on a Medicines Repurposing Program, we established the program's design.

- The program aims to improve patient outcomes by sourcing knowledge about safe and efficacious new uses for old medicines from the Australian community.
- It will target medicines for which a significant public health benefit has been identified but there is little or no commercial incentive for a sponsor to pursue regulatory approval and Pharmaceutical Benefits Scheme (PBS) listing to make this use more accessible.
- The program will strengthen the voice of clinician, academic and patient groups by encouraging their active participation in identifying new uses of medicines.
- The program will provide incentives for sponsors to seek extensions of indication(s) for their medicines and PBS subsidy. Such repurposed medicines will allow cheaper alternatives to be available for health professionals to prescribe for patients.

This program is funded as part of a broader PBS reforms package in the 2023-24 Federal Budget, and further consultation is underway with program launch expected in early 2024.

Clinical trials regulation

We are reforming clinical trials regulation, particularly of medical devices and cell and tissue products, to address safety concerns.

In late 2022 we undertook a public consultation on proposed regulatory changes that would involve the TGA strengthening its safety oversight of clinical trials for medical devices. Follow-up targeted consultation was undertaken in early 2023 to refine proposals that were less burdensome and built on and strengthened existing mechanisms, including requiring mandatory information about very high risk, first-in-human medical devices. In June 2023, the Minister for Health and Aged Care approved the development of changes to the existing notification pathway, and that these clinical trials of medical devices be included in the TGA's Good Clinical Practice Inspection Program. A review of the Clinical Trial Approval pathway has commenced, with consultation expected in 2024.

Medical device adverse event reporting

We are implementing enhancements to medical device adverse event reporting, including development of processes for mandatory reporting of serious adverse events by healthcare facilities.

On 21 March 2023, the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023* received Royal Assent. This amended the *Therapeutic Goods Act 1989* to establish a framework for the mandatory reporting of certain medical device adverse events, principally by public and private hospitals, to the TGA. Regulations to implement the mandatory reporting scheme are scheduled to be in place by 22 March 2025. Mandatory reporting of adverse events currently only applies to sponsors and manufacturers, and expanding this to cover hospitals is designed to ensure the earlier identification of, and quicker public health responses to, safety issues involving the use of medical devices.

We are collaborating with the ACSQHC to incorporate mandatory reporting within the existing hospital quality assurance and accreditation frameworks.

Between May and September 2023, we conducted a series of roundtable consultations with the ACSQHC and representatives from state and territory health departments and private and day hospital providers to identify the key data to be reported, methods of transmitting data, and analysis and feedback processes. The roundtables provided valuable insights into the existing incident reporting mechanisms, areas of jurisdictional duplication, and

inconsistencies. There was a shared consensus to collaboratively identify and implement effective measures to streamline processes. Our ongoing engagement with stakeholders will shape the regulatory amendments, policies and processes to support mandatory reporting.

Real World Evidence and Patient Reporting Outcomes

We have communicated how TGA implements Real World Evidence (RWE) and Patient Reported Outcomes (PROs) in its evaluation of medicines and medical devices, and refined regulatory guidance for industry on how to use RWE and PROs in regulatory submissions.

Following the 2021 review into the usage of real-world evidence[4], we adopted changes to clarify the use of RWE in submissions. These changes included:

- adoption of a definition of RWE
- revisions to the Pre-submission Planning Form for prescription medicines applications
- updated the clinical evidence guidelines for medical devices
- adoption of international scientific guidelines on this topic.

We established a central point for information about RWE and PROs on the TGA website, which is being updated to provide more robust guidance to industry on RWE. Guidance on RWE in software applications has also been published on our website. Further, clinical evidence guidelines have been drafted to provide more detail and clarity on the types and use of RWE, better reflecting the TGA's assessment of RWE in medical device applications.

[4] Real world evidence and patient reported outcomes in the regulatory context

Vapes

We continue education and enforcement of prescription-only access to nicotine vapes, as well as progressing the development and implementation of significant reforms to the regulation of all vapes.

Regulation of vapes, particularly those containing nicotine, is a concern for the Australian Government and many Australians. Current Commonwealth laws aim to prevent children and young people taking up nicotine vapes, whilst preserving access to nicotine vapes under medical supervision, for smoking cessation and the treatment of nicotine dependence.

During 2022-23, we sought to disrupt and address the unlawful importation, advertising, and supply of nicotine vapes by:

- gathering and using intelligence to identify non-compliance
- collaborating with other health and law enforcement agencies to increasingly target and address unlawful importation and supply
- taking enforcement action in relation to unlawful advertising of nicotine vaping products to Australians.

We conducted over 1,500 investigations of non-compliance, with a variety of enforcement actions taken. Over 1 million products were seized or surrendered to authorities and over 100 infringement notices were issued. We also commenced two civil penalty proceedings in relation to unlawful advertising.

However, vape use is increasing in the community, especially among young people. We undertook a significant consultation on potential regulatory reforms to address this issue between 30 November 2022 and 16 January 2023, receiving almost 4,000 submissions. We received strong support for strengthening regulatory controls on all vapes. On 2 May 2023, following consideration of the consultation feedback, the Minister for Health and Aged Care announced an intention to strengthen the regulatory requirements for all vapes. We progressed consideration of the reforms over the remainder of 2022-23 and this work will continue in 2023-24.

Paracetamol access

We will introduce revised access controls on paracetamol, in light of several recent overdose deaths.

Following concerns relating to the number of poisoning and deliberate overdoses of paracetamol obtained from general retail outlets, we commissioned an independent expert report to investigate whether access restrictions were appropriate. The report, published on 14 September 2022, investigated the risks of intentional self-poisoning and found an increasing incidence, particularly among adolescent females, with approximately 50 deaths per year.

On 3 May 2023, following 2 public consultation rounds, a final scheduling decision was published on the TGA website to reduce the maximum size of packs available for general sale (for example, in supermarkets and convenience stores) and in pharmacies without the supervision of a pharmacist (Schedule 2 ‘Pharmacy medicine’), with additional requirements for blister packaging. Larger pack sizes will now only be available under the supervision of a pharmacist, as a Schedule 3 ‘Pharmacy Only’ medicine.

The decision strikes a balance between minimising the incidence of harm from intentional paracetamol self-poisoning, and maintaining appropriate access to paracetamol for symptom relief. The changes will come into effect on 1 February 2025, allowing sufficient time for the industry to make the required changes to the labelling and packaging of paracetamol products.

Recall reforms

We continue the design and implementation of reforms to improve recall actions for all therapeutic goods.

During 2022-23, we continued to build on previous discovery activities by undertaking extensive consultation with state and territory governments, peak industry associations, individual sponsors, consumer groups and health care professionals, to develop purposeful recall reforms. The feedback received on our current processes informed a discussion paper and identified a number of reforms to pursue.

The *Therapeutic Goods Recall Processes – Discussion Paper*, published in February 2023, sets out potential changes to how product recalls are managed in Australia. The process improvements aim to increase awareness and understanding of recall information and adopt clearer recall terminology. Additionally, more efficient sponsor reporting timelines will be developed alongside processes aimed at reducing regulatory burden.

The discussion paper also canvassed the review of the TGA's existing legislative powers relevant to recalls and how greater transparency can be created throughout the supply chain. Approximately 70 submissions were received in response to the 6-week public consultation. These responses will inform the development of the policy approach and legislative changes required to continue the reforms in 2023-24.

Scheduling of cosmetics and fragrances

We implemented improvements associated with the scheduling of cosmetics and fragrances in the Poisons Standard.

We have undertaken a number of actions to improve the scheduling of cosmetic and fragrances in the Poisons Standard:

- introduction of a new online application form in January 2023, following input from stakeholders
- consultation with targeted stakeholders regarding:
  - guidance on derivatives of substances in the Poisons Standard
  - inclusion of Chemical Abstract Service (CAS) numbers for substances in Schedules 9 and 10 in the index of the Poisons Standard to improve searchability.

We will include CAS numbers towards the end of 2023, followed by additional consultation on substances in Schedules 5,6, and 7.

Strategic objective 2 – Actively engage with our stakeholders

We actively engage with our stakeholders, and strive to continuously improve our communication and respond to enquiries as quickly and effectively as possible. We proactively notify and educate sponsors, health practitioners and consumers on regulatory decisions, and work with them when we implement new regulatory requirements and address key issues. It is important to us that our stakeholders understand our policies, practices, and services.

The TGA contributes actively to domestic and international health systems, and we work closely with Australian regulatory bodies and state and territory governments. We also work with regulators and research institutions globally to ensure we have access to the latest science and research. Our active engagement with stakeholders helps to ensure Australians have access to safe and efficacious medicines, medical devices, and biological products.

Performance Indicators

2.1 Respond in a timely manner and effectively to enquiries and be clear about our regulatory decisions.

2.2 Actively communicate and educate stakeholders.

2.3 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 medical products industry representatives, 88% indicated they had contacted or interacted with the TGA. Overall, most were satisfied with their experience communicating with the TGA (67%), while 16% were dissatisfied and 17% were neither satisfied nor dissatisfied.

Smaller numbers of health professionals and consumers indicated they had contacted or interacted with the TGA. Overall, most consumers were satisfied with their experience communicating with the TGA (71%), while 13% were dissatisfied and 16% were neither satisfied nor dissatisfied. Among health professionals, 68% of those who had contacted or interacted with the TGA were satisfied, while 8% were dissatisfied and 24% were neither satisfied nor dissatisfied.

In performance indicator 2.1, we also look to assess our success at being clear about our regulatory decisions. 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 medical product industry stakeholders, 56% agreed that the TGA had clearly explained the outcome, while 18% disagreed.

In performance indicator 2.2, we look to assess our success at actively communicating with and educating stakeholders. In the Stakeholder Survey, a quarter of consumers (25%) 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, with a smaller number having received a

TGA email newsletter. Overall, 91% had found the education activity had been ‘slightly useful’, ‘moderately useful’, ‘very useful’ or ‘extremely useful’. Of this, 22% had found the educational activity ‘very useful’ or ‘extremely useful’.

About 2 out of 3 health professionals (67%) indicated they had seen or been involved in a TGA educational activity. Of this number, most had seen a social media campaign or post, with a smaller number having received a TGA email newsletter. Overall, 97% of consumers had found the education activity ‘slightly useful’, ‘moderately useful’, ‘very useful’ or ‘extremely useful’. Almost half (45%) had found the educational activity ‘very useful’ or ‘extremely useful’.

Well over half (57%) of medical product industry representatives had seen or been involved in a TGA educational activity in the past 12 months. Many of these respondents had seen a TGA email newsletter, attended a webinar, attended a TGA event such as the GMP Forum or seen a social media campaign or post. Overall, 97% had found the education activity had been ‘slightly useful’, ‘moderately useful’, ‘very useful’ or ‘extremely useful’. Of this, 52% had found the educational activity ‘very useful’ or ‘extremely useful’.

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 71 state and territory agencies, the majority from health departments, were asked whether they believed the TGA consults with state and territory governments on regulatory changes. 60% of respondents agreed while 21.7% disagreed. 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 44% agreeing that it does and 36% disagreeing.

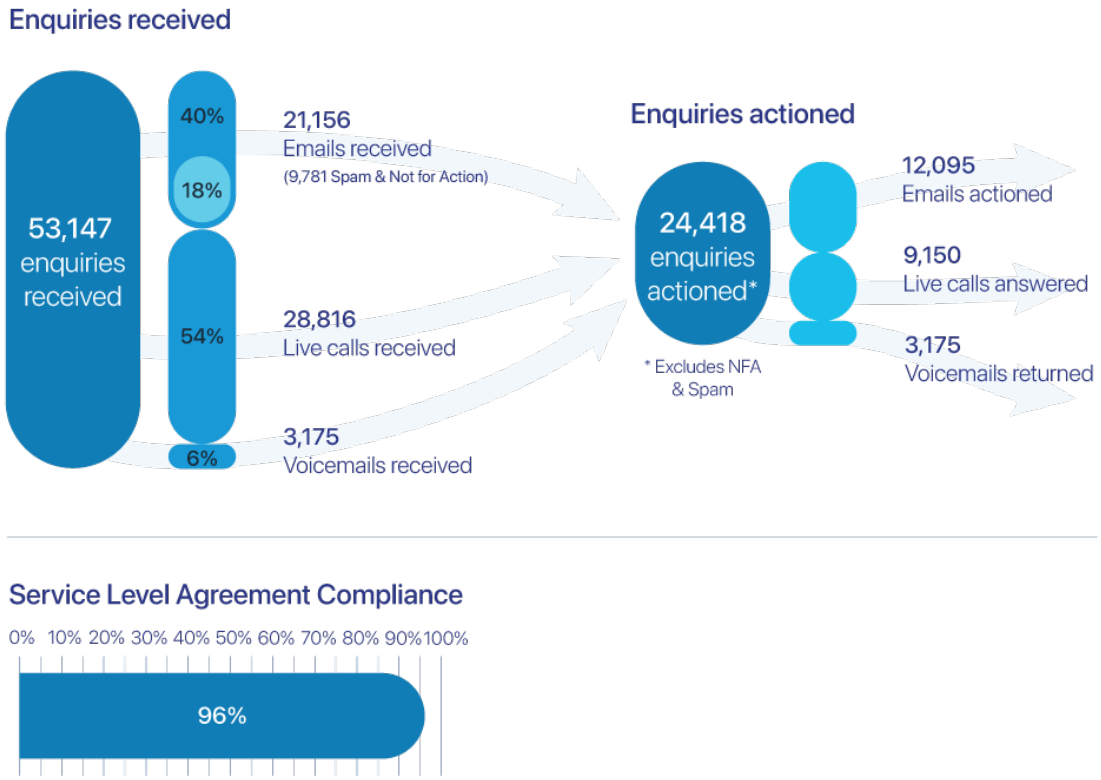
Enquiry management

We continue to implement a new enquiry management model that will improve the timeliness, efficiency and documentation on how the TGA responds to enquiries from sponsors, health professionals and the public.

Implementation of the TGA’s new enquiry management model is underway, and will continue into 2024. The objectives include delivering improved customer experience and a consolidation of enquiry channels for our external stakeholders. Improved data management will also be an important feature of the model, along with an uplift in staff training and TGA-wide knowledge sharing in best practice enquiry management.

In March 2023 we launched a new online enquiry form to enable external stakeholders to direct their enquiries through specific channels. This improvement enables more efficient direction to the Medical Devices, Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme teams for enquiries about prescribing of unapproved therapeutic goods and medical devices available in the Australian market.

Figure 2.1 TGA Contact Centre (TCC) Enquiry Overview in 2022-23



The TGA Contact Centre (TCC) received over 53,000 enquiries in 2022-23, actioning 87% of enquiries available to action while maintaining a compliance rate of 96% with our service level agreements for enquiry response times. These metrics represent a marked increase from the previous financial year, with an additional 31% of available enquiries actioned and an increase of 10% compliance with our service level agreements.

Engagement with industry and consumer groups

We are continuing our engagement with industry and increasing engagement with consumer groups to improve regulatory practices and transparency of our regulatory decisions.

The TGA continues to strengthen our engagement with industry and consumer groups through their involvement on, and with, multiple committees and working groups across the various therapeutic goods sectors. These fora, augmented by independent expert advice from statutory advisory committees, ensure decisions on scientific and technical matters, policy, and other issues are well informed. The advice provided by these committees is an important element in improving our regulatory functions and we continue to publish outcomes to ensure transparency with respect to our regulatory decision-making.

Medicines

In 2022-23, we have continued to engage with industry and consumer groups.

In relation to non-prescription medicines we:

- answered over 3,085 emails and 4,296 phone calls from stakeholders
- published the results of 203 listed medicine compliance reviews and published compliance information for consumers

- met with peak industry groups in 2 consultative forum meetings (Comtech), 5 bilateral meetings and 6 individual meetings
- published two public consultations on clarification and updates to the regulation of sunscreens and proposed changes to the Permissible Ingredients Determination
- published mandatory requirements and guidance for applications for new ingredients in listed medicines
- presented at a range of speaking events, such as ARCS (Association of Regulatory and Clinical Scientists) and industry organised webinars.

The Special Access Section within the International Regulatory Branch has responded to over 15,000 emails and 2,700 phone calls from stakeholders. The most frequent topics have been:

- accessing unapproved therapeutic goods
- the Special Access Scheme (SAS) and Authorised Prescriber (AP) pathway
- SAS/AP Online system
- personal importation and the traveller's exemption
- MDMA, Psilocybin, medicinal cannabis and vaping products
- sponsor requirements in relation to unapproved therapeutic goods.

Medical Devices

The TGA engages with the peak medical device stakeholders through regular meetings with the RegTech consultative committee to:

- prioritise and discuss regulatory and technical issues arising from current regulation, and propose solutions
- provide a forum for members to raise regulatory or technical concerns, both current and emerging, faced by the TGA, the representative associations or members of the medical device sector generally
- identify opportunities to improve current regulatory practices and compliance.

These meetings ensure that the TGA is transparent in the decision-making process and stakeholders provide valuable information on challenges and opportunities as the TGA continues to develop and implement its medical device reform agenda.

We also facilitate five working groups, which met regularly during the reporting period:

- Breast Implant Expert Working Group
- Medical Device Consumer Working Group
- Women's Health Products Working Group
- Ventilator Expert Working Group
- Surgical Mesh Expert Working Group

Manufacturing

We maintain regular engagement with peak bodies representing sponsors and manufacturers in our TGA-Industry Working Group on GMP (TIWGG). The TIWGG meet quarterly to discuss issues relating to the application of GMP to the supply of therapeutic goods in Australia.

TIWGG members provide valuable feedback on the proposed adoption of revised GMP codes and assist in identifying the need for specific updated guidance and educational materials.

Laboratories

Early in the COVID-19 pandemic, the Laboratories Branch initiated engagement with international manufacturers and standards setting bodies regarding the quality requirements for face masks and respirators. This work has continued, with TGA representatives contributing to the development and improvement of testing standards, particularly those of the American Society for Testing and Materials (ASTM).

We have continued to hold regular meetings with representatives from the disinfectant industry to discuss the existing guidance, and collaborate on improving the information available to industry stakeholders.

Laboratories staff participated in an industry roundtable discussion on mRNA Platform Regulation. Representatives of clinical development, research, state and Commonwealth government, and pharmaceutical manufacturers participated in open discussions on approaches to the regulation of mRNA medicines. An outcome of the discussion was for the development of an industry position paper on RNA platforms.

Advertising compliance

The TGA has continued to build positive relationships with a range of industry bodies and associations to educate their members on ways to comply with their legislative obligations for advertising therapeutic goods.

The TGA also maintains regular engagement with a range of industries through the Therapeutic Goods Advertising Consultative Committee (TGACC). The TGACC holds regular virtual and in-person meetings with representatives to discuss issues relating to the advertising of therapeutic goods.

In consultation with the TGACC, state and territory regulators and other stakeholders, the TGA developed appropriate compliance priorities to ensure the advertising compliance efforts are focused where they are most needed.

Further, the TGA holds regular meetings with digital platforms to encourage awareness of the TGA's compliance priorities and address non-compliance on these platforms more rapidly and effectively.

Partnerships with international regulators

We are continuing our partnerships with international regulators, including through alliances such as Project Orbis, the Pharmaceutical Inspection Cooperation Scheme, the International Coalition of Medicines Regulatory Authorities, the International Medical Devices Regulators Forum and the Access Consortium, to strengthen working arrangements, align regulatory practices and collaborate on regulatory policies.

Our partnerships with international regulators continue to strengthen working arrangements, align regulatory practices, and facilitate collaboration on regulatory policies. There were several important alliances and initiatives in 2022-23.

International Coalition of Medicines Regulatory Authorities

The International Coalition of Medicines Regulatory Authorities (ICMRA) was established in 2013 to better safeguard global public health by facilitating greater cooperation. It enables Heads of Medicines Regulatory Authorities to exercise concerted strategic leadership during a global public health crisis and share regulatory issues, challenges and solutions.

In November 2022, we attended and presented at the ICMRA annual summit and plenary meeting hosted by the Irish Health Products Regulatory Authority to discuss the future of medicines regulation. The summit had a strong focus on translating innovation into benefits for patients. Representatives from medicines regulatory authorities from around the world were present, as well as experts from the World Health Organization (WHO). Views were exchanged on a range of other topics, including:

- antimicrobial resistance
- the importance of establishing a pharmaceutical quality knowledge management system
- clinical trials in the context of public health emergencies
- use of real-world data
- consolidation of the pharmacovigilance network for vaccines.

We continue to co-chair the ICMRA COVID-19 Vaccine Pharmacovigilance Network (ICMRA VPN) with the UK's Medicines and Healthcare products Regulatory Agency. ICMRA VPN meets regularly to share knowledge, experience and communications on pharmacovigilance activities and the emerging benefit-risk profile of COVID-19 vaccines.

Throughout 2022-23, the ICMRA VPN shifted its focus slightly to:

- continue the information sharing forum function of the network, particularly on specific emerging safety issues or early warning of possible safety signals with COVID-19 vaccines
- advise the ICMRA Executive on approaches to better "real time" sharing of vaccine safety information and promote confidence in pharmacovigilance of vaccines
- expand the scope of the network's work to include other vaccines of interest where there may be a specific safety issue to discuss and no alternative forum that engages most ICMRA members is available
- discuss regulatory experience with new pharmacovigilance tools (for example, artificial intelligence methods in data collection).

Through TGA's joint leadership, the ICMRA VPN was a highly engaged and active network that assisted regulators globally with pharmacovigilance matters.

The Access Consortium: International work-sharing for prescription medicines and medical devices

The Access Consortium is a medium-sized coalition of comparable regulatory authorities- Australia, Canada, Singapore, Switzerland and the United Kingdom. These regulators work together to promote greater regulatory collaboration and alignment of regulatory

requirements. One significant area of collaboration is work-sharing the evaluation of a wide range of new chemical entities and generic medicines, which streamlines the evaluation process and reduces duplication of evaluation effort. The consortium published a statement in May 2023 offering joint pipeline meetings to pharmaceutical and biotechnology companies.

The heads of the five agencies met twice in this reporting period to review progress of the working groups and approve the work program for the upcoming year.

In 2022-23 the Access Consortium had 10 active working groups in place across a range of regulatory activities, including a newly established clinical trials working group and a dedicated Advanced Therapeutic Medicinal Products working group. The following working groups continued to facilitate work-sharing initiatives during this reporting period:

- New Active Substances (NAS) Working Group, which recently incorporated the COVID-19 Vaccines and Therapeutics Working Group (CVTWG)
- Generic Medicines Working Group
- Biosimilars Working Group.

In 2022-23, we approved 5 submissions through the Access NAS Work-Sharing Initiative, including the first two submissions to be work-shared by all five Access agencies, and 2 submissions through the Access Generic Medicines Work-Sharing Initiative. We also participated in the first formal work-sharing of a priority NAS submission. The Access Generic Medicines Work-sharing Initiative operational procedures have been updated to provide further clarity to sponsors on the expectations and requirements for entry into this evaluation pathway.

In June 2023 the Access Consortium delivered a presentation to industry at the Drug Information Association meeting in Boston, titled '*Access Consortium – what next: How can Access regulators support rapid and safe global access to the next generation of medicinal product through aligned, innovative regulatory processes'.* The presentation:

- highlighted Access's achievements in using work-sharing initiatives to expedite approvals
- showcased progress made against the Strategic Plan
- explored opportunities for industry to bring new, innovative products through Access pathways
- also incorporated a presentation from TGA on 'Lessons Learned during COVID-19'.

Project Orbis

Project Orbis is led by the US Food and Drug Administration (FDA) and provides a framework for concurrent submission and parallel review of oncology products among international partners. We continue to perform joint evaluations to share technical expertise and accelerate access to novel medicines. Currently the Project Orbis partners include:

- Australia (TGA)
- Canada (Health Canada)
- Switzerland (Swissmedic)
- Singapore (HSA)
- United Kingdom (MHRA)

- Brazil (Anvisa)
- Israel (MOH).

During 2022-23, 21 submissions were approved through Project Orbis, including 6 provisional submissions, 4 priority submissions and 3 orphan submissions.

International agreements and arrangements for Good Manufacturing Practice

We have various international agreements and arrangements with other countries and regulatory authorities. Some of these allow mutual reliance on Good Manufacturing Practice (GMP) inspection programs. The scope of these agreements, the regulatory authorities covered and how they can be used in applications for GMP Clearances from the TGA is published on our website under International agreements and arrangements for GMP clearance. In 2022, we worked closely with Access Consortium members on a joint statement on GMP Inspections Reliance and Recognition, which was published in November 2022.

Mutual Recognition Agreements (MRAs) are internationally binding agreements between countries to facilitate trade and market access. They can allow mutual recognition of the outcomes of GMP inspections of medicine manufacturers within the borders of each partner country. We have operationalised additional countries under the EU-Australia Mutual Recognition Agreement for GMP and established recurring forums with MRA partners. These include Europe, the UK, Canada, Singapore and New Zealand. Throughout 2022-23, we engaged with MRA partners on sites of common interest related to GMP inspections for COVID-19 vaccines to avoid duplication of effort.

Pharmaceutical Inspection Cooperation Scheme (PIC/S)

Many regulatory authorities, including the TGA, are members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), which is a non-binding, informal, cooperative arrangement between authorities that regulate GMP for human medicinal products, biologicals and veterinarian products.

We continue to work with our regulatory partners in PIC/S on best practice processes for remote inspection and reliance. We hold the Chair of the PIC/S Sub-committee on Strategic Development, attending twice yearly in-person meetings of the PIC/S Executive Bureau and regular teleconferences with both these groups.

We participated in the revision of and training for updates to the PIC/S guide to GMP for medicinal products (manufacturing standard) for sterile medicines, quality risk management and biological medicines. We chaired and contributed to various working groups within PIC/S aimed at fostering greater Inspection Reliance between members, consistency of data collection, development of training materials and alignment of processes.

Medical Device Standards Work

We are a member of 5 International Organization for Standardisation (ISO) Technical Committees (TC), as well as several ISO sub-committees, relating to medical devices. The ISO TC's include:

- anaesthetic and respiratory equipment
- implants for surgery
- biological evaluation of medical devices
- quality management and corresponding general aspects for medical devices

- clinical laboratory testing and in vitro diagnostic test systems.

ISO is an independent, non-governmental international organisation with a membership of 168 national standards bodies, bringing together experts to share knowledge and develop voluntary, consensus-based, market relevant international standards that support innovation and provide solutions to global challenges.

We are also on the ASTM International Committees for face masks and breast implants. ASTM is a developer of international voluntary consensus standards.

Comparable overseas regulators for medical devices

We now formally recognise the Health Sciences Authority (HSA) Singapore as a Comparable Overseas Regulator for medical devices, which allows Australian sponsors to apply for TGA approval to supply medical devices in Australia based on HSA approval.

In addition, the Medical Device Single Audit Program (MDSAP)[5] has been designed to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the Quality Management System[6] and regulatory requirements of medical device manufacturers. MDSAP certificates are issued by recognised auditing organisations, with oversight from the participating comparable overseas regulators and the TGA.

We have been a participating member of the MDSAP consortium since it was initiated as an IMDRF work item in 2012. Throughout 2022-23, we continued our leading role in the MDSAP, which now has over 6,500 manufacturing sites participating with one annual audit of the manufacturer being accepted by Australia, USA, Canada, Brazil and Japan.

Public awareness and education activities

Undertaking public awareness and education activities to inform consumers, health professionals and businesses about priority topics.

Throughout 2022-23, we delivered 9 paid public education campaigns, reaching a combined total of 22.7 million people:

- paracetamol safe use and storage – 12 December to 23 December 2022
- antibiotics and Ozempic shortages – 14 December to 26 December 2022
- pholcodine cancellation and recalls – 30 March to 19 April 2023
- MDMA and psilocybin – 5 April to 20 April 2023
- beware of buying online – 22 May to 9 June 2023
- mandatory statements – Do you read the label every time? – 6 June to 30 June 2023
- how to find out what's in your medicine – 7 June to 30 June 2023
- 5 questions to ask your health professional before you get a medical implant – 8 June to 30 June 2023

[5] Please refer to table 50 Appendix 8.3.4

[6] Please refer to table 48-49 Appendix 8.3.4

- travelling with medicines and medical devices – 8 June to 30 June 2023

The campaigns performed extremely well, reaching an average of more than 2.5 million people per campaign. We achieved more than 8.2 million impressions per campaign (the number of times the content was displayed), and drove 29,000 visitors to our website. The aim of our campaigns is to raise awareness among consumers and health professionals of priority educations topics, and we consistently outperformed the Australian Government benchmark, demonstrating that the content was relevant and engaging to the target audiences.

Case Study – Travelling with medicines and medical devices campaign

This campaign used a range of digital channels to reach and educate Australian and international consumers about their obligations when travelling to and from Australia with medicines and medical devices. The multi-faceted strategy delivered educational content and amplified its message through a paid promotion campaign, existing organic (non-paid) networks, and targeted stakeholders.

During the content design phase, the TGA project team worked closely with internal and external stakeholders to step out an improved educational journey for travellers entering or leaving Australia. This included a user discovery workshop with members of the Medical Device Consumer Working Group (MDCWG), who provided invaluable insights into the information needs and pain points for the groups they represent.

The paid advertising ran from 8 to 30 June 2023 on Facebook and Instagram, as well as digital display advertising on lifestyle websites that targeted consumers looking to travel. The campaign reached more than 2.2 million people and received 13.8 million impressions. This promotion resulted in 7,385 clicks through to the website and the Leaving Australia and Entering Australia videos have received over 2,000 views on YouTube.

Priority review pathway for biologicals

We have introduced a priority review pathway for biologicals to enable faster patient access to cell and tissue therapies.

Following a key recommendation of the TGA-commissioned MTPconnect report into a regulatory framework for gene, cell, and tissue therapies in Australia, we introduced a priority review pathway[7] for biologicals[8] to allow life-saving therapies to be brought to market faster, enabling quicker patient access to these products. The target timeframe of 150 working days is up to 105 days faster than the timeframe for the standard assessment pathway.

Aligning with other export-only therapeutic products that we regulate, we introduced an additional application pathway for export-only biologicals to support export[9] to countries

[7] Please refer to table 6 Appendix 1.4

[8] Please refer to table 33-34 Appendix 6

[9] Please refer to table 51 Appendix 9

where manufacture is not yet occurring or the product differs from that supplied in Australia, thereby minimising regulatory burden for these products.

Learning about stakeholder perspectives and emerging issues

We continue to learn about the perspectives and emerging issues relevant to our stakeholders through stakeholder surveys, public consultations, market research, and formal and informal forums.

In 2022-23 we provided opportunities for industry, health care professionals and consumers to hear from and speak with us at many in-person and online events. We spoke informally at universities and incubation hubs across Australia, in addition to participating in and presenting at seminars, exhibitions and conferences.

We attended the ARCS Annual Conference in Sydney in June 2023, an example of our commitment to engage face-to-face with our stakeholders. The conference brought together industry professionals, consumers, patients, practitioners, researchers, and academics to unite and educate. Twenty-four TGA staff presented on a diverse range of topics across the 3 days and educated attendees on the current and emerging regulatory environment in Australia. We also had an exhibition booth at the conference where we interacted with over 150 delegates on popular topics such as the Good Clinical Practice (GCP) Inspection Program, and Software as a Medical Device. Feedback from delegates confirmed the value in being able to speak directly with subject matter experts in the one place, as well as network with each other.

Delivered via the TGA Consultation Hub, our consultation processes are a critical mechanism for informing regulatory reforms and policy changes for consideration by government, and our surveys provide opportunity for stakeholders to provide feedback on changes we have made. Many topics of regulation were covered by 39 consultations and surveys opened in 2022-23. Examples include adoption of international scientific guidelines in Australia, reviewing regulatory requirements for medical devices containing materials of animal, microbial or recombinant origin, repurposing medicines, and improving patient access to critical medicines in acute care settings.

The TGA finalised the outcomes of a public consultation on regulatory options to allow references to the TGA in advertising. This was informed by 26 submissions received from the therapeutic goods industry (sponsors, manufacturers, and industry organisations), health care professional bodies, consumers, consumer representatives and advertising organisations.

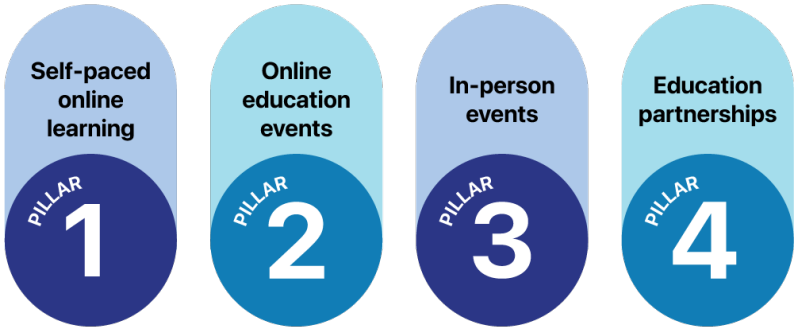
We learn a great deal about emerging issues and the perspectives of our stakeholders through the annual TGA Stakeholder Survey. This survey gathers opinions and feedback on our operations and services. In addition to industry contacts with a TGA Business Services account, in 2023 we surveyed 1,000 consumers, 180 health professionals and representatives from state and territory governments. The survey results support the planning cycles and process improvements for relevant line areas.

We also conduct market research through third-party organisations to help identify audience knowledge, perceptions, and sentiment on particular focus areas. For example, market research conducted by ORIMA Research about mandatory statements for certain medicines and medical devices helped to inform the communication objectives of the ‘Do you read the label every time?’ paid social media campaign that was run in 2022-23.

Supporting small and medium enterprises

We support small and medium sized enterprises (SMEs) and Australian innovators unfamiliar with therapeutic goods regulation to better understand regulatory requirements.

We continue to develop new ways to provide support and education to those unfamiliar with regulation. We have repositioned our SME Assist program to TGA Learn, so SMEs, start-ups, researchers and newcomers to regulation better understand their regulatory requirements.



Following consultation with industry groups we have developed TGA Learn to provide a comprehensive self-paced learning experience along with structured online learning events, targeted in-person events and strategic education partnerships. TGA Learn recognises the need for different learning methods and access to self-paced education. As such, it will allow individuals to tailor their learning experience and will introduce education-based partnerships with key industry groups. Through the TGA Learn package of learning options, SME Assist will continue to be provided as an advisory service to our stakeholders.

Providing guidance materials to regulated entities

We have continued to develop and publish new and updated guidance material that assists regulated entities to understand and meet their regulatory obligations.

In the 2022-23 financial year, there were 57 guidance content changes on the TGA website, including the publishing of new guidance and major and minor updates to existing guidance.

The more notable new guidance and updates included:

- Supplying substitute medicines during a medicines shortage (March 2023)
- Manufacturer evidence for IVD medical devices (June 2023)
- Applying the Advertising Code rules (parts 2 and 3 of the guidance added May 2023)
- updated guidelines for sunscreens (May 2023)
- Application requirements for new substances in listed medicines (May 2023)
- Listed medicine training (interactive guidance) to supplement the information in the Evidence Guidelines (January 2023)

In response to emerging trends in advertising non-compliance, we published guidance materials to assist regulated entities to understand their regulatory obligations regarding the advertising of therapeutic goods. Specific topics included advertising COVID-19 rapid antigen point-of-care tests and self-tests (home use tests), applying the Advertising Code rules, advertising relating to mushroom products, therapeutic goods advertising and ASX

announcements, and using scientific or clinical claims (representations) in therapeutic goods advertising.

Feedback gathered through the TGA Website Redevelopment Project showed our industry audiences need guidance that is complete, current, clear, easy to find (ideally without having to search) and easy to understand. In May 2023, in response to this feedback, we started exploring how to improve guidance through a discovery project with staff and external website users.

Several strategic and tactical interventions were identified following the discovery phase that will be implemented during the 2023-24 financial year.

Educating about adverse event reporting

We continue education and awareness raising activities to support adverse event reporting[10] by consumers and health professionals.

We have sought feedback from our Medical Devices Consumer Working Group about online guidance for reporting medical device adverse events, and provided information on how that data is used by the TGA to identify signals and emerging trends. We also work collaboratively with health professionals, particularly those in state and territory facilities, and members of our medical devices expert working groups, to exchange information and learn about emerging risks and suitable risk reduction measures.

We continued to publish alerts as safety issues were identified, with tailored information for consumers and health professionals. Regular Medicines Safety Update articles provided health professionals with practical information and advice on drug safety and information about emerging safety issues. The COVID-19 vaccine safety report was published regularly until the official end of the emergency response in November 2023. These avenues included information promoting adverse event reporting and the valuable role it plays in safety monitoring. We also established collaborative relationships with external medicine and health information services to explore opportunities to disseminate our safety information through these channels.

We actively engage consumers and health care professionals to educate and raise awareness through various channels, including our social media platforms, webinars and participation at external events. Activities that raise awareness of adverse event reporting include posts across our social media accounts and participation in MedSafetyWeek, an annual event in which regulators from around the world collaborate and promote reporting medicine adverse events.

We also educated hundreds of attendees at the ARCS annual conference on how we are improving access to adverse event data and showcased features of the new Database of Adverse Event Notifications (DAEN). We also engaged face-to-face with consumers and health professionals at our exhibition booths at other events, including the Pharmaceutical Society of Australian (PSA) Conference in Sydney, General Practice Conference and Exhibition (GPCE) in Melbourne, Rural Medicine Australia (RMA) conference, and Health Wellness and Fitness Show.

[10] Please refer to table 35 Appendix 7

Strategic objective 3 – Promote compliance with regulatory requirements

We use data and intelligence to manage risk and inform our compliance strategy and activities. By measuring risk of non-compliance in line with our regulatory requirements, we are able to implement mitigations and take proportionate actions ranging from education through to enforcement and litigation. Our risk framework is embedded in our regulatory activities to ensure the efficacy, safety and quality of the products we regulate.

Performance Indicators

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

3.2 Serious, deliberate, and repeated 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 look to 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 relates specifically to the TGA's enforcement of advertising regulations: 'The TGA takes strong action against illegal advertising for health products'. Agreement with this statement was 63% for consumers (8% disagreed), 66% for medical product industry stakeholders (9% disagreed), and 63% for health professionals (9% disagreed).

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'. Consumers were less likely to agree with this statement, with 60% agreeing (12% disagreed). Among medical product industry stakeholders 70% agreed (8% disagreed), and for health professionals, 61% agreed (6% disagreed).

A third statement aimed to gauge 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 67% of consumers agreeing (11% disagreed), 75% of medical product industry representatives agreeing (8% disagreed), and 74% of health professionals agreeing (7% disagreed).

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

In the Stakeholder 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 topics- the regulation of medicines, the regulation of medical devices and the regulation of complementary medicines, with a short description provided to give examples of each category.

For medicines, 71% of consumers agreed that the TGA would take appropriate action if an issue were identified (7% disagreed), 81% of medical product industry stakeholders agreed (4% disagreed), and 86% of health professionals agreed (4% disagreed). For medical devices, 72% of consumers agreed (6% disagreed), 79% of medical product device representatives agreed (4% disagreed), and 89% of health professionals agreed (2% disagreed).

Stakeholders were less positive regarding appropriate action being taken against complementary medicines. For consumers, 65% agreed that the TGA would take appropriate action if a safety issue were identified with a complementary medicine (8% disagreed). For medical product representatives 66% agreed (7% disagreed), and 66% of health professionals agreed (11% disagreed).

Many respondents across all categories answered 'unsure' or 'neither agree nor disagree'. When taken together, these results suggest that our stakeholders generally believe the TGA takes strong action in response to non-compliance with the therapeutic goods legislation.

Good Clinical Practice and Pharmacovigilance Inspection Programs

We implement Good Clinical Practice Inspection and Pharmacovigilance Inspection Programs to help medicines clinical trial sites and medicines sponsors respectively to understand their obligations and confirm compliance.

Following commencement of the Good Clinical Practice (GCP) Inspection Program in 2022, we conducted 7 inspections of clinical trial sites of medicines and biologicals[11].The first inspection was conducted in August 2022, following publication of guidance and education webinars introducing the new program. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The GCP Inspection Program strengthens the TGA's oversight of compliance, to verify that the rights, safety and wellbeing of clinical trial participants are protected and that the generated trial data are credible.

We also operated the Pharmacovigilance Inspection Program to help sponsors maintain compliance with our requirements, with 9 inspections completed in 2022-23 compared with 10 in the previous financial year[12]. Our pharmacovigilance inspectors conducted inspections, reviewed enforceable undertakings, and provided educational presentations. The inspectors conducted the 2022 Pharmacovigilance Inspection Program Risk Assessment Survey, which is a tool to help prioritise and schedule pharmacovigilance inspections based on risk.

The GCP and pharmacovigilance inspectors participated in international working groups and observed 4 inspections by international regulators to facilitate the ongoing development of the TGA's inspection programs in line with global best practice.

[11] Please refer to Table 84 Appendix 16

[12] Please refer to Table 83 Appendix 15

Enabling regulatory compliance through education and communication

We undertake education and communication activities to enable compliance with regulatory requirements, including in relation to manufacturing, importation and advertising of therapeutic goods.

In response to emerging trends in advertising non-compliance[13], we published 12 safety alerts or warnings, including in relation to counterfeit semaglutide products and various products containing undeclared substances such as sildenafil. Consumer awareness materials we published included:

- warnings about Ozempic scams
- A social media campaign to encourage people to read the labels of therapeutic goods every time they use them, even if they have used them before
- “have you spotted a dodgy ad? Report it to TGA”
- beware of buying medicines and medical devices online.

We have continued to provide information to consumers regarding counterfeit therapeutic goods through our publication of safety alerts on our website. In 2022-23 the alerts included:

- counterfeit semaglutide vials
- counterfeit nicotine vaping products
- erectile dysfunction treatment claiming to contain herbal ingredients but also containing the undisclosed ingredient sildenafil
- A warning for consumers, advertisers, importers, and suppliers regarding counterfeit nicotine vaping products.

In January 2023, we published two e-learning modules to supplement the June 2022 Evidence Guidelines for listed medicines, with a recorded webinar in May 2023, as additional sponsor educational resource tools. These resources assist sponsors to understand how to use the Evidence Guidelines and provide additional information regarding common questions and issues encountered.

On 21 March 2023 we held a GMP Forum in Sydney that bought together sponsors, manufacturers, and other industry stakeholders to share information on the regulation of the manufacturing of medicines and biologicals. The forum was attended by approximately 600 delegates and TGA staff. It provided provide industry stakeholders with a unique opportunity to connect with and learn from regulators and subject matter experts from across the TGA about their regulatory requirements relevant to Good Manufacturing Practices.

In September 2023, we held an information webinar prior to launching the Medical Devices Vigilance Program. A sponsor-self-assessment tool was developed as part of this program and aims to educate industry stakeholders of their regulatory requirements. The program’s desktop audits, and onsite inspection will complete sponsor education and promote compliance.

[13] Please refer to table 81 Appendix 14.2

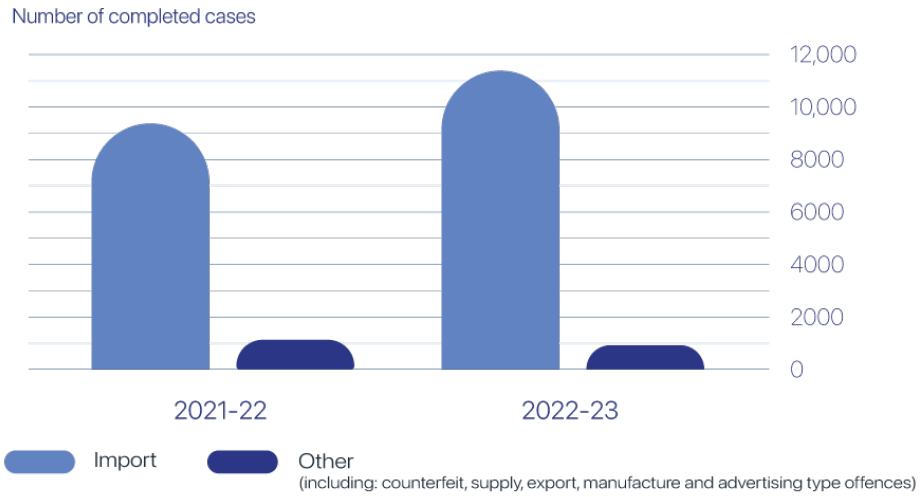
Monitoring and enforcing compliance

We monitor and enforce compliance on the import, export, manufacture, supply and advertising of therapeutic goods[14].

Over 2022-23, non-compliance was identified through analysis and review of complaints and reports received from the community, monitoring of digital platforms and advice from other regulators and agencies, including border and law enforcement agencies and state and territory regulators. The TGA used a risk-based approach to prioritise reports and other signals of non-compliance with the Act[15]. We worked closely with domestic and international agencies to detect, intercept, and investigate illicit therapeutic goods imported into Australia.

Our partnership with Australian Border Force has been crucial in building an effective compliance program. Together we manage the import and supply of therapeutic goods, undertaking assessments, including a review of prescriptions that consumers hold, to determine if goods are imported via a lawful pathway[16]. Where there is suspected non-compliance, our staff use proportionate regulatory action to achieve compliance.

Figure 3.1 Regulatory compliance and enforcement cases by offence type

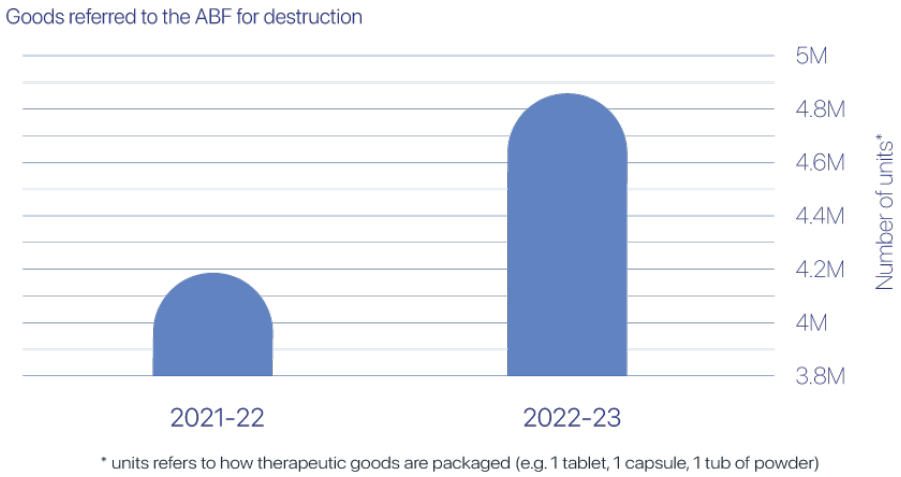


[14] Please refer to Table 77 to 80 Appendix 14.1

[15] Please refer to Table 28 Appendix 5.8

[16] Please refer to Table 80 Appendix 14.1

Figure 3.2 Goods referred to the ABF for destruction



We enhanced monitoring of therapeutic goods advertised on digital platforms and expanded our relationships with these platforms. This led to more than 15,000 unlawful advertisements being removed- an exponential increase on the 900 removed in the previous year. Some platforms introduced greater controls on how posts are released for publication, which has prevented unlawful advertisements being published.

We also addressed serious, deliberate, and repeated non-compliance through appropriate and proportionate enforcement responses, and collaborated with other local and international health and law enforcement agencies as appropriate.

Data analytics and operational intelligence

We enhanced our data analytics capability and further embedded operational intelligence to enhance the effectiveness and targeting of our education, compliance, and enforcement activities, for example in Listed Medicines compliance reviews.

Enhancing data analytics

We continue to develop new ways to visualise and report on the data held within compliance systems to inform executive and operational decision making. Systems enhancements are further supported by governance and record keeping activities to improve the accuracy and reliability of reporting capabilities over time.

Embedding operational intelligence

The use of operational intelligence and data analytics has become further embedded in processes that guide our compliance and enforcement actions including the review of the advertising, import and supply compliance priorities.

Through analysis of data and intelligence to inform our compliance priorities and focus our efforts where the greatest risk was identified, all issues identified as part of this process are considered. Factors that determine our compliance priorities include:

- trends of non-compliant behaviours within and across industry sectors
- the risk of non-compliance in relation to an upcoming regulatory change to ensure awareness of the regulatory requirements and early intervention, as a preventative measure to growth in non-compliance

- vulnerability of target consumers and likelihood of harm (likelihood of delayed alternative treatment, impact, and imminence of physical harm)
- threats to the integrity of health products regulation such as links to medium and long-term public health risks, widespread and serious non-compliance in relation to a class of goods, emerging markets
- serious and persistent non-compliant behaviours subject to a large quantity of reports both within and across industry sectors.

Teams responsible for the evaluation of prescription medicine applications now have access to standard workflow management reports in Power BI that enable data driven operational decision making. These reports are refreshed daily and enable teams to identify current priorities, optimise resource allocation and recognise emerging trends. The new standardised workflow management reports ensure a single source of truth and provide consistency in reporting.

Medical Officers responsible for clinical evaluation teams are now able to make more informed decisions around resource allocation and have additional capacity to support their teams. There has also been a reduction in applications exceeding their statutory timeframes as the teams responsible for completing the thousands of minor variations each year have more reliable data to prioritise tasks.

Compliance of listed medicines

For listed medicines, targeted compliance activities were conducted based on signals intelligence received through various avenues such as complaints, proactive scanning of the ARTG, and referrals from other agencies. We also identify potential non-compliance via actions from international counterparts, adverse events, and our laboratory testing results.

Case Study – Proactive scanning of ARTG

We conducted weekly ARTG scanning of a total of 1,722[17] newly listed medicines to detect potential non-compliance prior to the sponsor marketing the medicine. Early engagement with the sponsor soon after their listing allows sponsors to update their product before they suffer commercial losses. We triaged signals of potential non-compliance and assessed them for alleged breaches.

We took actions dependent on the risks posed, including educational correspondence, warning letters, cancellations, and infringement notices. A total of 345[18] signals were investigated and completed while 118[19] signals transitioned to compliance reviews. Two topics of potential broad non-compliance were detected, and mass educational emails were sent to sponsors that covered 539 listed medicines.[20]

Targeted reviews in 2022-23 included medicines containing caffeine, fennel, *Andrographis paniculate,* 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene carboxaldehyde (HICC) and aerosol sunscreen products. Indications and their presentation, including those suggested by the medicine name, were targeted where they did not reflect the permissible indications in the ARTG entry of the medicine. In addition, sponsors with a history of non-compliance were targeted.

For targeted reviews, we took a total of 905[21] compliance and enforcement actions, ranging from low level education actions such as mass email education, to higher level actions such as infringement notices and consumer level recall of stock. All listed medicine compliance activities facilitated a reach of at least 22%[22] of listed medicine sponsors.

[17] Please refer to Table 22 Appendix 5.3

[18] Please refer to Table 28 Appendix 5.8

[19] Please refer to Table 29 Appendix 5.8

[20] Please refer to Table 28 Appendix 5.8

[21] Please refer to Table 30 Appendix 5.8

[22] Please refer to Table 32 Appendix 5.8

Strategic objective 4 – Innovate and continuously improve

The TGA aims to continuously improve our regulatory activities, services and systems. We achieve this through the regular review of our processes to enhance efficiency and effectiveness, and we work with our stakeholders to understand the experience of sponsors, health practitioners and consumers when they access our services and interact with our staff and business systems. Improving our performance also means ensuring our staff are well trained and informed about the latest science and emerging developments relating to regulators around the world and our regulated entities.

Case Study – Continued capability development through the Regulatory Science Strategy 2020-2025

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

The first key focus area of the Regulatory Science Strategy is to 'maintain and build skills in regulatory science'. We continue to provide training and development opportunities that allow our staff to maintain their scientific expertise and further develop their skills to meet future challenges by:

- developing induction and technical e-learning modules to support effective and accessible staff training
- progressing the rollout of the Regulatory Scientist Capability Framework, which specifies the seven capabilities required within the regulatory scientific workforce to enable strong performance, into our Medical Devices and Product Quality Division
- working towards delivering a reporting tool for continuing professional development to empower staff and managers to maintain their technical and regulatory skills.

The digital transformation continues to be a key element in building an improved user experience. There are numerous projects completed in 2022-23 and continuing in 2023-24 that will have a positive impact for stakeholders and staff. The $61 million of TGA Public Good funding over 4 years provided in the 2023-24 Budget will enable the TGA to continue undertaking activities aimed at protecting public health. It will also allow us to uplift a number of regulatory services through reallocation of funding that was previously subsidising public good activities.

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.

Digital transformation

We progressed the implementation of new IT and business systems for TGA services, product evaluation and workflow management.

Through the digital transformation program of work, we are delivering modern digital tools to make it easier for staff and industry to complete business transactions and find the information they need. We commenced the development of portal and case management capabilities, including a new case management solution that will be onboarded with new functions over time. This is in response to industry feedback regarding opportunities to streamline applications, strengthen visibility of how an application is progressing, and make processes more efficient.

In 2022-23 the transformation work completed the following projects:

- **Website improvements (Phase 1)**
    - Modernised TGA and ODC websites released
    - Enhanced ARTG Search Visualisation Tool released and available on the TGA website
- **Website improvements (Phase 2 – commenced)**
    - Content and search enhancements based on feedback
    - New underpinning tools to support website data analytics and continuous improvement
- **User research, design and business process analysis**
    - Over 2,500 individuals, including health professionals, sponsors, consumers and system owners involved in user research and design activities
    - Over 50 business processes mapped and analysed to help identify common components
    - Delivering research insights that are now informing the portal and case management build stage
- **Laboratory Modernisation – design artefacts**
    - Supported the introduction of a new software system to manage testing information and case management, as well as introducing improved business processes
- **New Advertising Compliance App** for case management and public portal for reporting and enquiries
- **Special Access Scheme and Authorised Prescriber Scheme Online System** usability and access improvements

The 2023-24 period will build on these foundations and move into the next delivery stage. Our next priorities include:

- **Delivering portal foundations**, including the first stages of work on a new portal landing page, dashboard, service catalogue and search, notifications, customer identity management, user registration and organisation management and payment capability.
- **Delivering case management foundations**, including ready-to-configure ways to manage submissions, progress cases through stages to completion, and track and manage work, portal integrations, and a growing library of common functions such as payment integrations, document generations and task assignment.

- **Onboarding of the first TGA processes to new core solutions**, starting with new ingredient name proposal, pre-submission meeting request and designation applications.
- **Delivering the next round of enhancements to the TGA website**, including content improvements to improve search, as well as improvements to regulatory guidance will aid industry sponsors and manufacturers.

Consolidation of data assets

We are consolidating TGA's data assets to better support TGA's regulatory activities.

Through delivery of a new case management solution, we are providing greater consolidation of our data assets that support regulatory activities by gradually onboarding business areas that currently operate in silo systems. Over time, all regulatory activities will be managed through one case management solution.

Modernisation of the TGA Laboratories

We modernised the TGA Laboratories through transferring laboratory services to the new purpose-built facility at Fairbairn.

In August 2022, we relocated the TGA laboratories to a new purpose-built facility in Fairbairn ACT, the Gulgana and Yarwan Gawar buildings. The new facility has been designed to maximise functionality to ensure it meets new and emerging priorities and ensures the quality of therapeutic goods. The transition to the new facility was carefully planned to minimise the impact and output of the laboratories and the timeliness of regulatory decisions and safety monitoring actions.

Redeveloped TGA website

We redeveloped the TGA website to provide a more user centric design and modern digital services and information useful for consumers, health care professionals and industry.

We introduced new user experience management software to improve our data gathering capabilities and our understanding of users of the TGA website. Following the launch of the new TGA website, we discovered that 79% of our users were likely or very likely to return and 55% were satisfied or very satisfied with their user experience.

We also reduced the TGA website average page load time by 40%, improving our website user experience and presence on Google. Analysis using our new data gathering capabilities has improved our ability to prioritise content updates and redirect our work towards measurable user needs. We now know that 75% of participants surveyed are looking for information on a product or process administered by the TGA.

The TGA will continue to ensure the website is accessible, easy to navigate and accurate. Further upgrades to the website in 2023-24 will focus on content and search to provide timely benefits to industry, health professionals and the public.

Searchable Poison Standard database

We are developing a searchable database for the Poisons Standard which will explain medicines and chemicals scheduling decisions in plain English.

On 1 February 2023, we updated the Poisons Standard to a new structure that improves readability and clarity. This will assist regulated entities to understand their obligations, while ensuring the document aligns with modern drafting conventions and rules for Commonwealth legislative instruments. We suspended work on a publicly searchable Poisons Standard database until advancements in cognitive search technology and generative AI are cost effective and can be supported by our IT infrastructure.

Sharing of adverse event information

We are increasing transparency of and streamlining sharing of adverse event data through improvements to the Database of Adverse Event Notifications (DAEN-medicines) and implementation of new data exchange methods that enable receipt and sharing of adverse event information with state and territory health departments and health care professionals.

During the COVID-19 pandemic we experienced unprecedented public interest regarding the safety of medicines and vaccines, with large numbers of people searching our website for information about adverse events.

In June 2022, to maintain transparency of medicine and vaccine adverse events, we launched a trial (beta) version of the Database of Adverse Event Notifications (DAEN) for medicines. This allowed users to interact with search results through dynamic tables, filters, and graphs, and download search results. Based on positive feedback from a user survey, the old DAEN for medicines was decommissioned. We also published updated information for users, including tips on how to search and answers to frequently asked questions.

Users reported that the new interface made searching for products faster and it was easier to find the information they were looking for. Graphs simplified the interpretation of results and helped users to understand the prevalence of adverse events.

We have also progressed improvements in how we share and receive medicine and vaccine adverse event reports. We have implemented automated sharing of adverse event data for vaccines with state and territory health departments. In May 2023, following a public consultation, we created two new legislative instruments that enable sponsors to access adverse event reports relevant to their medicines using their existing login details. This has replaced the need for sponsors to email us to request reports, delivering better and faster access to relevant adverse event data with less effort.

Building links with universities, international regulators and industry

We continue to build and maintain links with universities, international regulators, and industry to improve our regulatory practices and enhance our responsiveness to emerging technologies.

We have hosted and participated in multiple workshops and events hosted by industry. At these events, we present educational information to build better understanding of regulatory requirements, explain recent changes, and outline better practices for those who seek to include new therapeutic goods or those who are supplying therapeutic goods. We also

delivered educational lectures and presentations in the higher education, research, and translation sectors. This included our ‘Meeting your obligations’ one-day workshop held in Brisbane, which attracted over 240 attendees across the sector. The session educated sponsors supplying medical devices and complementary medicines and featured a guest speaker from MTPConnect who spoke about taking a product from concept to consumers. The Q&A sessions from these events and lectures are also valuable, allowing us to hear about the emerging developments and areas of interest from researchers and incubators, and the experience is utilised in developing and updating our online resources.

We chair the Regulatory Science Network (RSN), a network of Australian government agencies responsible for regulating chemicals and biological agents. The RSN’s objective is to improve the performance of these agencies by strengthening evidence-based decision-making through capacity building and enhanced operational effectiveness and interagency cooperation.

We proactively cultivate close relationships with academic institutions to augment our signal investigation work and ensure that research activities align with our pharmacovigilance priorities. We partner with the National Centre for Immunisation Research Surveillance (NCIRS) to co-author papers, including the Communicable Diseases Intelligence publication of Surveillance of adverse events following immunisation in Australia. We also utilise NCIRS data in our enhanced influenza vaccine surveillance program. We meet regularly with the Centre of Research Excellence in Medicines Intelligence to bolster our regulatory practice, through visibility of current research into the quality use of medicines and medicines safety.

The TGA hosts an online platform to facilitate information exchange with 11 other international medical device regulators. This platform enabled timely and regular exchange of information and multilateral discussions on emerging and ongoing updates related to medical device safety or supply disruption issues.

Consolidated view of data to improve data analytics capabilities

We create and propagate data products across the TGA which combine key data sources into a single, consolidated view and increase data analytics capabilities.

Through the digital transformation program, we worked with our delivery partners to support a consolidated view of key TGA data sources through the Master Data Store (MDS) data solution. The MDS offers secure and governed data analytics functionalities, enabling management of data through a centralised platform. This centralised platform will provide the foundations to support evolving and new data product initiatives from within the program and broader group.

Preventing medicine shortages through data integration

We improved use and integration of data to better manage and prevent medicine shortages through earlier detection and analysis of shortage signals.

In August 2022, we held a virtual workshop for stakeholder organisations that hold or use medicine data. The workshop was intended to help stakeholders gain a common understanding of the information needed to predict and manage shortages and how such information could be more readily accessed and shared. A key aim was to reach agreement on opportunities for improved data sharing to better predict and respond to medicine shortages.

We will use the workshop outcomes to inform a new model of medicine availability that will allow us to forecast national medicine availability of any medicine using requested data from

key stakeholders. A data-sharing pilot is planned to test the model and gain experience with potential processes to improve continuity of medicine supply in Australia.

Post-market monitoring systems for medical devices

We are improving post-market monitoring systems for medical devices including early detection and action on emerging safety issues, allowing us to notify consumers earlier.

We used several strategies to receive and monitor medical device signals, including reviewing annual reports of high-risk medical devices, and monitoring risk factors identified with specific devices. We also worked with key industry stakeholders to improve monitoring and received information from several Australian medical device registries, including the:

- Australian Orthopaedic Association National Joint Replacement Registry
- Australian Breast Devices Registry
- Australasian Pelvic Floor Procedure Registry.

Registry data forms an important part of our approach monitoring medical device performance and emerging risks. Registry findings and information have assisted our investigations to determine the risk/benefit balance of devices, enabling the TGA to take action to reduce risk or communicate them to users and patients.

We will continue to build the capability of our systems and approach. In 2023-24 we will be undertaking internal data mapping and coordination of data fields between multiple systems to enable better data connectivity currently, with future data analytical capabilities to be established.

Management of complaints and feedback

We developed an updated complaints and feedback handling processes to be accountable and foster continuous improvement.

Following an audit in 2022-23 of our complaints handling processes, we commenced reviewing and implementing an internal complaint and feedback handling procedure that outlines clear lines of reporting and escalation points, in line with the Department of Health and Aged Care Complaints Management Policy. Following finalisation and publishing of the department's complaints management policy in 2023-2, we will develop enhanced processes incorporating the new policy and recommendations from the audit.

Appendices

The appendices provide detailed statistical information on our performance during 2022-23.

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, pre-clinical 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, pre-clinical 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, pre-clinical 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 2022 to June 2023

Application Type	Number Approved	Number Withdrawn	Number Rejected	Total (% Approved)
Category 1				
A: New chemical entity/New biological entity/Biosimilar [a]	37	5	1	43 (86%)
B: New fixed-dose combination	1	0	0	1 (100%)
C: Extension of indication	47	4	0	51 (92%)
D: New generic medicine	95	9	0	104 (91%)
F: Major variation	36	3	0	39 (92%)
G: Minor variation [b]	4	0	0	4 (100%)
H: Minor variation [c]	9	0	0	9 (100%)
J: Changes to Product Information	126	3	0	129 (98%)
S: Provisional registration to full registration	1	1	0	2 (50%)
T: Provisional registration extension [T]	11	0	0	11 (100%)
Comparable Overseas Regulator (COR) – A				
C: Extension of indication	3	0	0	3 (100%)
D: New generic medicine	2	0	0	2 (100%)
F: Major variation	2	0	0	2 (100%)
J: Changes to Product Information	1	0	0	1 (100%)
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/Biosimilar	7	0	0	7 (100%)
B: New fixed-dose combination	1	0	0	1 (100%)
D: New generic medicine	5	0	0	5 (100%)
F: Major variation	4	0	0	4 (100%)
Minor Variations				
Category 3				
G: Minor variation [b]	120	8	0	128 (94%)
H: Minor variation [c]	1422	31	0	1453 (98%)
Correction [9D(1)]	182	14	0	196 (93%)
Additional trade name [ATN]	38	1	0	39 (97%)
Extension of Indications - Generic	10	0	0	10 (100%)
Internal Review	2	0	0	2 (100%)
Minor editorial change [MEC]	195	2	0	197 (99%)
Self-assessable request [SAR]	564	15	0	579 (97%)
Safety-related request [SRR]	934	10	0	944 (99%)
Total	3859	106	1	3966 (97%)

[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 (s.14 and s.14A)

Consent to supply/import/export when not conforming to a standard [S.14 and S.14A]	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
Approved	94 (99%)	72 (100%)
Rejected	1 (1%)	0 (0%)
Total (excluding withdrawals)	95 (100%)	72 (100%)

1.2. Approval times

Table 3: Prescription medicine application approval time for July 2022 to June 2023

Application type	Submissions Approved	Legislated timeframe	Approval time (TGA working days)		
			Mean	Median	Range
Category 1					
A: New chemical entity/New biological entity/Biosimilar [a]	34	255	187	201	23-247
B: New fixed-dose combination	1	255	221	221	221-221
C: Extension of indication [b]	42	255	192	197	42-240
D: New generic medicine	95	255	136	133	75-231
F: Major variation	36	255	175	184	45-236
G: Minor variation	4	255	192	188	140-250
H: Minor variation	9	255	173	171	119-239
J: Changes to Product Information requiring the evaluation of data	126	255	147	173	6-249
S: Provisional registration to full registration	1	N/A	63	63	63-63
T: Provisional registration extension	11	N/A	25	26	4-45
Comparable Overseas Regulator (COR-A)					
C: Extension of indication b	3	120	86	87	80-90
D: New generic medicine	2	120	99	99	97-100
F: Major variation	2	120	108	108	108-108
J: Changes to Product Information requiring the evaluation of data	1	120	104	104	104-104
Comparable Overseas Regulator (COR-B)					
A: New chemical entity/New biological entity/Biosimilar	7	175	157	157	144-171
B: New fixed-dose combination	1	175	156	156	156-156
D: New generic medicine	4	175	128	128	121-133
F: Major variation	4	175	143	139	132-162

[a] Application type A figures do not include 3 submissions processed via the priority review pathway.
[b] Application type C figures do not include 5 submissions processed via the priority review pathway.

Table 4: Prescription medicine median approval time comparisons between 2021-22 and 2022-23

		Median approval time (TGA working days)	
Application type	**Legislated timeframe**	**2021-22**	**2022-23 (% Change)**
Category 1			
A: New chemical entity/New biological entity/Biosimilar [a]	255	191	199 (▲3%)
B: New fixed-dose combination	255	196	221 (▲13%)
C: Extension of indication [b]	255	198	197 (▼1%)
D: New generic medicine	255	139	133 (▼4%)
F: Major variation	255	170	184 (▲9%)
G: Minor variation	255	184	188 (▲2%)
H: Minor variation	255	186	171 (▼8%)
J: Changes to Product Information requiring the evaluation of data	255	183	173 (▼3%)
Comparable Overseas Regulator (COR) – A			
C: Extension of indication	120	105	87 (▼17%)
Comparable Overseas Regulator (COR) – B			
A: New chemical entity/New biological entity/Biosimilar	175	141	0 (▲0%)
D: New generic medicine	175	110	128 (▲17%)
Minor Variations			
Category 3			
G: Minor variation [c]	45	39	40 (▲3%)
H: Minor variation [d]	45	35	38 (▲9%)
Additional trade name [ATN]	45	35	40 (▲14%)
Extension of Indications - Generic	45	40	35 (▼11%)
Safety-related request [SRR]	N/A	37	39 (▲5%)
Self-assessable request [SAR]	45	32	31 (▼5%)
Minor editorial change [MEC]	45	33	35 (▲6%)
Correction [9D(1)]	N/A	42	41 (▼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] 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 2021-22		FY 2022-23	
Application Type	Number Approved (% of Total)	Median approval time (TGA working days)	Number Approved (% of Total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	16 (70%)	163	10 (48%)	191
C: Extension of indications	6 (26%)	196	8 (38%)	181
D: New generic medicine	0 (N/A)	N/A	2 (10%)	181
F: Major variation	1 (4%)	174	1 (4%)	172
Total	23 (100%)	174	21 (0%)	181

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 2021-22		FY 2022-23	
Application Type	Number Approved (% of Total)	Median approval time (TGA working days)	Number Approved (% of Total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	3 (50)	120	3 (37%)	139
C: Extension of indications	3 (50)	147	5 (63%)	137
Total	6 (100%)	144	8 (100%)	138

[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 2021-22		FY 2022-23	
Application Type	Number Approved	Total Applications	Number Approved	Total Applications
Provisional Determination	29	29	15	17

Table 8: Provisional registration approvals

	FY 2021-22		FY 2022-23	
	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	13 (46%)	88	14 (47%)	197
C: Extension of indications	10 (36%)	54	6 (20%)	127
F: Major variation	4 (14%)	23	4 (13%)	81
H: Minor variation	1 (4%)	183	1 (3%)	171
J: Changes to Product Information requiring the evaluation of data	0	N/A	5 (17%)	175
Total	28 (100%)	66	30 (0%)	171

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 80% of applications evaluated 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
N2	An application which complies with an OTC medicine monograph.	55
N3	New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4.	150
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
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
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
C2	Quality and non-quality changes classified as 'low risk' – no safety and/or efficacy data required; quality data may be required.	64
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
C4	Non-quality changes classified as 'moderate risk' – safety and/or efficacy data required unless justified.	170
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
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
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 2021-22	FY 2022-23
New medicine applications (days)		
N1	36	17
N2	28	31
N3	120	108
N4	163	132
N5	289	186
Change applications (days)		
C1	14	23
C2	24	26
C3	50	96
C4	0	0

Table 11: OTC medicine approval time against target time by application category – July 2022 to June 2023

Application type	Number completed (% of Total)	Range	Mean	Median	% within target
New medicines					
N1	85 (52%)	0-120	28	17	79
N2	24 (15%)	0-86	32	31	88
N3	40 (25%)	42-252	116	108	80
N4	13 (8%)	30-196	114	132	77
N5	1 (<1%)	186-186	186	186	100
Total	163 (100%)				
Change applications					
C1	288 (54%)	0-188	26	23	41
C2	237 (44%)	0-196	29	26	92
C3	8 (2%)	28-302	113	96	88
C4	0 (0%)	0	0	0	0
Total	533 (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 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
New medicine applications		
N1	90 (46%)	97 (45%)
N2	21 (11%)	16 (8%)
N3	57 (29%)	66 (31%)
N4	25 (13%)	32 (15%)
N5	3 (1%)	3 (1%)
Total	196 (100%)	214 (100%)
Change applications		
CN	184 (23%)	141 (20%)
C1	315 (39%)	293 (41%)
C2	293 (37%)	270 (38%)
C3	11 (1%)	7 (1%)
C4	0 (0%)	0 (0%)
Total	803 (100%)	711 (100%)

2.2.2 Completed applications

Table 13: Outcomes of completed new OTC medicine applications

	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
N1		
Approved	71 (95%)	85 (89%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	4 (5%)	11 (11%)
Returned/failed screening	0 (0%)	0 (0%)
Total	75 (100%)	96 (100%)
N2		
Approved	9 (100%)	24 (89%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	0 (0%)	3 (11%)
Returned/failed screening	0 (0%)	0 (0%)
Total	9 (100%)	27 (100%)
N3		
Approved	62 (97%)	40 (85%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	2 (3%)	6 (13%)
Returned/failed screening	0 (0%)	1 (2%)
Total	64 (100%)	47 (100%)
N4		
Approved	41 (89%)	13 (81%)
Rejected	2 (4%)	0 (0%)
Withdrawn by sponsor	2 (4%)	1 (6%)
Returned/failed screening	1 (2%)	2 (13%)
Total	46 (100%)	16 (100%)
N5		
Approved	10 (59%)	1 (100%)
Rejected	1 (6%)	0 (0%)
Withdrawn by sponsor	3 (18%)	0 (0%)
Returned/failed screening	3 (18%)	0 (0%)
Total	17 (100%)	1 (100%)

Table 14: Outcomes of completed OTC change applications

	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
C1		
Approved	278 (98%)	288 (97%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	6 (2%)	8 (3%)
Returned/failed screening	0 (0%)	0 (0%)
Total	284 (100%)	296 (100%)
C2		
Approved	300 (93%)	237 (96%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	21 (7%)	11 (4%)
Returned/failed screening	0 (0%)	0 (0%)
Total	321 (100%)	248 (100%)
C3		
Approved	20 (95%)	8 (80%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	1 (5%)	2 (20%)
Returned/failed screening	0 (0%)	0 (0%)
Total	21 (100%)	10 (100%)
C4		
Approved	0 (0%)	0 (0%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	1 (100%)	0 (0%)
Returned/failed screening	0 (0%)	0 (0%)
Total	1 (100%)	0 (0%)

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 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
Total	0	1
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]	13 (100%)	16 (100%)
Rejected	0 (0%)	0 (0%)
Total	13 (100%)	16 (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: Registered complementary medicine applications by outcome

	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
New medicines		
Approved	5 (50%)	2 (28.6%)
Rejected	2 (20%)	4 (57.1%)
Withdrawn	3 (30%)	1 (14.3%)
Returned/failed screening	0 (0%)	0 (0%)
Total	10 (100%)	7 (100%)
Variations		
Approved	21 (75%)	25 (100%)
Rejected	1 (4%)	0 (0%)
Withdrawn	6 (21%)	0 (0%)
Returned/failed screening	0 (0%)	0 (0%)
Total variations completed	28 (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	2 (67%)	6 (100%)
Rejected	0 (0%)	0 (0%)
Withdrawn	1 (33%)	0 (0%)
Total	3 (100%)	6 (100%)

4. Assessed Listed Medicines

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

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

Table 17: 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 18: Assessed listed medicine applications by outcome.

New medicines	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
Approved	0 (0%)	0 (0%)
Refused	1 (100%)	1 (100%)
Withdrawn	0 (0%)	0 (0%)
Failed screening	0 (0%)	0 (0%)
Total	1 (100%)	1 (100%)

Table 19: Applications received for new Assessed listed medicines and changes to existing medicines.

	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
New medicine applications		
L(A)1	0 (0%)	0 (0%)
L(A)2	0 (0%)	0 (0%)
L(A)3	2 (100%)	0 (0%)
Total	2 (100%)	0 (0%)
Change applications		
CN	0 (0%)	0 (0%)
C1	1 (100%)	1 (100%)
C2	0 (0%)	0 (0%)
Total	1 (100%)	1 (100%)

5. Listed Medicines

In comparison to registered medicines, listed medicines pose a lower risk and do not get assessed prior to market launch., The ingredients and indications are preapproved, and the sponsor certifies that their medicine complies with all relevant legislation and holds evidence that it will be fit for purpose.

A post market review is conducted on medicines randomly selected. We expect the sponsor to provide evidence of compliance with regulatory requirements, including the assessment of compliance with standards, efficacy, labelling and advertising. A listing can be suspended or cancelled if medicine does not comply with regulatory requirements.

5.1. New ingredients permitted for use in listed medicines

Table 20: New listed medicine ingredient applications by outcome

Application outcome	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
Approved	14 (56%)	8 (50%)
Rejected	4 (16%)	0 (0%)
Withdrawn	7 (28%)	8 (50%)
Returned/failed screening	0 (0%)	0 (0%)
Total completed	25 (100%)	16 (100%)

5.2. Indications permitted for use in listed medicines

Table 21: Permitted indication applications by outcome

Application outcome	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
Approved	0 (0%)	0 (0%)
Rejected	3 (75%)	1 (100%)
Withdrawn	1 (25%)	0 (0%)
Total completed	4 (100%)	1 (100%)

5.3. New listed medicines

Table 22: New listed medicines

	FY 2021-22	FY 2022-23
New listed medicines	1,929	1,722

5.4. Variations

Table 23: Listed medicine variations under subsection 9D(1) of the Act

Subsection 9D(1) of the *Therapeutic Goods Act 1989* 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	2021-22 (% of total)	2022-23 (% of total)
Approved	178 (88%)	101 (85%)
Rejected	0 (0%)	0 (0%)
Withdrawn	24 (12%)	17 (15%)
Total	202 (100%)	118 (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 2021-22	FY 2022-23
Applications Assessed		
Aristolochic Acid clearances		
Approved	45	28
Rejected	2	2
Total number of clearances	47	30
Consents under section 14/14A of the Act		
Approved	5	8
Extensions [a]	582	2
Rejected	1	5
Withdrawn	0	1
Total number of consents	588	16
Section 7 declaration		
Approved	0	0
Rejected	1	0
Withdrawn	0	0
Total number of declarations	1	0
Total completed	636	46

[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.

Up until 12 December 2022 we imposed, in writing, product-specific conditions of listing on listed medicines that contain plant species that look very similar or have a name that sounds very similar to plant species that are likely to contain aristolochic acids, as well as on sunscreen products to ensure they have appropriate SPF testing data following issues with AMA laboratories. 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 *Therapeutic Goods Act 1989.* The conditions of listing relating to Aristolochic Acids and testing of sunscreens by AMA laboratories are now automatically applied by the Determination. Therefore, from 13 December 2022 we are no longer required to impose these conditions in writing.

Product specific conditions of listing	FY 2021-22	FY 2022-23
Aristolochic Acid	3	0[a]
Chewing Gum	0	1
Sunscreens	296	85[a]
Total	299	86

[a] Conditions no longer manually imposed from 13 December 2022

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 2021-22	FY 2022-23
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines)- emails	3648	3085
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines)- emails – phone calls	627	429
FMI/CMI related enquires	33	35
Guidelines, media releases, factsheets, educational web content, social media posts	13	16
FMI/CMI educational correspondences (e.g. follow up on fact-sheet) [a]	4	3

[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. Some externals stakeholders include Food Standards Australia New Zealand and the state and territory food regulators, the Australian Border Force, and the Australian Federal Police. 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 2021-22	FY 2022-23
FMI/CMI referrals triaged and queued	60	55
FMI/CMI referrals triaged and closed via factsheet [a] [b]	8	9
Completed FMI/CMI assessments	38	17
Referral to another TGA area or government organisation	32	54

[a] Using factsheet developed in Table 26

[b] data unavailable or process was not in existence

5.8. Compliance and enforcement

The ARTG carries out a weekly scan of recently listed medicines, which captures signals of non-compliance in the form of complaints and referrals from internal and external stakeholders. In addition, the scan proactively captures non compliances prior to sponsor marketing the medicine and facilitates the sponsor to make timely amendments.

The right actions are meted to non-compliance activities based on potential breaches. A formal risk mitigation process is utilised, namely education correspondence for low level compliance actions and in-depth investigation to 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. When issues identified in a signal investigation are found to be of high risk, a compliance review will be triggered to conduct a more in-depth investigation and/or take further enforcement action.

Targeted compliance reviews may be initiated as a result of signals investigations or from intel/data that is available regarding a compliance topic. When issues identified in a signal investigation are found to be of high risk, a compliance review will be triggered to conduct a more in-depth investigation and/or take further enforcement action.

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

- no compliance breaches are identified against selected listing requirements, the review is concluded, and the medicine remains on the ARTG
- compliance breaches are identified for the selected listing requirements, and may take additional regulatory actions (cancellation, recalls, infringement notice)
- the review is closed due to the unavailability of information in determining its compliance status as the medicine is yet to be manufactured.
- we publish results of listed medicine compliance reviews on the TGA website to assist consumers to make informed choices about whether a listed medicine is appropriate for them.

The 2022-23 compliance strategy for listed medicines mainly included targeted compliance activities based on intelligence and data.

Table 28: Signals triaging and investigations

Signals monitored	FY 2021-22	FY 2022-23
Newly listed medicines monitored	2,115	1722
Intel signals of non-compliance (complaints and referrals)	42	110
ARTG signals of non-compliance (ARTG scanning)	288	294
Signals of non-compliance investigated and completed	221	345
Signals of non-compliance resolved with low to medium level compliance actions [a] (% success [b])	41 (53%)	202 (65%[c])
Signals of non-compliance transitioned to a compliance review	19	118
Medicines with potential non-compliance addressed via mass email education[d] (no. of topics)	104 (2)	539 (2)

[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 not been conducted for all correspondence sent, scheduled for September 2023.

[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 2021-22	FY 2022-23
Initiated reviews		
Compliance reviews	52	130
Compliance reviews transitioned from signal investigations	19	118
Total number of initiated reviews	71	248
Completed reviews		
Compliance reviews	49	133
Compliance reviews transitioned from signal investigations	29	70
Total number of completed reviews	78	203

Table 30: Compliance and enforcement actions

Compliance and enforcement actions[a]	FY 2021-22	FY 2022-23
Warning notices (cease and desist)	6	4
Educational correspondence (e.g. obligations notices, educational emails, other)	91	108
Mass email education[b]	50	192
Cease review notices	6	19
Conclusion notices	19	149
Deficiencies notices	13	36
Proposal to cancel notices	28	140
Cancellation notices	2	8
Directions/Prevention notice	1	2
Infringement notices	6	8
Published outcomes of compliance reviews	78	175
Referral to another TGA area or government organisation	17	43
Recalls[c]	N/A	21
Total actions undertaken [a]	317[d]	905

[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] New action reported, data unavailable for 2021-22
[d] Difference from 2021-22 report attributed to the addition of the 'Mass email education' field into this table

Table 31: All compliance review [a] outcomes

	FY 2021-22	FY 2022-23
Compliance status determined		
Medicines with no compliance breaches	21	57
Medicines with verified compliance breaches	50	128
Medicine no longer on the ARTG	26	63
Cancelled by the TGA	3	12
Cancelled by the sponsor after being notified of the compliance breaches	23	51
Medicine remains on the ARTG	24	17
Compliance breaches addressed after low level compliance action [b]	14	11
Compliance breaches addressed after proposal to cancel	10	6
Sub-total	71	185
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	7	11
Medicines not yet manufactured	0	6
Sub-total	7	17
Product is not a therapeutic good	0	1
Total completed	78	203

[a] All compliance reviews, including those that transitioned from signal investigations
[b] E.g., deficiencies/obligations/warning notices

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, publication of infringement/prevention notices have not been captured here.

Table 32: Reach of compliance activities for listed medicines

Sponsors reached	FY 2021-22	FY 2022-23
Sponsors who received any compliance interactions	226 (10%)	294 (22%)
Listings covered by any compliance interactions	609 (5%)	1000 (7%)

Figure 3[a] Outcomes of completed compliance reviews

Outcomes of completed compliance reviews	Count	Percentage (% of Total)
Cancelled by Sponsors after TGA contact	70	36%
Cancelled by TGA after proposal to cancel	6	3%
Compliant after proposal to cancel	51	26%
Compliant after education	12	6%
Compliant	57	29%
Total	**196**	**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 33: Applications for biologicals and blood received and on hand

	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Applications received		
Technical Master File (TMF)[b] new	0 (0%)	0 (0%)
TMF annual updates	3 (3%)	5 (5%)
TMF variations	6 (6%)	9 (8%)
TMF notifications	5 (5%)	10 (9%)
Plasma Master File[c] annual updates	12 (11%)	9 (8%)
Biological Class 1 – new applications	1 (1%)	0 (0%)
Biological Class 2 – new applications	5 (5%)	2 (2%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	3 (3%)	0 (0%)
Biological Class 2 – variations	24 (23%)	53 (48%)
Biological Class 3 – variations	10 (10%)	7 (6%)
Biological Class 4 – variations	35 (33%)	15 (14%)
Total received	104 (100%)	110 (100%)
Applications on hand		
TMF new	0 (0%)	0 (0%)
TMF annual updates	1 (4%)	2 (10%)
TMF variations	2 (9%)	3 (14%)
TMF notifications	1 (4%)	2 (10%)
Plasma Master File annual updates	2 (9%)	3 (14%)
Biological Class 1 – new applications	0 (0%)	0 (0%)
Biological Class 2 – new applications	3 (14%)	2 (10%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	3 (14%)	0 (0%)
Biological Class 2 – variations	5 (18%)	5 (24%)
Biological Class 3 – variations	3 (14%)	0 (0%)
Biological Class 4 – variations	3 (14%)	4 (19%)
Total on hand	23 (100%)	21 (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 34: Completed applications for biologicals and blood

Biologicals applications	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Technical Master File (TMF) new	0 (0%)	0 (0%)
TMF annual updates	3 (3%)	3 (3%)
TMF variations	4 (4%)	7 (7%)
TMF notifications	4 (4%)	10 (10%)
Plasma Master File annual updates	10 (11%)	6 (6%)
Biological Class 1 – new applications	1 (1%)	0 (0%)
Biological Class 2 – new applications	2 (2%)	2 (2%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	1 (1%)	3 (3%)
Biological Class 2 – variations	19 (22%)	50 (48%)
Biological Class 3 – variations	12 (13%)	7 (7%)
Biological Class 4 – variations	35 (39%)	17 (16%)
Total completed	91 (100%)	105 (100%)

7. Medicine and Vaccine Adverse Event Reports

7.1. Adverse medicine and vaccine event notifications

Table 35: Source of notifications of medicine and vaccine adverse events[a]

	FY 2021-22	FY 2022-23
Received		
Mean number of reports received weekly	2,421	530
Vaccine reports	107,961	10,183
Total	125,875	27,568
Accepted cases		
Reports by health professionals	11610	4,083
Patients/consumers	27,422	2,490
Pharmaceutical companies	15,950	13,469
Other source [b]	66,096	6,135
Total	121,084	26,177
Rejected/withdrawn cases	4,980	1,391

[a] Data is subject to change due to receipt of further information related to individual reports or further case processing. Notifications for 202122 have been updated since the last Regulator Performance Report to reflect the most recent data. Reporting an adverse event does not mean that the details of the event have been confirmed by the TGA, or that the event has been determined to be related to a medicine or a vaccine.

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

8. Medical Devices

The Medical Devices Regulatory Framework spans the life cycle for these products, including:

Priority review of medical devices: This pathway allows faster processing of applications for devices that meet certain criteria such as being a novel device or 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.

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. Certification of the manufacturer's conformity assessment procedure may (or for particular products, must) be undertaken by the TGA, or we may recognise conformity assessment certification from comparable regulators in other jurisdictions such as European notified bodies.

Inclusion on 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 on the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

8.1. Conformity assessment

8.1.1 Applications

Table 36: Number of conformity assessment applications (medical devices including IVDs)

	FY 2021-22	FY 2022-23
Conformity assessment applications		
Applications received	191	202
Applications on hand	169	119
Applications completed (including withdrawn or lapsed applications).	278	204

8.1.2 Outcomes

Table 37: Outcomes of conformity assessment applications

	FY 2021-22	FY 2022-23
New		
Approved	51	22
Rejected	0	0
Withdrawn/ Lapsed	36	28
Variation (changes and re-certifications)		
Approved	162	136
Rejected	0	0
Withdrawn/ Lapsed	29	18

8.1.3. Processing timeframes

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

Table 38: TGA conformity assessment processing times for new devices and variations

	FY 2021-22	FY 2022-23
New devices		
Mean TGA processing time (days)	139	148
Mean TGA processing time (days) – applications requiring assessment [a]	190	193
Median TGA processing time (days)	168	213
Median TGA processing time (days) – applications requiring assessment [a]	222	219
% of applications completed within legislated timeframe (255 working days)	100%	100%
Variations (changes and recertifications)		
Mean TGA processing time (days)	146	142
Mean TGA processing time (days) – applications requiring assessment [a]	154	151
Median TGA processing time (days)	168	145
Median TGA processing time (days) – applications requiring assessment [a]	174	148
% of applications completed within legislated timeframe (255 working days)	100%	100%

[a] Some applications do not require assessment and those applications reduce the overall mean and median timeframes. For this reason, we also report the timeframes without those applications included.

8.2. Inclusion of medical devices (including IVDs)

8.2.1 Applications

Table 39: Applications for inclusion – medical devices (including IVDs)

	FY 2021-22	FY 2022-23
Class I medical devices		
Applications received	2,365	1,492
Applications completed	2,259	1,459
Applications on hand	321	197
Class I measuring medical devices		
Applications received	48	33
Applications completed	49	36
Applications on hand	1	0
Class I sterile medical devices		
Applications received	279	264
Applications completed	298	262
Applications on hand	16	2
Class IIa medical devices		
Applications received	1,377	1,179
Applications completed	1,451	1,162
Applications on hand	79	109
Class IIb medical devices		
Applications received	610	648
Applications completed	644	602
Applications on hand	100	72
Class III medical devices		
Applications received	469	668
Applications completed	463	572
Applications on hand	297	448
Active Implantable Medical Devices (AIMD)		
Applications received	21	18
Applications completed	19	27
Applications on hand	23	14
Class 1 IVDs [a]		
Applications received	151	83
Applications completed	141	86
Applications on hand	17	14
Class 2 IVDs		
Applications received	59	101
Applications completed	60	83

	FY 2021-22	FY 2022-23
Applications on hand	9	27
Class 3 IVDs		
Applications received	526	157
Applications completed	275	361
Applications on hand	294	92
Class 4 IVDs		
Applications received	12	17
Applications completed	5	12
Applications on hand	7	12

[a] The number of Class 1 IVD applications includes auto-included devices and applications completed with or without audit.

Table 40: Applications for device change requests and variations to the ARTG – medical devices (including IVDs)

	FY 2021-22	FY 2022-23
Device Change Request (DCR)		
Applications received	1,035	857
Applications completed	951	742
Applications on hand	310	209
Variations to Class III medical devices		
Applications received	117	108
Applications completed	123	110
Applications on hand	8	6
Variations to Active Implantable Medical Devices (AIMD)		
Applications received	0	0
Applications completed	1	0
Applications on hand	0	0
IVD Device Change Request (DCR)		
Applications received	83	107
Applications completed	72	99
Applications on hand	35	46
IVD Variations		
Applications received	97	52
Applications completed	100	58
Applications on hand	33	27

Note: Similar to 2021-22, in 2022-23, we had an unprecedented number of COVID-19 test applications (mostly Class 3 IVDs), and prioritised applications for combination COVID-19/Influenza test kits to meet the public health need during the winter flu season. The number of IVD application audits and the mean processing time to complete the audits increased in 2022-23.

8.2.2 Processing times

A Level 1 audit may include clarification of the device classification, a conformity assessment procedure, and/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 one or more of the following: clinical evidence, risk management report(s), efficacy, and performance data, and/or audit reports from Notified Bodies. The target timeframe for Level 1 application audits is 30 TGA workdays and for Level 2 application audits is 60 TGA workdays (reflected in 'TGA days').

Table 41: Processing times for medical device application audits (including IVDs)

	2021-22			2022-23		
	Total completed	Processing times (TGA days)		Total completed	Processing times (TGA days)	
		Mean	Median		Mean	Median
Medical devices						
Class I applications completed without audit	1,533	2	1	1,459	2	2
Class I applications completed with audit	763	39	15	709	33	8
Non class I applications completed without audit	2,101	10	9	2,094	12	12
Non-compulsory audits (Non class I)	106	90	44	142	109	78
Level 1 compulsory audits	41	27	14	38	89	91
Level 2 compulsory audits	269	190	165	208	179	172
IVDs						
Class I IVD applications completed without audit	82	2	1	58	4	2
Class I IVD applications completed with audit	37	26	10	23	99	56
Non class I IVD applications completed without audit	72	2	1	56	5	4
IVD non-compulsory audit	3	23	22	6	46	40
IVD compulsory audit	219	48	35	358	156	154
IVD Device Change Request	72	67	67	99	99	94
IVD Variation	100	67	67	58	115	68

Table 42: Number of priority review determinations [a] granted

Application type	FY 2021-22	FY 2022-23
A: Conformity Assessment (priority applicant) determinations [b]	0	0
B: Medical Devices (priority applicant) determinations [b]	0	0

[a] Priority designation is a formal decision by the TGA to assign priority to the assessment of an application to include a medical device in the ARTG. Granting of priority designation does not guarantee approval for the application itself.
[b] No determinations were granted in 2022-23.

Table 43: Number of medical devices approved through the priority review pathway.

	FY 2022-23	
Application Type	Number of applications with Priority determinations Approved (% of Total)	Median approval time (TGA working days)
A: Conformity Assessment	0	N/A
B: Medical Devices (ARTG inclusion)	0	N/A
Total [a]	0	N/A

[a] No applications were approved in this reporting period

8.3. Post-market monitoring

8.3.1 Post-market reviews

Post-market reviews 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 may 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 44: Medical device post-market reviews

Post market reviews	FY 2021-22	FY 2022-23
Reviews commenced – number of ARTG entries	5,049	899
Reviews completed – number of ARTG entries	2,554	1,592
Reviews on hand – number of ARTG entries	5,741	5,048

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 some 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 45: Applications for consent to supply (CtS) non-compliant medical devices

Consent to supply applications	2022-23
Total number of CtS applications received	99
Number of ARTG entries included in the CtS applications	401
Number of Applications for Inclusion in the ARTG included in the CtS applications	21

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.

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

Table 46: Number of medical device incident reports and processing times

	FY 2021-22	FY 2022-23
Incident report outcomes		
Device incident reports [a]		
Reports received	8,737	8,403
Reports completed	7,978	6,893
Reports still in progress	207	1,509
Processing time		
Mean TGA processing time (days)	23.2	10.7
Median TGA processing time (days)	6	5
Percentage processed within target timeframe	94%	80%

[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 47: Medical device incident report outcomes [a]

Incident report outcome	FY 2021-22	FY 2022-23
Reviewed and used for trend analysis purposes	7,337	6,613
Reviewed, no further action required	426	173
Product recall	66	9
Product device correction	90	14
Hazard alert	32	5
Product notification	12	0
Safety alert	10	17
Product enhancement/improvement notice	2	2
Instructions for use amended	10	2
Referral for post-market review	39	9
Refer to another TGA Branch or Section	26	8
Company warned	0	0
Product suspended from ARTG	1	0
Product cancelled from ARTG	14	3
Manufacturing process improvements	8	5
Quality system process improvements	2	3
Maintenance carried out by the hospital	4	1
Change to design	6	2
Not device related	2	0
TGA Publication	20	2
User education	6	1
Other	29	54

[a] Outcomes are not mutually exclusive.

8.3.4 Devices manufacturing

Table 48: Outcomes of Quality Management System (QMS) audits of Australian manufacturers

	FY 2021-22	FY 2022-23
QMS audits (Australia)		
Number of audits completed	24	14
Satisfactory compliance (of completed audits)	19 (80%)	13 (93%)
Marginal compliance (of completed audits)	4 (16%)	1 (7%)
Unacceptable compliance (of completed audits)	1 (4%)	0 (0%)
Audits not finalised at period end	6	4
Processing time		
Initial audits conducted within 3 months of application	33%	100%
Re-audits conducted within 6 months of due date	0%	7%

Table 49: Outcomes of QMS audits of overseas manufacturers

	FY 2021-22	FY 2022-23
QMS audits (overseas)		
Number of desktop audits conducted	54	32
Number of onsite/remote audits completed	3	11
Satisfactory compliance (of completed audits)	2 (67%)	9 (82%)
Marginal compliance (of completed audits)	0 (0%)	2 (18%)
Unacceptable compliance (of completed audits)	1 (33%)	0 (0%)
Audits not finalised at period end	4	9
Processing time		
Initial certification audits conducted within 6 months of application	67%	39%
Certification re-audits conducted within 6 months of due date	0%	14%

Table 50: Outcomes of overseas MDSAP (Medical device single audit program) Assessments

	FY 2021-22	FY 2022-23
MDSAP Assessments (overseas)		
Number of auditing organisation assessments	9	7
Number of witnessed manufacturing audits	3	2

9. Exports

9.1. Export only products

Table 51: Number of approved applications for export-only medicines and export certifications and relevant processing time for July 2022 to June 2023

	2021-2022	2022-2023	Target processing time (days)	2021-22	2022-23
	Total approved			Average processing time (days)	
Export-only medicines					
New applications	286	308	30	29	26
Variation and grouping applications	147	129	30	20	19
Export certification					
Medicines	1,622	1958	15	10	10
Medical devices	547[a]	393[a]	10	5	5

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

10. Access to Unapproved Therapeutic Goods

10.1. Special Access Scheme

The Special Access Scheme (SAS) refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis. For this reporting period, 3 pathways existed under the scheme, and they 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 52: SAS medicine notifications and applications

	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Category A notifications		
Total Category A notifications	25,305 (15%)	32,962 (16%)
Category B applications		
Approved	121,938 (98%)	131,585 (98%)
Cancelled	78 (<1%)	305 (<1%)
Withdrawn	665 (<1 %)	1,480 (1%)
Rejected	0 (0%)	13 (<1%)
Pending at end of reporting period	1,411 (1%)	1,088 (1%)
Total Category B applications	124,092 (74%)	134,471 (67%)
Category C notifications		
Total Category C notifications	19,399 (12%)	32,646 (16%)
Total SAS notifications/applications received (all categories)	168,796 (100%)	200,079 (100%)

Table 53: SAS medical device notifications and applications

	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Category A notifications		
Total Category A notifications	3,662 (43%)	4,999 (40%)
Category B applications		
Approved	3,559 (93%)	5,471 (90%)
Cancelled	23 (<1%)	64 (1%)
Withdrawn	64 (2%)	81 (1%)
Rejected	3 (<1%)	9 (<1%)
Pending at end of reporting period	196 (5%)	441 (7%)
Total Category B applications	3,845 (45%)	6,066 (48%)
Category C notifications		
Total Category C notifications	1,107 (13%)	1,540 (12%)
Total SAS notifications/applications received (all categories)	8,614 (100%)	12,605 (100%)

Table 54: SAS biological notifications and applications

	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Category A notifications		
Total Category A notifications	74 (7%)	132 (5%)
Category B applications		
Approved	239 (73%)	339 (75%)
Cancelled	14 (4%)	43 (10%)
Withdrawn	64 (20%)	58 (13%)
Rejected	0 (0%)	0 (0%)
Pending at end of reporting period	9 (3%)	12 (3%)
Total Category B applications	326 (31%)	452 (16%)
Category C notifications		
Total Category C notifications	663 (62%)	2,219 (79%)
Total SAS notifications/applications received (all categories)	1,063 (100%)	2,803 (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 55: Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

Therapeutic good type	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Medicine	483 (41%)	390 (37%)
Device	166 (14%)	161 (015%)
Biological	10 (1%)	9 (1%)
Medicine and device	514 (43%)	477 (45%)
Device and biological	4 (<1%)	5 (<1%)
Medicine and biological	4 (<1%)	2 (<1%)
Medicine, device and biological	4 (<1%)	6 (<1%)
Total	1,185 (100%)	1050 (100%)

Table 56: Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

Clinical trial type	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Phase 1	377 (32%)	346 (33%)
Phase 2	303 (26%)	263 (25%)
Phase 3	273 (23%)	229 (22%)
Phase 4	53 (4%)	37 (4%)
Device	172 (14%)	164 (16%)
Bioavailability/equivalence	7 (1%)	11 (1%)
Total	1,185 (100%)	1050 (100%)

Table 57: 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 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Medicine	1,278 (32%)	1,159 (32%)
Device	320 (8%)	323 (9%)
Biological	16 (<1%)	24 (<1%)
Medicine and device	2,344 (59%)	2,117 (58%)
Device and biological	10 (<1%)	16 (<1%)
Medicine and biological	7 (<1%)	6 (<1%)
Medicine, device and biological	24 (<1%)	22 (<1%)
Total	3,999 (100%)	3667 (100%)

Table 58: Number of new clinical trials and variations to previously notified clinical trials involving unapproved therapeutic goods received by phase

Phases	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Phase 1	1,200 (30%)	1,069 (29%)
Phase 2	1,024 (26%)	954 (26%)
Phase 3	1,311 (33%)	1,167 (32%)
Phase 4	117 (3%)	120 (3%)
Device	338 (8%)	341 (9%)
Bioavailability/equivalence	9 (<1%)	16 (<10%)
Total	3,999 (100%)	3667 (100%)

10.3. 10.3 Authorised Prescribers

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

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

Approvals by therapeutic good type	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Number of approvals for medicines	11,895 (98%)	13,641 (98%)
Number of approvals for medical devices	277 (2%)	235 (2%)
Number of approvals for biologicals	0 (0%)	0 (0%)
Total	12,172 (100%)	13,876 (100%)

11. Medicines and Biologicals Manufacturing

11.1. Manufacturing licences issued to Australian manufacturers

Table 60: Status of manufacturing licence applications

	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
New licences granted	14 (16%)	13 (14%)
Withdrawn application	57 (67%)	68 (69%)
Revoked licences – at request of licence holder	10 (12%)	13 (14%)
Revoked licences – TGA	0 (0%)	0 (0%)
Suspended – at request of licence holder	4 (5%)	3 (3%)
Suspended – TGA	0 (0%)	0 (0%)
Total	85 (100%)	97 (100%)

[a] As at 30 June 2023, there were 265 Australian companies holding manufacturing licences covering 413 sites.

Table 61: Outcomes of inspections of Australian manufacturers

	FY 2021-22	FY 2022-23
	Number (% of Total)	
Compliance status (Australia)		
Number of inspections conducted	139	132
Satisfactory compliance (of completed inspections)	99 (71%)	98 (74%)
Marginal compliance (of completed inspections)	25 (18%)	21 (16%)
Unacceptable (of completed inspections)	7 (5%)	2 (2%)
Compliance under assessment	8 (5%)	11 (8%)
Processing time		
Initial inspections conducted within 3 months of application	9 of 15 (60%)[a]	10 of 15 (67%)[b]
Re-inspections conducted within 6 months of due date	34 of 95 (36%)[c]	16 of 90 (18%)

[a] Six domestic initial inspections did not achieve the three-month processing timeframe in 2021-22 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.
[c] Twenty-six of the delayed re-inspections were blood and biological manufacturers.

11.2. Approval (certification) of overseas manufacturers

Table 62: Manufacturing certification application by status (overseas)

	FY 2021-22	FY 2022-23
	Number (% of Total)	
Applications (overseas) [a]		
New applications received [b]	71 (61%)	52 (48%)
Re-inspection applications [b]	46 (39%)	57 (52%)
Total applications	117 (100%)	109 (100%)
Applications completed		
Certified	71 (60%)	124 (65%)
Rejected [c]	48 (40%)	68 (35%)
Total completed	119 (100%)	192 (100%)

[a] As at 30 June 2023, there were 148 overseas manufacturers covering 178 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 63: Outcomes of inspections of overseas manufacturers

	FY 2021-22	FY 2022-23
	Number (% of Total)	
Inspection status (overseas)		
Number of inspections conducted	104	118
Satisfactory compliance (of completed inspections)	80 (77%)	85 (72%)
Marginal compliance (of completed inspections)	17 (16%)	20 (17%)
Unacceptable (of completed inspections)	2 (2%)	0 (0%)
Compliance under assessment at period end	5 (0%)	13 (11%)
Processing time		
Initial certification inspections conducted within 6 months of application	8 of 37 (22%)[a]	9 of 33 (27%)[b]
Certification re-inspections conducted within 6 months of due date	2 of 66 (3%)	4 of 66 (6%)

[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 64: GMP clearance application status

	FY 2021-22	FY 2022-23
	Number (% of Total completed)	
Applications received	9,007	11,511
Applications completed		
Approved	8,103 (91%)	8,714 (90%)
Rejected	799 (9%)	996 (10%)
Total completed	8,902 (100%)	9,710 (100%)

Table 65: Number of GMP clearance applications received and completed by type from 1 July 2022 to 30 June 2023

Application Category	Applications received	Applications completed
Cancel	5	3
Extend	5,364	4,646
New	1,599	1,321
Reactivate	97	83
Variation	4,451	3,657

Table 66: Number of GMP clearance applications actioned by pathway from 1 July 2022 to 30 June 2023

Pathway	Applications received	Applications completed	Applications Approved	Applications not approved
Compliance Verification	1,927	1,083	1,055	28
Mutual Recognition Agreement	3,390	3,058	2,902	156

12. Recalls

12.1. Medicine recalls

Table 67: Medicine recalls by reason for recall

Reason for recall	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Adverse reactions	2 (2%)	11 (10%)
Foreign matter	4 (5%)	3 (3%)
Illegal supply	1 (1%)	0 (0%)
Impurity	10 (13%)	7 (7%)
Labelling or Instructions	24 (31%)	29 (27%)
Mechanical or Physical defect	4 (5%)	15 (14%)
Microbial/Fungal contamination	6 (8%)	2 (2%)
Observed difference	2 (2%)	3 (3%)
Packaging or closure defect	10 (13%)	9 (8%)
Potency	3 (4%)	3 (3%)
Sterility	3 (4%)	1 (1%)
Variable content	3 (4%)	14 (13%)
Other [a]	6 (8%)	9(9%)
Total	78 (100%)	106 (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 68: Medical device (including IVDs) recalls by reason for recall

Reason for recall	FY 2021-22 Number (% of Total)	FY 2022-23 Number (% of Total)
Adverse incidents	2 (<1%)	3 (<1%)
Diagnostic inaccuracy	25 (4%)	23(4%)
Electrical defect	13 (2%)	14(3%)
Illegal supply	0 (0%)	0 (0%)
Labelling and packaging	115 (17%)	89 (17%)
Mechanical and physical defects	285 (43%)	271 (51%)
Software defects	170 (26%)	87 (16%)
Sterility	11 (2%)	4 (1%)
Other [a]	43 (6%)	45 (8%)
Total	664 (100%)	536 (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 69: Blood recalls

	FY 2021-22	FY 2022-23
Recalls to hospital level	71	54

Table 70: Biological recalls

	FY 2021-22	FY 2022-23
Recalls to hospital level	6	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 principals 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 2022-23 period, the TGA Laboratories relocated to a new, purpose-built facility, designed and built over the preceding three-year period. The new laboratories facility was designed to maximise functionality and future-proof the facility to meet new and emerging testing capacity and capability for ensuring the quality of therapeutic goods. The relocation process required further prioritisation of testing in accordance with the TGA Laboratory's established risk management approach. The testing schedule during this reporting period focussed on high-risk product groups, and delayed testing of lower risk product groups, resulting in a decrease in the overall number of samples tested for the 2022-23 period.

The TGA Laboratories have now completed the testing for the post market review of face masks, which are medical devices. The peak of this testing occurred in previous years. This explains the difference in medical device testing between 2021-22 and 2022-23. Further information regarding this testing can be found on the testing of face masks and respirators webpage.

The 2022-23 reporting period had a decrease in the number of prescription medicines tested. This decrease was due to our efforts focused on the evaluation and release of COVID19 and other vaccines, and the availability of our testing facilities, some of which were impacted by the relocation process.

Compliance with normal testing timeframes has also been affected by the building relocation, as well as ongoing testing efforts in relation to the COVID-19 pandemic.

Table 71: Samples and products tested by type of therapeutic good and percentage which failed

		FY 2021-22	FY 2022-23
Therapeutic good type			
Prescription medicines	Total	900	125
	% fail	2%	2%
OTC medicines	Total	0	34
	% fail	0%	50%
Complementary medicines [a]	Total	53	32
	% fail	9%	6%
Medical devices	Total	1,738	409
	% fail	35%	20%
External [a]	Total	8	7
	% fail	13%	0%
Pacific Medicines Testing Program	Total	26	66
	% Fail	9%	23%
Unregistered [b]	Total	371	401
	% fail	73%	75%
Total samples (excluding AHQ samples)		3096	1074
Total samples [c]		3449	1230
Percentage fail		30%	39%
Total number of products tested [d]		1345	621

[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 72: Samples that failed laboratory testing by reason for July 2022 to June 2023

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Contamination	0	0	0	0	1	0	0	1 (<1%)
Formulation	0	1	3	290	1	0	13	308 (74%)
Label and packaging deficiencies	17	0	0	0	0	0	0	17 (4%)
Performance [a]	63	16	0	0	0	0	1	80 (19%)

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Physical or mechanical properties	0	0	0	0	0	0	1	1 (<1%)
Unregistered	0	0	0	10	0	0	0	10 (2%)
Total	80	17	3	300	2	0	15	417

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

Table 73: Batch release and export certification

Batch releases and certifications	FY 2021-22	FY 2022-23
Batch release [a]	588	649
Export certification [b]	18	18

[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 74: 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 75: Compliance with testing timeframes[a] for July 2022 to June 2023

Therapeutic good type [b]	Priority	Number (% of Total)
Medical devices	Routine	395 (48%)
	Priority	14 (57%)
	Urgent	0 (0%)
OTC medicines	Routine	26 (12%)
	Priority	8 (13%)
	Urgent	0 (0%)
Prescription medicines	Routine	5 (80%)
	Priority	5 (60%)
	Urgent	0 (0%)
Complementary Medicines	Routine	3 (0%)
	Priority	29 (0%)
	Urgent	0 (0%)
Unregistered products	Routine	80 (50%)
	Priority	278(55%)
	Urgent	39 (0%)

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

14. Regulatory Compliance

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.

Table 76: Civil and criminal court proceedings

Criminal and civil court	FY 2021-22	FY 2022-23
Criminal actions commenced	1	1
Criminal actions finalised	2	1
Civil actions commenced	2	2
Civil actions finalised	4	0

14.1. 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 77: Number of compliance actions taken against completed investigations

Completed investigations	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
No offence identified	357 (<4%)	158 (1%)
Goods released under Personal Import Scheme	285 (<3%)	324 (3%)
Referred internally	27 (<1%)	8 (<1%)
Referred to external agency	227 (2%)	179 (2%)
Warning letters issued [a]	8015 (90%)	9,946 (94%)
Infringement notices	74 (<1%)	82 (1%)
Total [c]	8,988 (100%)	10,969 (100%)
Units of goods referred to ABF for destruction [d]	4,195,431	4,848,735

[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.

Table 78: Regulatory compliance investigations by number

Compliance cases [a]	FY 2021-22	FY 2022-23
Cases received	11501	7,908
Cases active [b]	2,213	785
Cases finalised [b]	8625	10,438

[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 79: Regulatory compliance investigations by special interest categories

Compliance investigation category	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
Goods not on the ARTG	21847 (95%)	21,648 (98%)
Goods on the ARTG	151 (1%)	25 (<1%)
Counterfeit product	1079 (5%)	431 (2%)
Total [a]	16,053 (100%)	21,104 (100%)

[a] There can be multiple special interest categories in a single case.

Table 80: Number of offence types related to completed cases

Offence type	FY 2021-22 Number (% of total)	FY 2022-23 Number (% of total)
Import	9237 (90%)	11,197 (95%)
Export	3 (<1%)	6 (<1%)
Counterfeit	716 (8%)	369 (3%)
Manufacture	4 (<1%)	12 (<1%)
Supply	261 (3%)	247 (2%)
Advertising (relating to an import, manufacture or supply case)	4 (<1%)	2 (<1%)
Total completed [a]	9,307 (100%)	11,833 (100%)

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

14.2. 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). Further information relating to advertising compliance is available in the Therapeutic Goods Advertising Compliance Annual Report 2022-23.

Table 81: Reports of alleged advertising non-compliance volumes

Compliance cases [a]	FY 2021-22	FY 2022-23
Reports received	3,113	3,064
Cases created [b]	3,061	3,273
Cases finalised [b]	2,348	3,450

[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 82: Compliance actions recorded

Action taken	FY 2021-22	FY 2022-23
Assessed - no further action [a]	718	1,589
TGA requested removal of advertising [b]	0	16,328
Warning letter sent [C]	376	256
Infringement notice issued	99	228
Referred within or outside of the TGA	11	78
Direction notice issued	1	4
Enforceable undertaking entered	1	1

[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

15. Pharmacovigilance Inspection Program

Table 83: Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified

	FY 2021-22	FY 2022-23
Total inspections completed	10	9
Total inspections with deficiencies	10	9

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 84: GCP Inspection Program inspections undertaken and deficiencies identified

	FY 2021-22	FY 2022-23
Total inspections completed		7
Total inspections with deficiencies		7

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 Shortages

Table 85: Number of medicine shortage reports [a] by shortage reason

	FY 2021-22	FY 2022-23
	Number (% of Total)	
Shortages Reported		
New – Commercial changes	37 (3%)	46 (3%)
New – Discontinuation	177 (15%)	168 (12%)
New – Manufacturing related	666 (56%)	827 (59%)
New – Product recall	5 (<1%)	6 (<1%)
New – Unexpected increase in demand	135 (11%)	180 (13%)
New – Unexpected increase in demand due to other sponsors unable to supply	42 (4%)	55 (4%)
New – Transport / Logistic issues / Storage capacity issues	122 (10%)	110 (8%)
New – Seasonal depletion of stock	6 (<1%)	6 (<1%)
Total	1,190 (100%)	1,398 (100%)

[a] New reports only, does not include updates of previously reported shortages.

Table 86: Number of medicine shortage notifications received

Notifications received	FY 2021-22	FY 2022-23
New	1,190	1,398
Update [a]	3,386	3,807
Total	4,576	5,205

[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.

18. Serious Scarcity Substitution Instruments (SSSIs)

Under section 30EK of the *Therapeutic Goods Act 1989*, the Minister for health 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.

Serious Scarcity Substitution Instruments (SSSIs) allow community pharmacists to substitute specific medicines without prior approval from the prescriber if the permitted circumstances within the SSSI are met.

Table 87: Number of SSSI's made

	FY 2021-22	FY 2022-23
Number of SSSIs made	4	5

Table 88: Serious Scarcity SSSI's table of Alerts

Issue date	Alert	Scarce Medicine(s)	Serious Scarcity Substitution Instrument	Duration of SSSI
5/12/2022	Substitution allowed to address shortage of amoxicillin	A registered medicine that contains: • amoxicillin 100 mg/mL in a 20 mL suspension • amoxicillin 500 mg/5 mL in a 100 mL suspension • amoxicillin 125 mg/5 mL in a 100 mL syrup or suspension • amoxicillin 250 mg/5 mL in a 100 mL syrup or suspension • amoxicillin 500 mg capsules • amoxicillin 1 gram tablets	Therapeutic Goods (Serious scarcity and substitutable medicine) Amoxicillin instrument 2022	6 Dec 2022 to 31 May 2023
20/12/2022	Substitution allowed to address shortage of Cefalexin	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 • cefalexin 500 mg capsules	Therapeutic Goods Cefalexin Instrument 2022	21 Dec 2022 to 31 July 2023
16/03/2023	Substitution instrument to address the shortage of Coumadin warfarin 5mg tablets	COUMADIN warfarin sodium 5mg tablet (AUST R: 42279)		
14/04/2023	Substitution allowed to address shortage of phenoxymethylpenicillin	• PHENOXYMETHYLPENICILLIN-AFT phenoxymethylpenicillin (as potassium salt) 125mg/5ml powder for oral liquid bottle (AUST R 159753) • CILICAINE V phenoxymethylpenicillin (as benzathine) 150mg/5mL oral liquid, suspension bottle (AUST R 151598) • PHENOXYMETHYLPENICILLIN-AFT phenoxymethylpenicillin (as potassium salt) 250mg/5ml powder for oral liquid bottle (AUST R 159754)	Therapeutic Goods Serious Scarcity and Substitutable medicine PHENOXYMETHYLPENICILLIN instrument 2023	17 April 2023 to 30 Sept 2023
28/04/2023	Substitution allowed to address shortage of cefaclor	• KEFLOR cefaclor 125mg/5mL (as monohydrate) powder for oral liquid bottle (AUST R 58651); • CECLOR cefaclor 125mg/5mL (as monohydrate) powder for oral liquid bottle (AUST R 54899) • KEFLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle (AUST R 58653); • CECLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle (AUST R 347593)	Therapeutic goods (Serious scarcity and substitutable Medicine), Cefaclor instrument 2023	1 May 2023 to 30 September 2023

18.1. Section 19A approvals

Section 19A of the *Therapeutic Goods Act 1989* provides the legislative basis for the Secretary of the Department of Health 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 2021-22	FY 2022-23
New	89	75
Renewals	52	65
Total	141	140