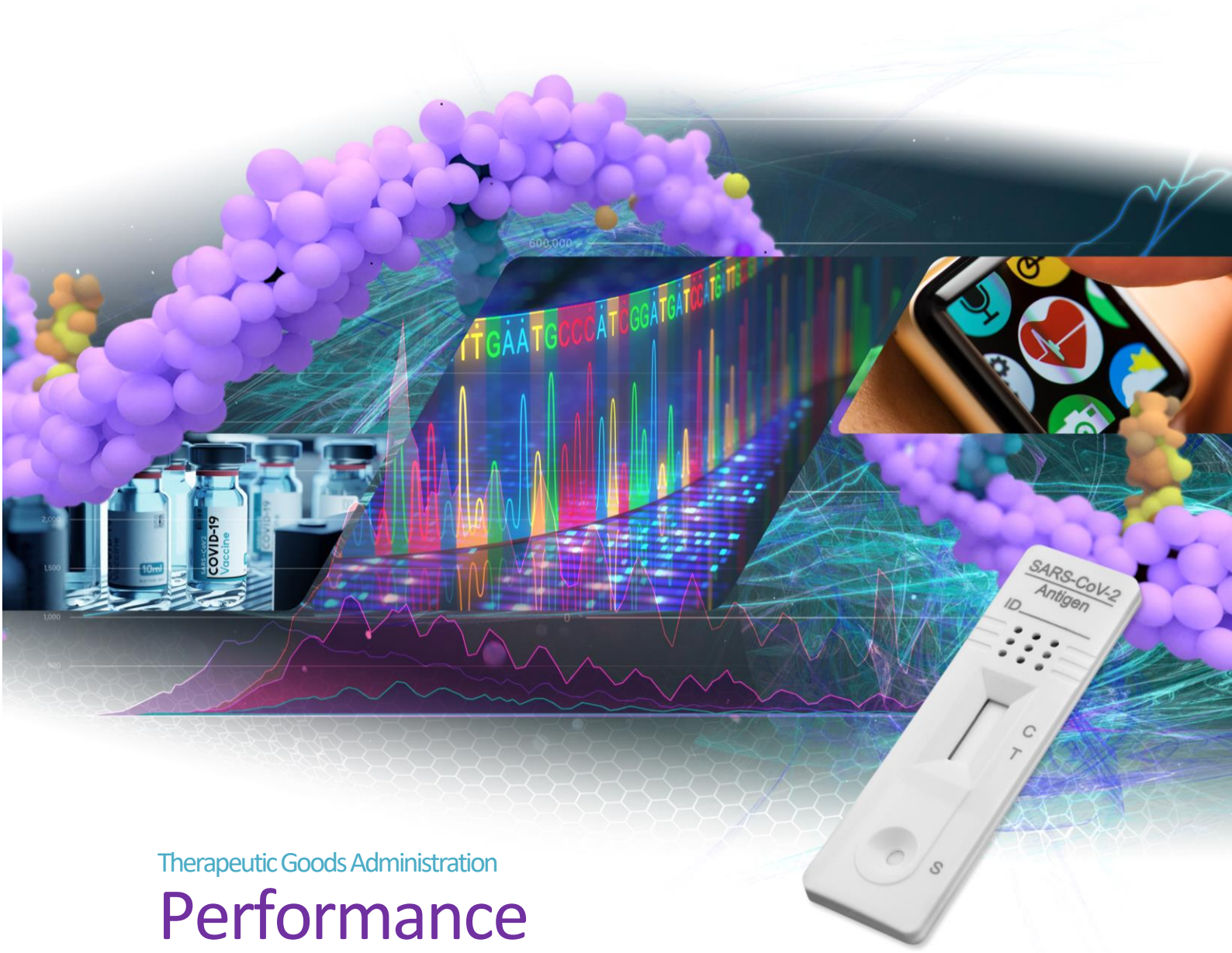
Australian Government

Department of Health

Therapeutic Goods Administration



Therapeutic Goods Administration

Performance statistics report

2020-21

Contents

About the Therapeutic Goods Administration

The Australian Government Department of Health, through the Therapeutic Goods Administration (TGA), is responsible for assessing whether therapeutic goods available for supply in Australia are safe and fit for their intended purpose.

Products for which therapeutic claims are made are assessed by the TGA and entered on the Australian Register of Therapeutic Goods (ARTG). At 30 June 2021 there were 93,545 therapeutic goods on the ARTG, including 9,490 new products added during the reporting period. All therapeutic goods registered on the ARTG can be lawfully manufactured and supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices.

The TGA regulates the supply of:

- medicines prescribed by a doctor or dentist
- medicines available from behind the pharmacy counter
- medicines available in the general pharmacy
- medicines available from retail outlets
- complementary medicines, such as vitamins, herbal and traditional medicines
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- products used to test for various diseases or conditions (in vitro diagnostic devices (IVDs)), such as blood tests
- vaccines, blood products, and other biologicals.

We play a regulatory role in overseeing the manufacturing process and advertising of therapeutic goods. We support compliance with the regulatory framework, working with state, territory and federal counterparts to remove unsafe/non-compliant therapeutic goods from the Australian market.

More information about how therapeutic goods are regulated in Australia can be found on our website (www.tga.gov.au).

Executive Summary

Each year we provide information about our regulatory performance through the *TGA Annual Performance Statistics Report* and the *Half Yearly Performance Snapshot*. We also report annually on our performance against the *Regulator Performance Framework* through the *TGA Self-Assessment (Key Performance Indicators) Report*.

The statistics contained within this report cover the period 1 July 2020 to 30 June 2021 and contribute to annual publications that track our progress against the priorities we have established for the financial year.

Performance Highlights

Notable performance changes

Medical devices

- There was a significant increase in COVID-19 related device and disinfectant applications which affected processing times for device applications. Processing times were longer than in previous years but remained within legislated timeframes.
- We received and responded to 32,374 medical device enquires in 2020-21. This was made up of 8,923 calls and 23,751 emails.

Medicines

Prescription medicines

- There was a notable decrease in median approval times for prescription medicine applications in the 2020-21 period (77 days in 2020-21 compared to 135 days in 2019-20), largely due to the expedited evaluation timeframes for COVID-19 vaccines and treatments.

Over-the-counter medicines

- The number of new product applications received in 2020-21 (236) was 9% higher than in 2019-20 (216).
- The number of applications received to vary existing medicines decreased substantially, from 1026 in 2019-20, to 731 in 2020-21. This was primarily due to a large drop in low risk C2 variation applications, from 615 to 349, due to cessation of the transition period for updating of labelling to comply with Therapeutic Goods Order No. 92.
- We approved 197 new over-the-counter medicine applications (N1 to N5[a]) during this period, compared to 167 in 2019-20.
- We approved 572 applications to vary existing medicines during this period compared to 915 in 2019-20.
- The percentage of applications processed within target time was at or greater than 80% for N2 new product applications and C1 and C2 variation applications.
- We received and processed a significantly higher number of requests (81) for consent to supply under s 14/14A of the Act during this period compared with 2019-20 (7).

[a] The categorisation of over-the-counter medicine applications is described in Table 11.

Registered complementary medicines

- We approved 9 new registered complementary medicine applications during this period, which is same as the number approved during 2019-20.
- We approved 71 Registered Complementary Medicine variation applications during this period which is double the number approved 2019-20. The majority of applications were for label variations to comply with the Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.
- All applications were completed within legislated timeframes.

Assessed listed medicines

- We approved the first and second assessed listed medicine applications during this period. We refused one assessed listed medicine application.
- All applications were completed within legislated timeframes.

Listed medicines

- The number of new listed medicine submissions in this period was 2184 which is an increase from the same period in 2019 (1893).
- We completed processing of a significantly higher number of requests (39) for consent to supply under s14/14A of the Act during this period compared with 2019-20 (24).

Unapproved medicines

- We received an increased number of Special Access Scheme Category B (SAS B) and Authorised Prescriber applications for medicines during this period, primarily due to an increase in applications for unapproved medicinal cannabis products which are approved on a per product basis.
  - We saw a 76% increase in SAS B applications to 106,140 applications during this period, compared with 60,289 applications during the same period in 2019-20.
  - We saw a 370% increase in Authorised Prescriber applications to 5,087 applications during this period, compared with 1,071 applications during the same period in 2019-20.
- We saw a marked decrease in Special Access Scheme Category B applications for unapproved biological products this period. We received 501 applications during this period, compared with 1,036 during the same period in 2019-20. It is possible that the re-categorisation of some biologicals to the Category C notification type contributed to the observed Category B decrease.

Impacts of COVID-19

Medical devices

- The TGA prioritised and expedited applications for medical devices, including in vitro medical devices (IVDs), intended for the prevention, detection and/or treatment of COVID-19. These applications underwent full regulatory assessments, some being approved with specific conditions.
- TGA published COVID-19 related fact sheets to help increase consumer awareness and knowledge, as well as guidance and videos to support new manufacturers about COVID-19 tests, face masks, disinfectants, thermometers, ventilators and thermal scanners.

- We have seen a sustained increase in medical device applications in response to the COVID-19 pandemic, 6,300 medical devices were included in the ARTG from 1 July 2020 to 30 June 2021.
- 99 COVID-19 tests were approved for supply during 1 July 2020 to 30 June 2021.
- Significant numbers of new sponsors and manufacturers continue to seek to supply disinfectants in response to the pandemic. The TGA has approved 160 applications making specific COVID-19 claims.
- There was a slight increase (8%) in recall actions for medical devices (including IVDs). This increase primarily related to TGA's post-market review of face masks and respirator products. Manufacturing anomalies at a sterilisation facility also contributed to the increased recall actions.

Laboratory testing

- TGA Laboratories staff were directly involved in providing advice and developing strategies around various pandemic-related issues, specific examples being vaccines, hand sanitisers, ventilators, disinfectants, and PPE, as well as assisting other areas of the Australian Government.
- The 2020-21 reporting period saw a significant rise in the number of medical devices tested. This was predominantly due to the testing of face masks and respirators included on the ARTG.

Medicines

Provisional determinations

- Three COVID-19 vaccines were provisionally approved in this period following a rolling submission process. The Pfizer COVID-19 vaccine was approved in 54 days (working days from dossier acceptance to registration decision). The AstraZeneca COVID-19 vaccine was approved in 48 days and the Janssen COVID-19 vaccine was approved in 136 days.

Medicine shortages and discontinuations

- The increase in demand for medicines that occurred at the beginning of the COVID-19 pandemic has gradually stabilised. The average monthly total of new national medicine shortages published on the TGA website during 2020-21 was largely consistent with the previous year's average.
- The TGA published 8 Serious Shortage Substitution Notices during this reporting period. The Notices, when adopted into state and territory legislation, allowed a pharmacist to supply a specific substitute medicine to a patient when a medicine was in shortage, without the prior approval from the prescriber.
- The TGA continued to monitor any potential effects on medicine supply into Australia associated with global outbreaks including:
  - Continued modelling of COVID-19 intensive care unit medicines availability through the establishment of a new Medicine Availability Working Group.
  - Working with sponsor peak bodies to receive early intelligence about potential supply chain disruptions.
  - Working with pharmaceutical wholesalers under Australian Competition and Consumer Commission authorisation to constrain supply to facilitate equitable access to important medicines in short supply.

Over-the-Counter Medicines

- The COVID-19 pandemic has resulted in increased usage and demand for some OTC medicines, particularly hand sanitisers and paediatric paracetamol preparations.
- An exemption for specified hand sanitisers was established in March 2020 to facilitate the urgent supply of hand sanitisers in Australia due to the increased demand. Specified hand sanitisers have been excluded from TGA regulation provided they contain only particular ingredients in particular quantities, comply with certain manufacturing practices, and comply with certain advertising, labelling and presentation requirements.
- The increased usage and demand for some crucial OTC medicines adversely affected supply due to impacts on overseas manufacturers, and shortages of ingredients and packaging materials.
- The significant increase in enquiries and the redirection of resources has impacted the performance statistics for some OTC medicine application levels. For N1, N3, N4, N5, C3 and C4 applications, the percentage of applications processed within the target time was below 80%.
- COVID-19 impacted the ability of the pharmaceutical industry to implement new medicine labels that complied with TGO 92, which came into force 1 September 2020. The TGA established a temporary process for sponsors to request consent to supply non-compliant products. In this period, we received a total of 135 applications for consent to supply such products.

Listed and Registered Complementary Medicines

- The number of compliance reviews that were completed in this period (76) was lower than for the same period last year (195). This was mainly due to the diversion of resources to respond to COVID-19, and a greater focus on complex enforcement actions in relation to serially non-compliant sponsors.

Medicine and Vaccine Adverse Event Reports

- Since the commencement of the Australian Government's COVID-19 vaccine roll-out in February 2021, TGA has been closely monitoring COVID-19 vaccine safety to identify issues requiring investigation and possible regulatory action, through enhancements to the existing robust vaccine safety monitoring system, including:
  - Promotion of adverse event reporting to consumers and health professionals and greater accessibility of reporting channels (through an improved online reporting form, extended hours for the NPS Adverse Medicine Events Line, and IT enhancements to streamline information transfer between TGA and state and territory public health units). This has led to a 2.4-fold increase in the number of adverse event reports received this year compared to last year.
  - Robust and rapid signal detection and investigation, based on knowledge of vaccine baseline safety profiles, internationally accepted case definitions for adverse events of special interest and population background rates.
  - Collaboration and information sharing with expert bodies including international medicines regulators and state and territory Jurisdictional Immunisation Coordinators to obtain rapid and detailed safety information.
- Throughout 2020-21, the TGA has rapidly issued communications in response to significant emerging safety concerns to inform clinical practice through web statements, media releases and department spokespeople. We have worked with vaccine and medicine sponsors to update the approved Product Information for the COVID-19 vaccines, as well as all other medicines and vaccines on the ARTG, with new safety information for health professionals.

Good Manufacturing Practice

- The TGA performed priority assessments to approve 49 overseas manufacturers to support the quality and timely supply of COVID-19 vaccines and treatments.
- The onsite/remote/hybrid inspection process continued for domestic inspections and in August 2020 a remote overseas inspections process was introduced.
- The Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for medicinal products (version 14) was adopted by the TGA on 1 July 2020. GMP describes the principles and procedures that when followed helps ensure that therapeutic goods are of high quality. A transition period was provided to allow manufacturers time to implement the new requirements, with full compliance expected from 30 June 2021.
- In November 2020, the TGA published the GMP Annual Report 2019-20 providing further details of activities in stakeholder engagement, regulatory activity and operational changes in relation to GMP.

International collaborations

- Since August 2020 the TGA, as Vice Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) and Chair of the Centre for Innovation in Regulatory Sciences (CIRS) Scientific Advisory Board, has co-chaired the ICMRA COVID-19 Vaccine Pharmacovigilance Network with the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). Participants included other international regulators such as the European Medicines Agency, US Food and Drug Administration and New Zealand Medsafe, as well as the World Health Organization (WHO).
- We have also participated in the Access Consortium's COVID-19 Vaccines & Therapeutics Working Group pharmacovigilance subgroup since its establishment in February 2021. This group, which included Health Canada, Singapore Health Sciences Agency (HSA), Switzerland Swissmedic and the UK MHRA, met for detailed discussion and information sharing regarding emerging safety signals.
- The TGA exchanged detailed written information on emerging safety signals with its trusted international regulatory counterparts throughout 2020-21 via the International Post-market Surveillance Teleconference, including Medsafe, USFDA, Health Canada, HSA, Swissmedic and the MHRA.
- We also met monthly with Medsafe throughout 2020-21 to discuss in detail, emerging safety signals for both medicines and vaccines.

Regulatory compliance

- In January 2021, Australian Border Force (ABF) referrals to the TGA on unregulated COVID-19 related imports started to decline. These goods included PPE facemasks, COVID-19 IVD test kits and antibiotic and antiviral medicines. However, by April 2021 referrals began increasing. This trend was observed during the INTERPOL-led Operation Pangea XIV in May 2021, when 450 unapproved medicines and medical devices were detected at international mail facilities.
- During the year, a review of the Therapeutic Goods Advertising Code was commenced, and public consultation completed. A legal permission, allowing the advertising of COVID-19 vaccines subject to certain conditions, was also put in place in support of the national vaccination program.
- In May 2021, the TGA released guidance on the management of GMP compliance signals associated with the manufacture of medicines and biological products at Australian and overseas manufacturing sites.

Reforms

Complementary and OTC Medicines

- A data protection scheme for assessed listed medicines was implemented. Assessed listed medicine applications with a new therapeutic use for an existing permitted ingredient can be granted five years data protection for clinical trial data supporting the new use. This scheme provides incentives for innovation for the Australian complementary medicines industry by preventing competitors from seeking market authorisation of generic forms of an assessed listed medicine by relying on data generated by the originator.
- As of 5 March 2021, listed medicines can only use permitted indications included in the Therapeutic Goods (Permissible Indications) Determination. This provides a single exclusive list of pre-approved indications permitted for use in listed medicines that sponsors must use when applying to list their medicine in the ARTG. The permitted indications list helps ensure that sponsors do not overstate the therapeutic benefits of their products and provide greater protection for consumers from misleading health claims.
- Certain sports supplements were clarified to be medicines rather than food by making a declaration under section 7 of the *Therapeutic Goods Act 1989* to ensure that sports supplements are regulated commensurate with their risk and that, where safety concerns arise, appropriate regulatory action can be taken in a timely manner. The products declared to be medicines are those that are used, advertised or presented for supply to improve or maintain physical or mental performance in sport, exercise or other recreational activity (therapeutic use) and either contain higher risk ingredients (e.g. ingredients scheduled in the Poisons Standard); and/or are presented in dosage forms of tablet, pills or capsules. The declaration came into effect on 30 November 2020 for products with ingredients identified in the declaration. For sports supplements presented as tablets, pills or capsules there is a 3-year transition period.
- Enhancements were implemented to the TGA Business Services Portal to provide the capability for sponsors of relevant non-prescription medicines and some biologicals to electronically lodge Product Information and Consumer Medicine Information documents.

Prescription medicines

- Opioid reforms continued with more than 200 Product Information statements updated to include boxed warnings, class statements and revised indications.
- We introduced a new standard for serialisation of medicines and use of data matrix codes. The Therapeutic Goods (Medicines - Standard for Serialisation and Data Matrix Codes) (TGO 106) Order 2021 will commence on 1 January 2023 to provide clarity for adopters of serialisation and data matrix codes on medicines supplied in Australia.
- From January 2021, the TGA commenced publishing details of major innovator medicine applications that are under evaluation by the TGA. Information about the potential future availability of new medicines, new uses for existing medicines and new combinations is published on the TGA website. This change provides health practitioners and their patients the opportunity to discuss new treatment options.

Biologicals

- The regulation of faecal microbiota transplant (FMT) products as biologicals commenced on 1 July 2021, which includes the new Therapeutic Goods Order No. 105 – Standard for Faecal Microbiota Transplant Products (TGO 105).

Recalls

- There was a significant increase (58%) of recall actions performed for medicines. This was primarily due to a large number of recalls performed following reviews of the safety of certain ingredients in listed medicines, including Fallopia multiflora and Artemisia.
- In November 2020, the TGA published a report providing details of recalls activity, highlighting the important contribution of this function to the regulation of therapeutic goods.

Medicine shortages and discontinuations

- During this period, the TGA has implemented multiple reforms following recommendations from the Medicine Shortage Working Party in December 2019, including:
  - Reforms to improve the accuracy, timeliness and reach of medicine shortages information for consumers and health professionals. These included changes to the IT system for reporting shortages and how information is displayed on the TGA website, mandatory publishing of all current shortages and discontinuations, and formation of a Medicine Shortages Communication Champions group.
  - Amendments to the *Therapeutic Goods Act 1989* passed in February 2021 to allow pharmacists to dispense a specified substitute medicine in place of a medicine in 'serious scarcity', without prior approval from the prescribing doctor, formalising the national implementation of Serious Substitution Shortage Notifications (SSSN) that were in operation from May 2020.
  - Monitoring for shortages using data supplied by pharmaceutical wholesalers and forecasting supply at a national and jurisdictional level through a coordinated approach with states and territories.

Endorsement of an ongoing program of GCP inspections

- In October 2020 the Government endorsed the implementation of an ongoing GCP clinical trials inspection program.

Medical Device Reforms

- Steady progress was made on implementing the *Action Plan for Medical Devices,* in parallel with preparing for the flow-on implications of sweeping changes that commenced on 26 May 2021 in Europe. A report card detailing the achievements was published on TGA's website. Since the medical device reforms began, more than 21 consultations, and over 26 pieces of guidance have been published, with ongoing workshops and stakeholder engagement meetings about the reforms occurring. Key regulatory changes that commenced during 2020-21 included:
  - the Personalised Medical Devices (PMD) Framework on 25 February 2021, which introduced new rules for how medical devices manufactured to suit individuals were regulated, including custom-made devices and clarifying some exemptions
  - new arrangements for software based medical devices on 25 February 2021, that clarified a range of software products to be 'carved out'; new classification rules more clearly expressed the requirements for software-based medical devices. A classification tool was developed and published to support the Framework.
  - remaking of the Therapeutic Goods (Excluded Purposes) Specification 2020 on 1 October 2020, to allow a limited number of self-tests to be available in Australia where the tests can be safely administered and demonstrate particular benefits to the public or individual health.

- We published a range of consumer-focused fact sheets and updated materials on our dedicated information hubs for breast implants and urogynaecological surgical mesh. We simplified online reporting forms, making it easier for consumers and healthcare practitioners to report adverse events to the TGA.
- Outcomes from consultations were published on our website, including for
  - changes to requirements for medical device systems or procedure packs
  - assistive technology aids for people with a disability
  - enhancements to post market processes.
- Legislation to establish an Australian Unique Device Identification database (AusUDID) was passed in February 2021 and development of the UDI database commenced. Whilst the introduction of a UDI is a regulatory requirement, if used in the healthcare setting, can assist to identify specific medical devices, including through supply chains to identify and record information to help track and trace medical devices, including if the identifier is stored in patient records.
- From 1 July 2021, organisations can apply to become an Australian conformity assessment body (Australian CAB) for medical devices. An Australian CAB needs to demonstrate competency and recognition in medical device product assessments and quality management system auditing and may assist medical devices to be supplied earlier in Australia. The TGA remains responsible for including medical devices in the ARTG.
- Urogynaecological mesh devices that were not able to meet stricter clinical and safety requirements by 1 December 2020 were cancelled from supply.

Processing and Approval Times

Processing and approval times are defined as the number of working days from the acceptance of an application until formal notification of decision, unless otherwise specified. These exclude times where we were unable to progress the application due to waiting for:

- the sponsor to provide additional information;
- the payment of fees; or
- a 'mutual clock stop' period, agreed with the applicant or unless otherwise specified.

Under the Act, TGA working days also excludes public holidays and weekends. The timeframes applicable to many of our activities are mandated by legislation. For other activities we conduct we self-impose target timeframes, to ensure that we perform our functions efficiently and in a timely manner. Target timeframes are subject to ongoing review.

1. Prescription Medicines

Applications to register new or vary existing prescription medicines are accompanied by supportive scientific data and evaluated, with timeframes underpinned by legislation and/or 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

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 2020 to June 2021

	Number			
Application Type	Approved	Withdrawn	Rejected	Total (% Approved)
Category 1				
A: New chemical entity/New biological entity/Biosimilar[a]	42	3	0	45 (93%)
B: New fixed-dose combination	5	0	0	5 (100%)
C: Extension of indication	48	3	0	51 (94%)
D: New generic medicine	78	5	1	84 (93%)
F: Major variation	46	2	0	48 (96%)
G: Minor variation[b]	3	0	0	3 (100%)
H: Minor variation[c]	6	2	0	8 (75%)
J: Changes to Product Information	129	2	0	131 (99%)
T: Provisional registration extension [T]	1	0	0	1 (100%)
Comparable Overseas Regulator (COR) – A				
A: New chemical entity/New biological entity/Biosimilar	0	1	0	1 (0%)
G: Minor variation	1	0	0	1 (100%)
J: Changes to Product Information	1	0	0	1 (100%)
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/Biosimilar	3	0	0	3 (100%)
C: Extension of indication	1	0	0	1 (100%)
D: New generic medicine	5	0	0	5 (100%)
Minor Variations				
Category 3				
G: Minor variation[b]	71	3	0	74 (96%)
H: Minor variation[c]	1,454	25	0	1,479 (98%)
Correction [9D(1)]	340	34	0	374 (91%)
Additional trade name [ATN]	23	0	0	23 (100%)
Extension of Indications - Generic	8	0	0	8 (100%)
Internal Review	2	0	0	2 (100%)
Minor editorial change [MEC]	344	2	0	346 (99%)
Notification	1,631	27	0	1,658 (98%)
Self-assessable request [SAR]	807	12	0	819 (99%)
Safety-related request [SRR]	1,045	19	0	1,064 (98%)
Total	6,095	140	1	6,236 (98%)

[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.
[c] The minor variations (type H) refer to applications to change the formulation, composition or design specification or the container for the goods or any other attribute that results in the goods being separate and distinct. These 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

	2019-20	2020-21
	July to June	
Consent to supply/import/export when not conforming to a standard [S.14 and S.14A]	**Number (% of Total)**	
Approved	93 (100%)	170 (100%)
Rejected	0 (0%)	0 (0%)
Total (excluding withdrawals)	93 (100%)	170 (100%)

1.2. Approval times

Table 3 Prescription medicine application approval time for July 2020 to June 2021

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]	38	255	183	195	5 - 305
B: New fixed-dose combination	5	255	207	197	186 - 231
C: Extension of indication[b]	41	255	185	194	68 - 240
D: New generic medicine	78	255	153	148	121 - 253
F: Major variation	46	255	158	170	21 - 250
G: Minor variation	3	255	110	139	24 - 166
H: Minor variation	6	255	153	137	108 - 207
J: Changes to Product Information requiring the evaluation of data	129	255	112	111	8 - 253
T: Provisional registration extension	1		37	37	37 - 37
Comparable Overseas Regulator (COR-A)					
G: Minor variation	1	120	124	124	124 - 124
J: Changes to Product Information requiring the evaluation of data	1	120	111	111	111 - 111
Comparable Overseas Regulator (COR-B)					
A: New chemical entity/New biological entity/Biosimilar	3	175	160	166	148 - 167
C: Extension of indication	1	175	173	173	173 - 173
D: New generic medicine	5	175	138	145	112 - 163

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

Table 4 Prescription medicine median approval time comparisons between 2019-20 and 2020-21

Application type	Legislated timeframe	Median approval time (TGA working days)	
		2019-20	2020-21 (% Change)
Category 1			
A: New chemical entity/New biological entity/Biosimilar[a]	255	196	195 (▼ 1%)
B: New fixed-dose combination	255	184	197 (▲ 7%)
C: Extension of indication[b]	255	186	194 (▲ 4%)
D: New generic medicine	255	159	148 (▼ 8%)
F: Major variation	255	186	170 (▼ 9%)
G: Minor variation	255	220	139 (▼ 37%)
H: Minor variation	255	112	137 (▲ 22%)
J: Changes to Product Information requiring the evaluation of data	255	123	111 (▼ 9%)
Comparable Overseas Regulator (COR) – A			
A: New chemical entity/New biological entity/Biosimilar	120	109	117 (▲ 7%)
Comparable Overseas Regulator (COR) – B			
A: New chemical entity/New biological entity/Biosimilar	175	168	166 (▼ 1%)
C: Extension of indication	175	165	173 (▲ 5%)
D: New generic medicine	175	164	145 (▼ 12%)
F: Major variation	175	148	0 (-)
Minor Variations			
Category 3			
G: Minor variation[c]	45	38	38 (▲ 0%)
H: Minor variation[d]	45	32	35 (▲ 9%)
Additional trade name [ATN]	45	30	18 (▼ 38%)
Extension of Indications - Generic	45	38	36 (▼ 5%)
Safety-related request [SRR]	N/A	37	33 (▼ 11%)
Self-assessable request [SAR]	45	39	36 (▼ 8%)
Minor editorial change [MEC]	45	34	32 (▼ 6%)
Correction [9D(1)]	N/A	74	173 (▲ 116%)

[a] Application type A figures do not include submissions processed via the priority review pathway.
[b] Application type C figures do not include submissions processed via the priority review pathway.
[c] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry.
[d] The minor variations (type H) refer to applications to change the formulation, composition or design specification or the container for the goods or any other attribute that results in the goods being separate and distinct. These 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.

Figure 1 Mean approval times (TGA working days) for submissions [a] by pathway 2018-19 [b] and 2019-20

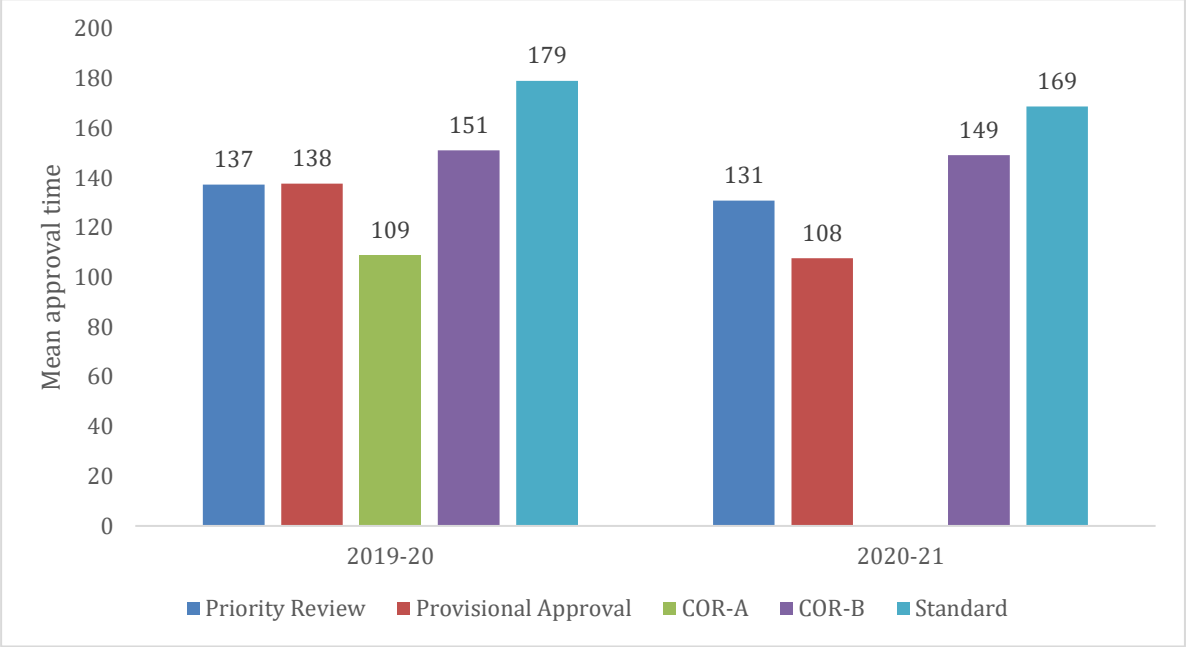
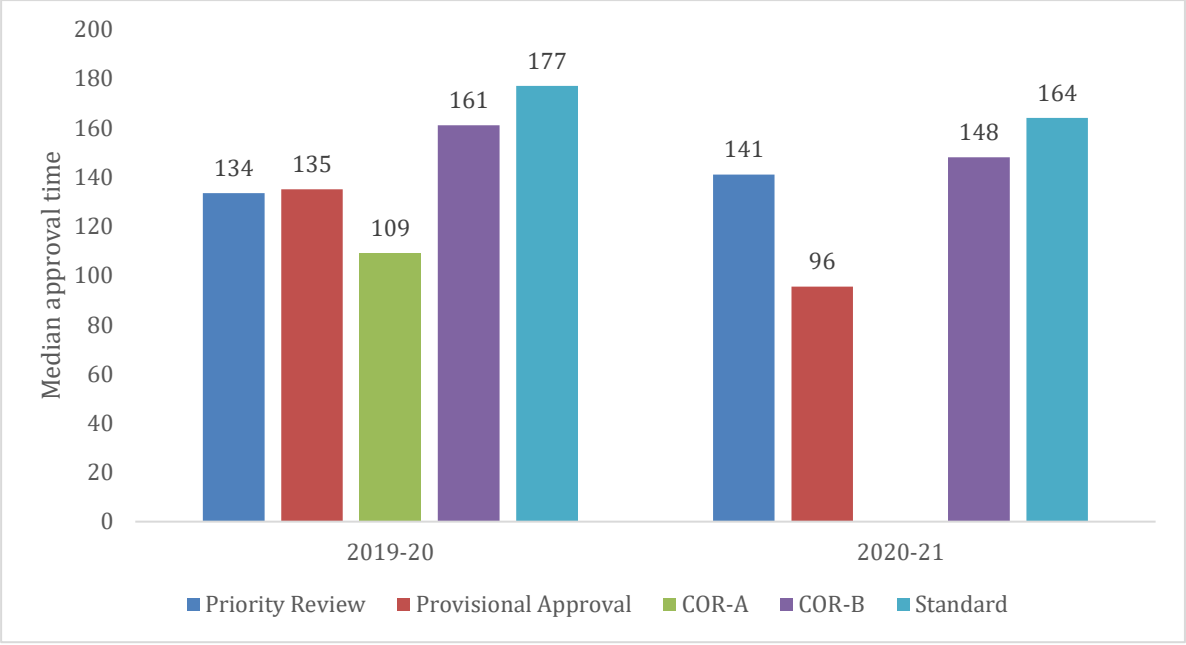


Figure 2 Median approval times (TGA working days) for submissions [a] by pathway 2019-20 [b] and 2020-21



[a] For new chemical entities, new combinations, extension of indications, new generic medicines and major variations. During these periods, volumes of submission approvals for 2019-20 and 2020-21 were: standard - 223 and 202, priority review - 6 and 11, provisional approval - 10 and 6, COR-A - 2 and 0 and COR-B - 8 and 9, respectively.

[b] No COR-A for the reported types were reported in 2020-21.

1.3. Orphan drug designations

The objective of the orphan drug program is to provide an incentive to sponsors to bring medicines for a small population to market and make medicines available to Australian patients who may not otherwise be able to access them. The program incentive is a 100% waiver of TGA fees for application and registration. Designation is a formal process that allows us to make a decision

regarding whether a medicine is eligible for orphan drug designation. This precedes the registration application. The eligibility criteria aim is to focus the program on the greatest unmet need. A prescription medicine must have a valid orphan drug designation at the time of application to be eligible for a waiver of application and evaluation fees.

Table 5 Number of orphan drug designations

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	22 (76%)	18 (58%)
C: Extension of indications	6 (21%)	10 (32%)
F: Major variation	1 (3%)	1 (3%)
Unknown yet	N/A	2 (6%)
Total	29 (100%)	31 (100%)

Table 6 Number of orphan drug registrations

Orphan drug registrations and approval times quoted in Table 6 are also included in the total number of applications reported in each respective application category in the tables and figures below.

	2019-20		2020-21	
	July to June			
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	12 (57%)	184	15 (75%)	170
C: Extension of indications	9 (43%)	175	2 (10%)	111
F: Major variation	0 (0%)	N/A	3 (15%)	180
Total	21 (100%)	181	20 (100%)	172

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. The flexible approach 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 7 Number of priority review determinations granted

	2019-20	2020-21
	July-June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	6 (60%)	3 (23%)
C: Extension of indications	4 (40%)	7 (54%)
S: Provisional registration to full registration	N/A	2 (15%)
Unknown yet	N/A	1 (8%)
Total	10 (100%)	13 (100%)

Table 8 Number of medicines approved through the priority review pathway[a]

	2019-20		2020-21	
	July to June			
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	5 (83%)	137	4 (36%)	134
C: Extension of indications	1 (17%)	105	7 (64%)	141
Total	6 (100%)	133	11 (100%)	133

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

1.5. Provisional approval pathway

The provisional approval pathway supports patient access to vital and lifesaving prescription medicines years 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 9 Number of provisional determinations granted

	2019-20	2020-21
	July-June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	4 (40%)	12 (67%)
C: Extension of indications	6 (60%)	6 (33%)
Total	10 (100%)	18 (100%)

Table 10 Provisional approval registrations

	2019-20		2020-21	
	July-June			
	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	4 (40%)	199	6 (86%)	96
C: Extension of indications	6 (60%)	68	0 (0%)	N/A
T: Provisional registration extension	0 (0%)	N/A	1 (14%)	37
Total	10 (100%)	135	7 (100%)	77

2. Over-the-Counter Medicines

Over-the-counter 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 and the key application criteria.

Table 11 Categorisation of OTC medicine applications

Application category	Definition	Timeframe in days
N1	An application submitted as a 'clone'.	45 working days
N2	An application which complies with an OTC medicine monograph.	55 working days
N3	New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4.	150 working days
N4	An application for a 'generic' medicine where the medicine: requires supporting safety and/or efficacy (clinical/toxicological) data or a justification for not providing such data; and/or requires a higher level of assessment due to the umbrella branding segment of the product name; and/or has not been previously registered as an OTC medicine following down-scheduling.	170 working days
N5	An application for a new product that is an extension to a 'generic category' product or an application for a product containing a new chemical entity as an active ingredient.	210 working days
CN	'Notification' changes, where their implementation would not impact the quality, safety or efficacy of a medicine. Includes quality and non-quality changes classified as 'negligible risk'.	N/A (Automated validation and approval)
C1	Quality and non-quality changes classified as 'negligible risk'.	20 working days
C2	Quality and non-quality changes classified as 'low risk' – no safety and/or efficacy data required; quality data may be required.	64 working days
C3	Quality and non-quality changes classified as 'low risk' – safety and/or efficacy data required unless justified; quality data may be required. Umbrella branding segment of new name requires a higher level of assessment.	120 working days
C4	Non-quality changes classified as 'moderate risk' – safety and/or efficacy data required unless justified.	170 working days
B1	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that does not contain clinical data.	20 working days
B3	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that contains clinical data or a justification as to why such data is not needed.	120 working days
Requests for consent under section 14/14A of the Act	Request for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard.	N/A

2.1. Approval times

We aim to have 80% of applications completed within target timeframes. The following target timeframes apply to OTC medicine applications:

Table 12 Median approval time for OTC medicine applications

	2019-20	2020-21
	July to June	
New medicine applications (days)		
N1	20	38
N2	0.5	37
N3	104	90
N4	159	126
N5	113	223
Change applications (days)		
C1	6.5	7
C2	29	40
C3	N/A	88
C4	75	318

Table 13 OTC medicine approval time against target time by application category for July 2020 to June 2021

Application type	Number completed (% of Total)	Range	Mean	Median	% within target
New medicines					
N1	101 (51%)	1-82	35	38	79
N2	19 (10%)	6-60	29	37	95
N3	49 (25%)	8-336	113	90	61
N4	20 (10%)	63-318	155	126	60
N5	8 (4%)	189-317	229	223	25
Total	197 (100%)				
Change applications					
C1	212 (37%)	0-74	11	7	80
C2	350 (61%)	0-166	37	40	91
C3	4 (0.7%)	79-188	111	88	75
C4	6 (1%)	105-318	262	318	17
Total	572 (100%)				

2.2. Applications

2.2.1 New OTC medicine applications

Table 14 Applications received for new OTC medicines and changes to existing medicines

	2019-20	2020-21
	July to June	
	Number (% of Total)	
New medicine applications		
N1	96 (44%)	107(45%)
N2	10 (5%)	23 (10%)
N3	64 (30%)	71 (30%)
N4	27 (13%)	30 (13%)
N5	19 (9%)	5 (2%)
Total	216 (100%)	236 (100%)
Change applications		
CN	157 (15%)	128 (17%)
C1	240 (23%)	234 (32%)
C2	615 (60%)	349 (48%)
C3	7 (0.7%)	19 (3%)
C4	7 (0.7%)	1 (0.1%)
Total	1,026 (100%)	731 (100%)

2.2.2 Completed applications

Table 15 New OTC medicine applications completed and outcomes

	2019-20	2020-21
	July to June	
	Number (% of Total)	
N1		
Approved	75 (96%)	101 (94%)
Rejected	0	0
Withdrawn by sponsor	3 (4%)	6 (6%)
Returned/failed screening	0	0
Total	78 (100%)	107 (100%)
N2		
Approved	6 (86%)	19 (83%)
Rejected	0	0
Withdrawn by sponsor	1 (14%)	4 (17%)
Returned/failed screening	0	0
Total	7 (100%)	23 (100%)
N3		
Approved	52 (93%)	49 (73%)
Rejected	0	0
Withdrawn by sponsor	1 (2%)	13 (19%)
Returned/failed screening	3 (5%)	5 (7%)
Total	56 (100%)	67 (100%)
N4		
Approved	19 (86%)	20 (83%)
Rejected	0	0
Withdrawn by sponsor	0	2 (8%)
Returned/failed screening	3 (14%)	2 (8%)
Total	22 (100%)	24 (100%)
N5		
Approved	15 (79%)	8 (100%)
Rejected	0	0
Withdrawn by sponsor	2 (11%)	0
Returned/failed screening	2 (11%)	0
Total	19 (100%)	8 (100%)

Table 16 OTC change applications completed and outcomes

	2019-20	2020-21
	July to June	
	Number (% of Total)	
C1		
Approved	229 (99%)	212 (95%)
Rejected	0	0
Withdrawn by sponsor	1 (0.4%)	12 (4%)
Returned/failed screening	0	0
Total	230 (100%)	224 (100%)
C2		
Approved	685 (99%)	350 (98%)
Rejected	0	0
Withdrawn by sponsor	5 (0.7%)	7 (2%)
Returned/failed screening	0	0
Total	690 (100%)	357 (100%)
C3		
Approved	0	4 (80%)
Rejected	0	0
Withdrawn by sponsor	4 (100%)	1 (20%)
Returned/failed screening	0	0
Total	4 (100%)	5 (100%)
C4		
Approved	1 (100%)	6 (86%)
Rejected	0	0
Withdrawn by sponsor	0	1 (14%)
Returned/failed screening	0	0
Total	1 (100%)	7 (100%)

2.2.3 Other applications

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

Table 17 Number of other OTC medicine applications

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
Total	0	0
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]	7 (100%)	81 (99%)
Rejected	0	1 (1%)
Total	7 (100%)	82 (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 considered to be 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 18 Registered complementary medicine applications by outcome

	2019-20	2020-21
	July to June	
	Number (% of Total)	
New medicines		
Approved	9 (56%)	9 (64%)
Rejected	0	1 (7%)
Withdrawn	6 (38%)	4 (29)
Returned/failed screening	1 (6%)	0
Total	16 (100%)	14 (100%)
Variations		
Approved	32 (97%)	71 (100%)
Rejected	1 (3%)	0
Withdrawn	0	0
Returned/failed screening	0	0
Total variations completed	33 (100%)	71 (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	1 (100%)	4 (100%)
Rejected	0	0
Withdrawn	0	0
Total	1 (100%)	4 (100%)

4. Assessed Listed Medicines

Assessed listed medicines are considered to be 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 19 Categorisation of assessed listed medicine applications

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

Table 20 Assessed listed medicine applications by outcome

	2019-20	2020-21
	July to June	
	Number (% of Total)	
New medicines		
Approved	0	2 (67%)
Refused	0	1 (33%)
Withdrawn	0	0
Failed screening	0	0
Total	0 (100%)	3 (100%)

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

	2019-20	2020-21
	July to June	
	Number (% of Total)	
New medicine applications		
L(A)1	0	0
L(A)2	0	0
L(A)3	3 (100%)	1 (100%)
Total	3 (100%)	1 (100%)
Change applications		
CN	0	0
C1	0	1
C2	0	0
Total	0 (100%)	1 (100%)

5. Listed Medicines

Listed medicines are considered to be of relatively lower risk than other medicines on the basis that they can only contain pre-approved ingredients and indications. Unlike registered medicines, we do not assess each listed medicine before it goes onto the market. However, we do require sponsors to certify that the medicine complies with all relevant legislation, and that they hold evidence at the time of listing (and at all times) that their medicine does what it says it will.

We may select a listed medicine for a post-market review where we require the sponsor to provide evidence of compliance with regulation. This includes assessment of evidence of efficacy and labelling. If we find the medicine does not comply with all applicable regulatory requirements, the medicine's listing may be suspended or cancelled.

5.1. New ingredients permitted for use in listed medicines

Table 22 New listed medicine ingredient applications by outcome

	2019-20	2020-21
	July to June	
Application outcome		
Approved	9 (75%)	5 (38%)
Rejected	0	3 (23%)
Withdrawn	3 (25%)	5 (38%)
Returned/failed screening	0	0
Total completed	12 (100%)	13 (100%)

5.2. Indications permitted for use in listed medicines

Table 23 Permitted indication applications by outcome

	2019-20	2020-21
	July to June	
Application outcome		
Approved	3 (14%)	3 (43%)
Rejected	8 (36%)	3 (43%)
Withdrawn	11 (50%)	1 (14%)
Total completed	22 (100%)	7 (100%)

5.3. Listed medicines

Table 24 New listed medicines

	2019-20	2020-21
	July to June	
New listed medicines	2,008	2,184

Table 25 Listed medicine variations under section 9D(1) of the Act

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

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Medicine variation		
Approved	161 (88%)	142 (88%)
Rejected	4 (2%)	2 (1%)
Withdrawn	19 (10%)	18 (11%)
Total	184 (100%)	162 (100%)

Table 26 Listed medicine applications under section 14/14A of *the Therapeutic Goods Act 1989*

Sections 14 and 14A of the Act provides for consent to be given in writing for the import, supply or export of therapeutic goods that do not comply with applicable standards. These applications are considered by a Delegate.

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Application		
Exemption granted	15 (63%)	34 (92%)
Rejected	5 (21%)	3 (0%)
Withdrawn	4 (16%)	2 (8%)
Total	24 (100%)	39 (100%)

5.3.1 Investigations

Investigations arise from notifications, complaints and referrals from internal and external stakeholders and screening of recently listed medicines on the ARTG and can also include products not listed on the ARTG. All investigations are prioritised based on a risk management approach to provide the perceived greatest overall benefit for the Australian public. Investigations may be completed with a number of actions, such as initiating a targeted review or referral to another area of the TGA.

Table 27 Listed medicine investigations and actions undertaken

	2019-20	2020-21
	July to June	
	Number (% of total)	
Initiated investigations	130	176
Completed investigations[a]	83	139
Initiated compliance review(s)	28 (34%)	21 (14%)
Issued warning or educational letter	9 (11%)	54 (37%)
Advice provided to complainant	4 (5%)	1 (1%)
Referred to another TGA area or government organisation	28 (34%)	50 (34%)
Issued Infringement notice	N/A	3 (2%)
No further action taken[b]	14 (16%)	17 (12%)
Total actions undertaken[c]	83 (100%)	146 (100%)

[a] Investigations with ensuing actions completed.

[b] The outcome 'no further action taken' includes examples where the investigation was resolved by other means such as the product has been or is currently under review; or the complaint was not justified and did not warrant further action.

[c] An investigation may give rise to more than 1 action.

5.3.2 Compliance reviews

Listed medicines are not individually evaluated by the TGA before they are included on the ARTG. However, a proportion are reviewed post-market to check their compliance against relevant regulatory requirements. Compliance reviews may only review selected listing requirements.

Medicines may be randomly selected or targeted for a review. Medicines are randomly selected for review by a computer, based on a mathematical model. Targeted reviews can originate from a number of signals and are initiated following an investigation.

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
- the review is not completed as the sponsor has cancelled the medicine
- the review is closed due to the unavailability of information in determining its compliance status as the medicine is yet to be manufactured.

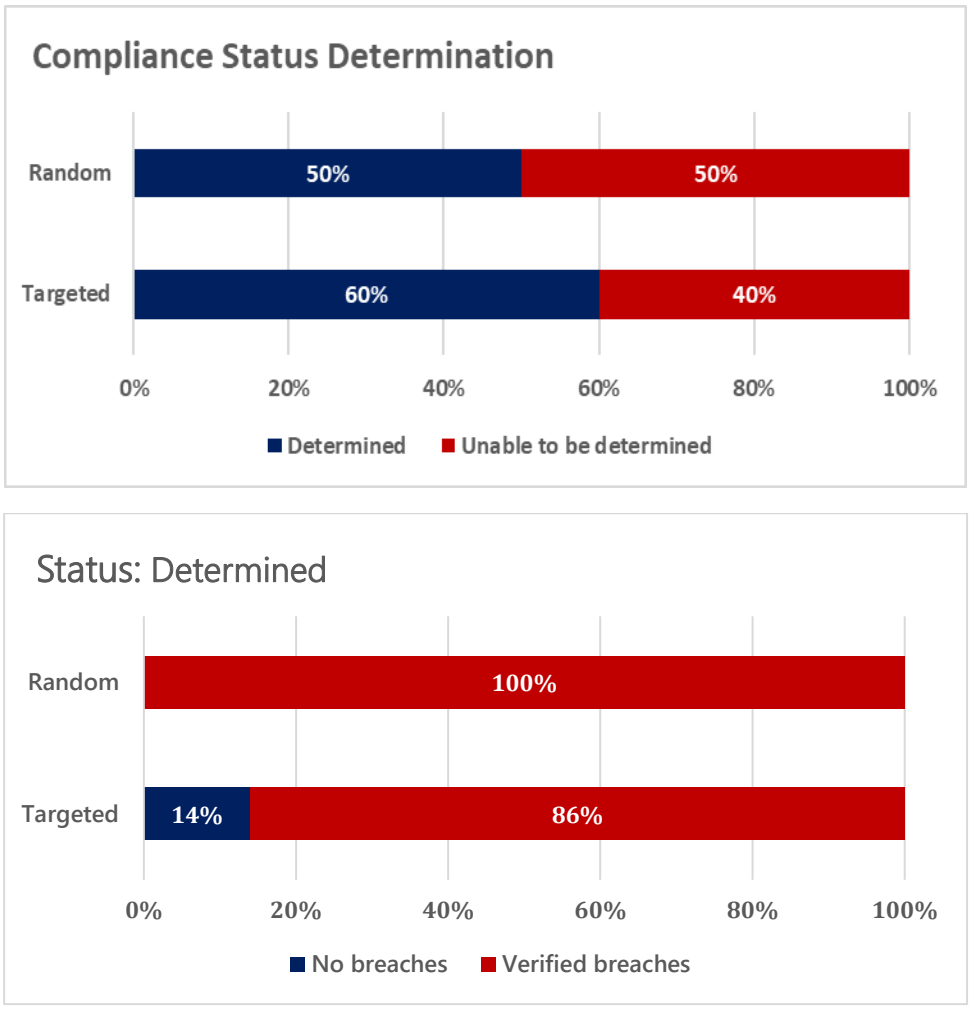
Table 28 Listed medicine reviews by type

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Initiated reviews		
Targeted reviews	163 (95%)	96 (96%)
Random reviews	9 (5%)	5 (5%)
Total	172 (100%)	101 (100%)
Reviews on hand	111	133
Completed reviews		
Targeted reviews	162 (83%)	70 (92%)
Random reviews	33 (17%)	6 (8%)
Total	195 (100%)	76 (100%)

Table 29 Completed listed medicine reviews by outcome

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Compliance status determined		
Medicines with no compliance breaches	42 (26%)	6 (13%)
Medicines with verified compliance breaches	118 (74%)	39 (87%)
Sub-total	160 (100%) (82%)	45 (100%) (59%)
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	26 (74%)	23 (74%)
Medicines not yet manufactured	9 (26%)	8 (26%)
Sub-total	35 (100%) (18%)	31 (100%) (41%)
Product not a therapeutic good	0 (0%)	0 (0%)
Total completed	195 (100%)	76 (100%)

Figure 3 Outcomes of compliance reviews by reason for initiation[a]



[a] In this period, of the medicines for which we were able to determine a compliance status, 100% had verified compliance breaches when initiated by random selection; this is higher than the previous period (89%), but is based on a small sample size (3 random reviews). Compliance status was not determined either because: the sponsor cancelled the medicine after the request for information, or the unavailability of information as the medicine was yet to be manufactured.

Table 30 Types of listed medicine compliance issues identified

Of the completed compliance reviews, the following are the types of issues identified in those medicines where a compliance breach was verified. Individual medicines may have multiple issues identified.

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Type of compliance issue		
Information provided in ARTG entry[a]	32 (14%)	12 (12%)
Manufacturing, quality and/or formulation	8 (4%)	3 (3%)
Labelling	68 (30%)	27 (27%)
Advertising	42 (19%)	24 (24%)
Unacceptable presentation[b]	35 (16%)	19 (19%)
Evidence[c]	21 (9%)	13 (13%)
Safety[d]	0 (0%)	0 (0%)
Non-response to a request for information[e]	3 (1%)	1 (1%)
Other[f]	16 (7%)	2 (2%)
Total	225 (100%)	100 (100%)

[a] 'ARTG information' broadly refers to situations where the information on the ARTG is incorrect, including indications that are not eligible for listing and ingredients that do not comply with listing requirements.

[b] 'Unacceptable presentation' means that aspects such as name, labelling, packaging, advertising or other material state or suggest that the medicine has ingredients, components or characteristics that it does not have.

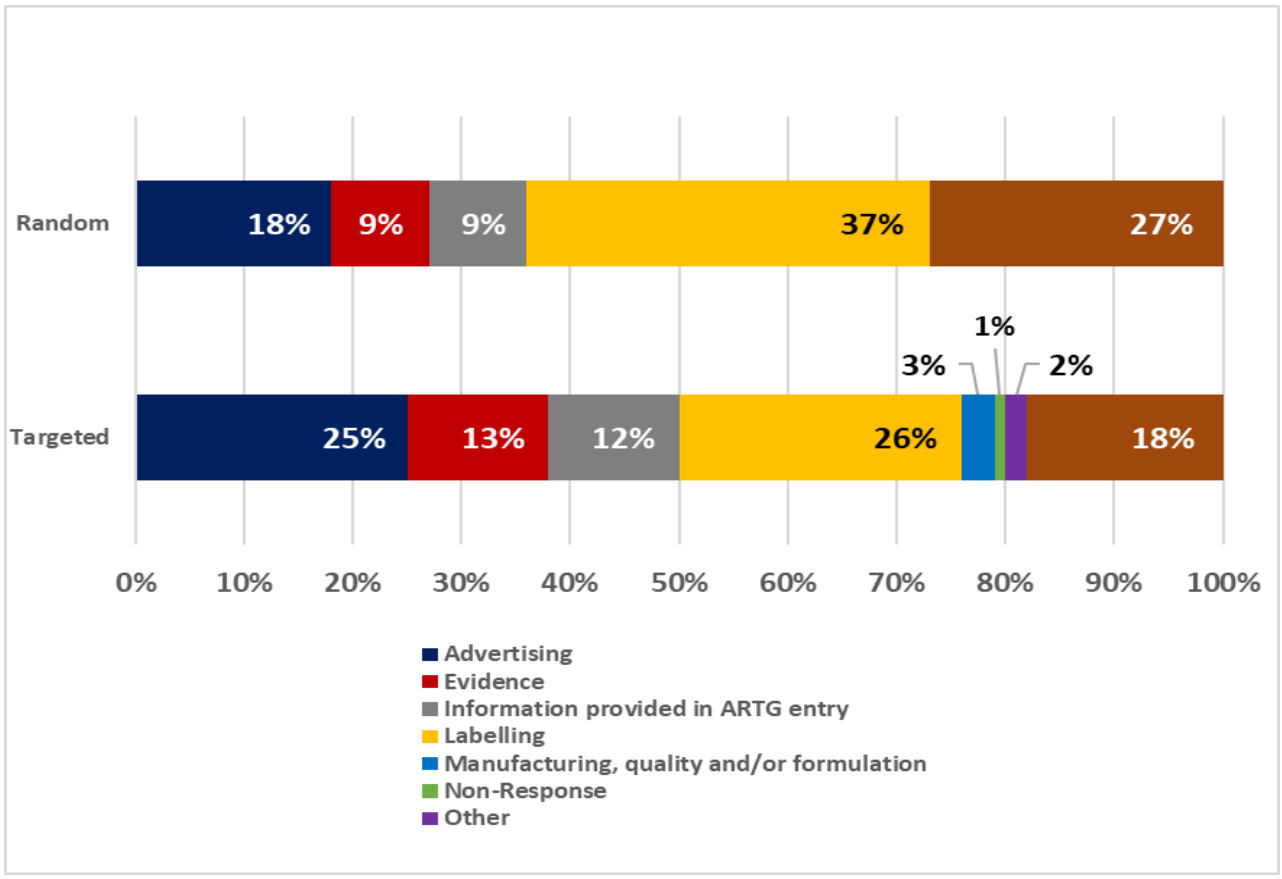
[c] 'Evidence' means the evidence held by the sponsor does not support the claims relating to the medicine.

[d] 'Safety' means that the medicine is not safe for the purposes for which it is to be used.

[e] In previous reports 'other' included non-response to a request for information. However, this is now being reported separately.

[f] 'Other' compliance issues may include the sponsor failing to comply with a condition that the medicine is subject to.

Figure 4[a] Types of compliance issues identified by reason for initiation



[a] Reviews are either randomly selected or targeted for a particular issue. Multiple breaches may be identified for each medicine that is found to be non-compliant; for example, 64% of all targeted non-compliant medicines were found to have issues related to the labelling of the medicine, yet this breach accounted for 26% of the total breaches identified across all targeted non-compliant medicines. These figures are not corrected for the nature of information assessed during a review. For example, of those targeted non-compliant medicines for which Labelling was assessed, 75% were found to have a 'labelling' breach.

Table 31 Actions taken following listed medicine reviews

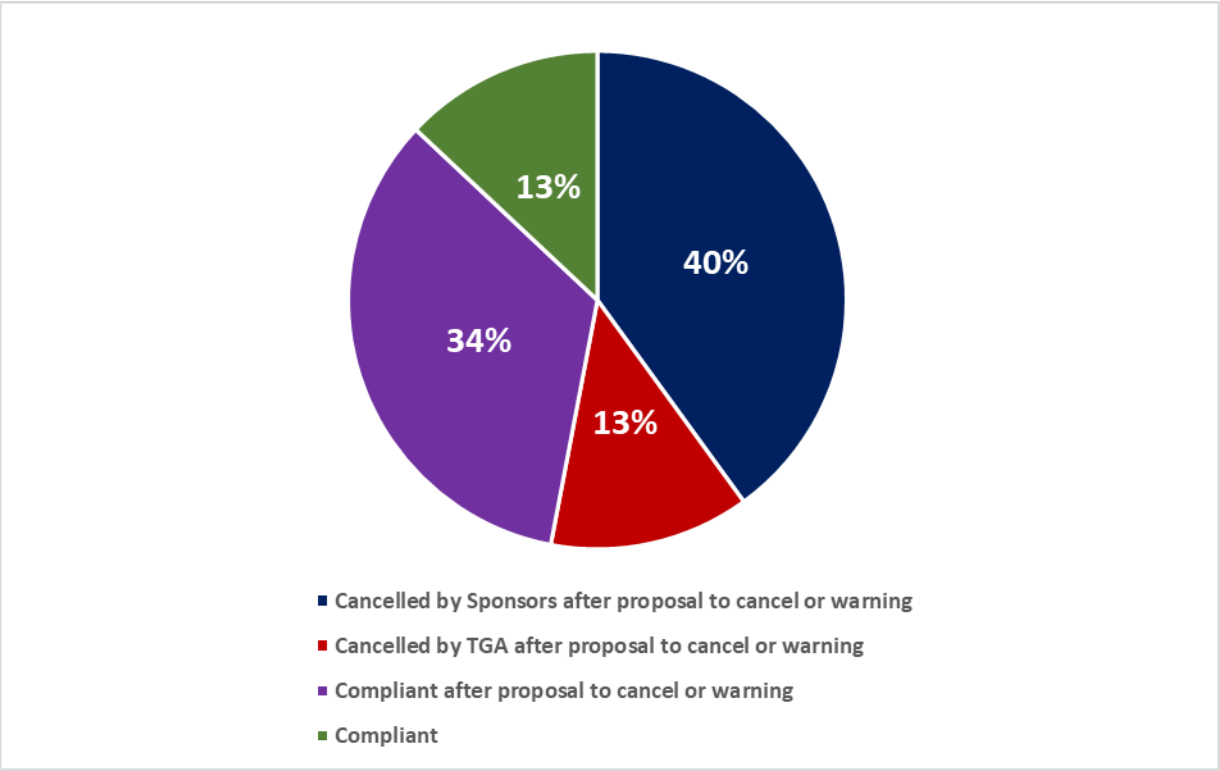
	2019-20	2020-21
	July to June	
	Number (% of Total)	
Actions following a Request for Information		
Medicines found to be compliant and review concluded	41 (26%)	6 (14%)
Medicines cancelled by the TGA without a proposal to cancel notice	0 (0%)	0 (0%)
Proposal to cancel notice or warning[a] sent by the TGA	119 (74%)	39 (84%)
Total	160 (100%)	45 (100%)
Actions following Proposal to Cancel notice[b] by outcome		
Medicines no longer on the ARTG	45 (100%) (38%)	24 (100%) (62%)
Cancelled by the TGA	7 (16%)	6 (25%)
Cancelled by sponsors after being notified of compliance breaches	38 (84%)	18 (75%)
Medicines remaining on the ARTG	71 (100%) (60%)	15 (100%) (38%)
Reviews concluded after compliance breaches were addressed	59 (83%)	12 (86%)
Reviews concluded after sponsor reminded of their obligations	11 (15%)	3 (14%)
No further action required	1 (2%)	0 (0%)
Other[c]	3 (100%) (2%)	0 (0%)
Total	119 (100%)	39 (100%)

[a] In some targeted review projects, sponsors are sent a 'warning' letter instead of a 'proposal to cancel' letter. A proposal to cancel or warning letter is considered the same for reporting purposes.

[b] The figures provided under 'Actions following a Proposal to Cancel notice by outcome' are a breakdown of the corresponding figures provided for the same under 'Actions following a Request for Information'.

[c] Includes reviews of medicines that are exempt from inclusion in the ARTG.

Figure 5[a] Outcomes of completed compliance reviews



[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. There was an increase in the number of listed medicines cancelled by the TGA following a Proposal to Cancel or warning letter (13%) compared with the previous period (4%).

6. Biologicals and Blood Components

6.1. Inclusion of biologicals

Table 32 Applications for biologicals[a] and blood received and on hand

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Applications received		
Technical Master File (TMF)[b] new	0	0
TMF annual updates	4 (5%)	3 (5%)
TMF variations	20 (27%)	7 (12%)
TMF notifications	10 (14%)	7 (12%)
Plasma Master File[c] annual updates	9 (12%)	14 (25%)
Biological Class 1 – new applications	0	2 (4%)
Biological Class 2 – new applications	0	5 (9%)
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	1 (1%)	4 (7%)
Biological Class 2 – variations	16 (22%)	8 (7%)
Biological Class 3 – variations	5 (7%)	1 (2%)
Biological Class 4 – variations	9 (12%)	6 (11%)
Total received	74 (100%)	57 (100%)
Applications on hand		
TMF new	0	0
TMF annual updates	3 (18%)	1 (5%)
TMF variations	7 (41%)	2 (10%)
TMF notifications	1 (6%)	1 (5%)
Plasma Master File annual updates	2 (12%)	6 (30%)
Biological Class 1 – new applications	0	0
Biological Class 2 – new applications	1 (6%)	5 (25%)
Biological Class 3 – new applications	1 (6%)	0
Biological Class 4 – new applications	1 (6%)	2 (10%)
Biological Class 2 – variations	0	3 (15%)
Biological Class 3 – variations	0	0
Biological Class 4 – variations	1 (6%)	0
Total on hand	17 (100%)	20 (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 33 Completed applications for biologicals and blood

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Biologicals applications		
Technical Master File (TMF) new	0	0
TMF annual updates	2 (3%)	3 (5%)
TMF variations	15 (22%)	6 (11%)
TMF notifications	9 (13%)	8 (14%)
Plasma Master File annual updates	11 (16%)	8 (14%)
Biological Class 1 – new applications	0	2 (4%)
Biological Class 2 – new applications	0	1 (2%)
Biological Class 3 – new applications	0	1 (2%)
Biological Class 4 – new applications	1 (1%)	2 (4%)
Biological Class 2 – variations	18 (26%)	14 (25%)
Biological Class 3 – variations	4 (6%)	2 (4%)
Biological Class 4 – variations	9 (13%)	10 (18%)
Total completed	69 (100%)	57 (100%)

7. Medicine and Vaccine Adverse Event Reports

7.1. Adverse medicine and vaccine reaction notifications

Table 34 Source of notifications of medicine and vaccine adverse reactions[a]

	2019-20	2020-21
	July to June	
Accepted cases total	23,476	57,771
Reports by health professionals	4,744	7,960
Patients/consumers	904	8,896
Pharmaceutical companies	14,418	14,128
Other source	3,410	26,787
Rejected/withdrawn cases	1,422	1,868
Total received	24,898	59,639
Mean number of reports received weekly	479	780
Vaccine reports	4,103	40,555

[a] Data is subject to change due to receipt of further information related to individual reports resulting in their amendment, or further case processing.

8. Medical Devices

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

- Priority review of medical devices: A new pathway has been developed to allow faster processing of applications for devices that meet certain criteria for novelty and health benefits.
- Medical device manufacturing: The TGA assesses 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, the TGA is 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 on 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 on 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 35 Number of conformity assessment applications (medical devices including IVDs)

	2019-20	2020-21
	July to June	
Conformity assessment applications		
Applications received	308	328
Applications on hand	222	256
Applications completed (including withdrawn or lapsed applications).	342	294

8.1.2 Outcomes

Table 36[a] Outcomes of conformity assessment applications

	2019-20	2020-21
	July to June	
New		
Approved	54	38
Rejected	0	0
Withdrawn/ Lapsed	39	39
Variation (changes and re-certifications)		
Approved	228	192
Rejected	0	0
Withdrawn/ Lapsed	21	25

8.1.3 Processing timeframes

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

Table 37 TGA processing times for new devices and variations

	2019-20	2020-21
	July to June	
New devices		
Mean TGA processing time (days) [a]	129	157
Median TGA processing time (days) [a]	158	200
% of applications completed within legislated timeframe (255 working days)	100%	100%
Variations (changes and recertifications)		
Mean TGA processing time (days)	137	124
Median TGA processing time (days)	144	117
% of applications completed within legislated timeframe (255 working days)	100%	100%

[a] Note that 26 applications were withdrawn prior to 6 TGA days processing time

8.2. Inclusion of medical devices (including IVDs)

8.2.1 Applications

Table 38 Applications for inclusion – medical devices (including IVDs)

	2019-20	2020-21
	July to June	
Class I medical devices		
Applications received	3,992	3,632
Applications completed	3,998	3,436
Applications on hand	N/A	251
Class I measuring medical devices		
Applications received	73	73
Applications completed	74	73
Applications on hand	0	3
Class I sterile medical devices		
Applications received	273	318
Applications completed	271	308
Applications on hand	3	19
Class IIa medical devices		
Applications received	1,384	1,579
Applications completed	1,376	1,544
Applications on hand	24	105
Class IIb medical devices		
Applications received	685	646
Applications completed	681	655
Applications on hand	41	88
Class III medical devices		
Applications received	298	501
Applications completed	249	365
Applications on hand	254	311

	2019-20	2020-21
	July to June	
Active Implantable Medical Devices (AIMD)		
Applications received	55	20
Applications completed	34	53
Applications on hand[a]	40	9
Class 1 IVDs[b]		
Applications received	114	93
Applications completed	112	97
Applications on hand[a]	3	5
Class 2 IVDs		
Applications received	64	57
Applications completed	60	56
Applications on hand[a]	11	10
Class 3 IVDs		
Applications received	126	128
Applications completed	105	127
Applications on hand[a]	29	43
Class 4 IVDs		
Applications received	13	12
Applications completed	13	12
Applications on hand[a]	0	0

[a] Applications on hand.

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

Table 39 Applications for device change requests and variations to the ARTG – medical devices (including IVDs)

	2019-20	2020-21
	July to June	
Device Change Request (DCR)		
Applications received	775	959
Applications completed	834	952
Applications on hand[a]	N/A	132
Variations to Class III medical devices		
Applications received	55	97
Applications completed	58	88
Applications on hand[a]	N/A	18
Variations to Active Implantable Medical Devices (AIMD)		
Applications received	0	3
Applications completed	1	2
Applications on hand[a]	N/A	1
Class 1 IVDs[b]		
Applications received	7	7
Applications completed	7	8
Applications on hand[a]	N/A	1
Class 2 IVDs		
Applications received	11	16
Applications completed	11	15
Applications on hand[a]	N/A	2
Class 3 IVDs		
Applications received	23	67
Applications completed	25	51
Applications on hand[a]	N/A	23
Class 4 IVDs		
Applications received	0	0
Applications completed	0	0
Applications on hand[a]	N/A	0

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 work days and for Level 2 application audits is 60 TGA work days (reflected in 'TGA days').

Table 40 Processing times for medical device application audits (including IVDs)

	2019-20			2020-21		
	Number of applications (% of Total)	**Sponsor days**	**TGA days[a] (mean)**	**Number of applications (% of Total)**	**Sponsor days[b, d]**	**TGA days[a, d] (mean)**
Mean Processing Time						
Medical devices						
Applications completed without audit (class I)[e]	N/A			887 (21%)		
Applications completed without audit (other classes)	2,330 (87%)			2,432 (56%)		
Non-mandatory audit (class I)[e]	N/A			435 (10%)	17	3
Non- mandatory audit[c]	89 (3%)	52	82	167 (4%)	58	88
Level 1 mandatory audit	47 (2%)	44	55	33 (1%)	41	48
Level 2 mandatory audit	212 (8%)	74	115	352 (8%)	64	169
Total	2,678 (100)			4,306 (100%)		
IVDs						
Applications completed without audit	119 (61%)			77 (34%)		
IVD non- mandatory audit	13 (7%)	18	36	10 (4%)	15	23
IVD mandatory audit	64 (33%)	19	19	141 (62%)	39	59
Total	196 (100)			228 (100%)		

[a] TGA time starts when the application is selected for audit, is based on working days, and excludes the time when we wait for information or payment from the sponsor.

[b] Days taken for sponsor to provide further information/pay fees etc.

[c] Non-mandatory audit – estimate for the audit processing time for class Is, Im, IIa, IIb, III and AIMD devices

[d] Due to technical and data migration issues the timeframes calculated for this reporting period may have some minor inaccuracies.

[e] Statistics for class I audits are new to 2020-2021 due to the changes to how class I products are processed.

Table 41 Number of priority review determinations[a] granted

	2019-20	2020-21
	July-June	
Application type		
A: Conformity Assessment (priority applicant) determinations	5	2
B: Medical Devices (priority applicant) determinations	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.

Table 42 Number of medical devices approved through the priority review pathway

	2020-21	
	July-June	
Application Type	**Number of applications with Priority determinations Approved (% of Total)**	**Median approval time (TGA working days)**
A: Conformity Assessment	50	70
B: Medical Devices (ARTG inclusion)	N/A	N/A
Total	50	70

8.3. Post-market monitoring

8.3.1 Compliance reviews

In previous years, Class I medical devices were included in the ARTG following an online self-certification by the sponsor through a computer-generated decision process. The TGA would undertake, when necessary, a post-market compliance review for these devices. The targeted review process included surveillance of all new Class I inclusions where potentially inappropriately included Class I devices, identified by the intended purpose of the device having restricted words indicative of risk, or known issues relating to the improper inclusion of the device. The inclusion process changed from October 2020, with all new Class I medical device, Class 1 IVD device, and export only ARTG applications now reviewed prior to inclusion, and requests for information are sent out where there may be uncertainty regarding the appropriateness of the device for inclusion in the ARTG. The number of applications are included above in Table 38.

We also conduct targeted compliance reviews initiated on a case by case basis. These may be conducted for devices of any Class.

8.3.2 Post-market reviews

In 2020-21 the post-market review database was upgraded, and data was migrated from several sources including the targeted Class I post-market reviews and reports of breaches of the Act, many of which commenced in the previous financial year. There is a disparity in the number of reviews on hand at the end of the 2019-2020 financial year and the number carried into the new financial year.

Table 43 Medical device targeted reviews

	2019-20	2020-21
	July to June	
Post market reviews		
Reviews commenced – number of ARTG entries	1,315	1,658
Reviews completed – number of ARTG entries	435	851
Reviews on hand – number of ARTG entries	1,557	3,246

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 44 Number of medical device incident reports and processing times

	2019-20	2020-21
	July to June	
Incident report outcomes		
Device incident reports		
Reports received	6,230	6,142
Reports completed	5,944	6,010
Reports still in progress	162	183
Processing time		
Mean TGA processing time (days)	17	13
Median TGA processing time (days)	1	4
Percentage processed within target timeframe	93%	97%

Table 45 Medical device incident report outcomes[a]

	2019-20	2020-21
	July to June	
Incident report outcome		
Reviewed and used for trend analysis purposes	5,354	5,201
Reviewed, no further action required	448	518
Product recall	21	17
Recall for product correction	20	46
Hazard alert	20	5
Product notification	3	1
Safety alert	5	4
Product enhancement/improvement notice	1	1
Instructions for use amended	4	7
Referral for post-market review	101	59
Refer to another TGA Branch or Section[b]	18	20
Company warned	3	5
Product suspended from ARTG	0	11
Product cancelled from ARTG	34	19
Manufacturing process improvements	16	7
Quality system process improvements	1	5
Maintenance carried out by the hospital	1	0
Change to design	4	8
Not device related	5	9
Other	175	151

[a] Outcomes are not mutually exclusive.

[b] The Incident report may be referred onto another section including to Recalls, Regulatory Compliance, Clinical Trials and Advertising.

8.3.4 Devices manufacturing

Table 46 Outcomes of Quality Management System (QMS) audits of Australian manufacturers

Note: Due to travel restrictions related to COVID-19, the onsite/remote/hybrid inspection process continued for domestic inspections and remote auditing was implemented for overseas inspections.

	2019-20	2020-21
	July to June	
QMS audits (Australia)		
Number of audits conducted	21	28%
Satisfactory compliance (of completed audits)	100%	81%
Marginal compliance (of completed audits)	0%	19%
Unacceptable (of completed audits)	0%	0%
Close-out in progress [a]	62%	43%
Processing time		
Initial audits conducted within 3 months of application	20%	44%
Re-audits conducted within 6 months of due date	13%	21%

a Percentage of audits not completed by 30th June timepoint and no compliance rating yet assigned

Table 47 Outcomes of QMS audits of overseas manufacturers

	2019-20	2020-21
	July to June	
QMS audits (overseas)		
Number of audits conducted	15	2*
Satisfactory compliance (of completed audits)	0%	0%
Marginal compliance (of completed audits)	0%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in Progress	40%	100%
Processing time		
Initial certification audits conducted within 6 months of application	55%	50%
Certification re-audits conducted within 6 months of due date	50%	0%

* Remote audits conducted late in the financial year

Table 48 Outcomes of MDSAP

	2019-20	2020-21
	July to June	
MDSAP Assessments (overseas)		
Number of auditing organisation assessments	3	9
Number of witnessed manufacturing audits	6	5

9. Disinfectants

Following regulatory amendments in 2018, disinfectants that includes claims (including virucidal claims) have been downregulated from registered products to listed products. Products that make 'specific' claims to kill micro-organisms such as viruses, spores, tuberculosis bacteria and fungi are required to be included on the ARTG as a listed other therapeutic good (OTG) before they are supplied to the market.

9.1. Disinfectants

9.1.1 Applications

Table 49 Applications for listing – listed OTG

	2020-21
	July to June
Listed OTG (Disinfectants)	
Applications received	306
Applications completed	314
Applications on hand	42

Table 50 Outcomes of listed OTG applications[a]

	2020-21			
	July to June			
	Number (% of Total)			
	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Total of applications
Listed OTG (Disinfectants)	160 (51%)	35 (11%)	119 (38%)	314 (100%)

10. Exports

10.1. Export only products

Table 51 Number of approved applications for export-only medicines and export certifications and relevant processing time for July 2020 to June 2021

	2019-20	2020-21	Target processing time (days)	2019-20	2020-21
	Total approved			Average processing time (days)	
Export-only medicines					
New applications	165	255	30	16	27
Variation and grouping applications	106	132	30	16	25
Export certification					
Medicines	1,501	1,540	15	10	13
Medical devices	362	796	10	4	7.5

11. Access to Unapproved Therapeutic Goods

11.1. 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, three 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 for drugs in Schedule 9 of the Poisons Standard and forbidden from supply in most states and territories.

Table 52 SAS medicine notifications and applications

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	40,069 (35%)[a]	39,675 (24%)
Category B applications		
Approved	58,735 (97%)	102,877 (97%)
Cancelled	39 (0%)	28 (0%)
Withdrawn	501 (1%)	742 (1%)
Rejected	0 (0%)	7 (0%)
Pending at end of reporting period[b]	1,014 (2%)	2,486 (2%)
Total Category B applications	60,289 (53%)	106,140 (65%)
Category C notifications		
Total Category C notifications	13,956[c] (12%)	16,814 (11%)
Total SAS notifications/applications received (all categories)	114,314 (100%)	162,629 (100%)

[a] The number of notifications received during some of this reporting period has been estimated
[b] SAS C notifications figures for the period do not include all notifications submitted via fax or email
[c] SAS C notifications figures were correct as at October 2019.

Table 53 SAS medical device notifications and applications

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	4,113 (50%)	5,641 (46%)
Category B applications		
Approved	3,218 (94%)	5,398 (95%)
Cancelled	7 (0%)	9 (0%)
Withdrawn	43 (1%)	86 (2%)
Rejected	66 (2%)	16 (0%)
Pending at end of reporting period[b]	120 (4%)	151 (3%)
Total Category B applications	3,454 (100%) (42%)	5,660 (46%)
Category C notifications		
Total Category C notifications	699 [c] (8%)	1,002 (8%)
Total SAS notifications/applications received (all categories)	8,266 (100%)	12,303 (100%)

[a] The number of notifications receive during some of this report period has been estimated

[b] SAS C notifications figures for the period do not include all notifications submitted via fax or email

[c] SAS C notifications figures were correct as at October 2019.

Table 54 SAS biological notifications and applications

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	89 (7%)[a]	78 (7%)
Category B applications		
Approved	955 (92%)	399 (80%)
Cancelled	0 (0%)	5 (1%)
Withdrawn	25 (3%)	42 (8%)
Rejected	0 (0%)	1 (0%)
Pending at end of reporting period[b]	56 (6%)	54 (11%)
Total Category B applications	1,036 (100%) (75%)	501 (47%)
Category C notifications		
Total Category C notifications	256[c] (19%)	485 (46%)
Total SAS notifications/applications received (all categories)	1,381 (100%)	1,064 (100%)

11.2. 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 three types of goods.

Table 55 Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	409 (42%)	495 (43%)
Device[a]	168 (17%)	171 (15%)
Biological	11 (1%)	7 (1%)
Medicine and device	384 (39%)	451 (40%)
Device and biological	7 (1%)	1 (0.1%)
Medicine and biological	3 (0.3%)	2 (0.2%)
Medicine, device and biological	2 (0.2%)	4 (0.3%)
Total	984 (100%)	1,131 (100%)

[a] 'Device' includes both medical device and therapeutic device categories.

[a]The number of notifications receive during some of this reporting period has been estimated.
[b]SAS C notifications figures for the period do not include all notifications submitted via fax or email
[c]SAS C notifications figures were correct as at October 2019.

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

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Clinical trial type		
Phase 1	297 (30%)	341 (30%)
Phase 2	212 (22%)	291 (26%)
Phase 3	235 (24%)	270 (24%)
Phase 4	58 (6%)	49 (4%)
Device	169 (17%)	175 (15.5%)
Bioavailability/equivalence	13 (1%)	5 (0.5%)
Total	984 (100%)	1,131 (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

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	1,085 (34%)	1,242 (37%)
Device[a]	272 (8%)	301 (9%)
Biological	19 (0.5%)	12 (0.4)
Medicine and device	1,803 (56%)	1,741 (53%)
Device and biological	23 (1%)	8 (0.2%)
Medicine and biological	8 (0.2%)	4 (0.1)
Medicine, device and biological	15 (0.5%)	10 (0.3)
Total	3,225 (100%)	3,318 (100%)

[a] Device includes both medical device and therapeutic device categories.

A variation to a previously notified clinical trial may include an addition of a site(s), change to a therapeutic good, or change in principal investigator etc.

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

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Phases		
Phase 1	832 (26%)	933 (28%)
Phase 2	788 (25%)	882 (27%)
Phase 3	1,209 (37%)	1,080 (33%)
Phase 4	122 (4%)	104 (3%)
Device	256 (8%)	306 (9%)
Bioavailability/equivalence	18 (0.5%)	13 (0.5)
Total	3,225 (100%)	3,318 (100%)

[a] A variation may include any change to a previously notified clinical trial such as an additional site, change to a therapeutic good, or change in principal investigator.

11.3. 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

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Approvals by therapeutic good type		
Number of approvals for medicines	1,071 (74%)	5,087 (94%)
Number of approvals for medical devices	383 (26%)	311 (6%)
Number of approvals for biologicals	0 (0%)	0 (0%)
Total	1,454 (100%)	5,398 (100%)

11.4. Section 19A approvals

Section 19A of the Therapeutic Goods Act 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 60 Section 19A applications

	2019-20	2020-21
	July-June	
Applications processed		
New	84	66
Renewals	67	61
Total	151	127

12. Medicines and Biologicals Manufacturing

12.1. Manufacturing licences issued to Australian manufacturers

Table 61 Status of manufacturing licence applications

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Licence status (Australia) [a]		
New licences granted	23 (30%)	13 (14%)
Withdrawn application [b]	45 (55%)	60 (65%)
Revoked licences – at request of licence holder	10 (12%)	15 (17%)
Revoked licences – TGA	0 (0%)	0 (0%)
Suspended – at request of licence holder	3 (3%)	4 (4%)
Suspended – TGA	0 (0%)	0 (0%)
Total	81 (100%)	92 (100%)

[a] As at 30 June 2019, there were 254 Australian companies holding manufacturing licences covering 396 sites.
[b] In previous financial years the number of new applications withdrawn at applicant request were reported. The method of calculation has changed this year to include all applications withdrawn at the applicant's request.

Table 62 Outcomes of inspections of Australian manufacturers

	2019-20[a]	2020-21
	July to June	
	Number (% of Total)	
Compliance status (Australia)		
Number of inspections conducted	190	210
Satisfactory compliance (of completed inspections)	128 (67%)	139 (66%)
Marginal compliance (of completed inspections)	47 (25%)	35 (17%)
Unacceptable (of completed inspections)	12 (6%)	9 (4%)
Compliance under assessment	3 (2%)	27 (13%)
Processing time		
Initial inspections conducted within 3 months of application	12 of 17 (71%)	8 of 12 (67%)[a]
Re-inspections conducted within 6 months of due date	82 of 117 (70%)	117 of 162 (72%)[b]

a. The number of domestic inspections conducted in 2019-20 has been revised.
b. Four domestic initial inspections did not achieve the three-month processing timeframe in 2020-21.
c. Forty-five domestic re-inspections did not achieve the six-month processing timeframe. 18 of the 45 delayed re-inspections were blood and biological manufacturers.

12.2. Approval (certification) of overseas manufacturers

Table 63 Manufacturing certification application by status (overseas)

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Applications (overseas) [a]		
New applications received [b]	22 (22%)	38 (36%)
Re-inspection applications [b]	76 (78%)	67 (64%)
Total applications	98 (100%)	105 (100%)
Applications completed		
Certified	86 (54%)	38 (26%)
Rejected [c]	72 (46%)	111 (74%)
Total completed	158 (100%)	261 (100%)

[a] As at 30 June 2021, there were 205 overseas manufacturers covering 227 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.

Table 64 Outcomes of inspections of overseas manufacturers

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Inspection status (overseas)		
Number of inspections conducted	51	54
Satisfactory compliance (of completed inspections)	31 (61%)	41 (76%)
Marginal compliance (of completed inspections)	13 (25%)	4 (7%)
Unacceptable (of completed inspections)	3 (6%)	1 (2%)
Compliance under assessment at period end	4 (8%)	8 (15%)
Processing time		
Initial certification inspections conducted within 6 months of application	11 of 17 (65%)	0 of 15 (0%)[a]
Certification re-inspections conducted within 6 months of due date	20 of 28 (71%)	6 of 29 (21%)[b]

[a.] Fifteen overseas initial inspections did not achieve the six-month processing timeframe.

[b.] Twenty-three overseas re-inspections did not achieve the six-month processing timeframe.

12.3. Good Manufacturing Practice (GMP) clearances

GMP clearance is required by an Australian sponsor when a step in the manufacture of a medicine or an Active Pharmaceutical Ingredient is manufactured overseas and the manufacturing step is recorded on the ARTG.

Table 65 GMP clearance application status

	2019-20	2020-21
	July to June	
	Number (% of Total completed)	
Applications received	7,153	7,604
Applications completed		
Approved	6,414 (91%)	6,778 (93%)
Rejected	637 (9%)	524 (7%)
Total completed	7,051 (100%)	7,302 (100%)

Table 66 Number of GMP clearance applications received and completed by type from 1 July 2019 to 30 June 2020

Application Category	Applications received	Applications completed
Cancel	5	5
Extend	2,463	2,419
New	2,031	1,974
Reactivate	39	40
Variation	3,066	2,864

Table 67 Number of GMP clearance applications actioned by pathway from 1 July 2019 to 30 June 2020

Pathway	Applications received	Applications completed	Applications approved	Applications not approved
Compliance Verification	1,513	1,277	1,227	50
Mutual Recognition Agreement	2,802	2,720	2,607	113

13. Recalls

13.1. Medicine recalls

Table 68 Medicine recalls by reason for recall

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse reactions	1 (2%)	12 (13%)
Foreign matter	0	1 (1%)
Illegal supply	2 (3%)	3 (3%)
Impurity and degradation	13 (22%)	2 (2%)
Labelling and packaging	18 (30%)	44 (46%)
Micro-organisms	4 (7%)	2 (2%)
pH	0	0
Potency	4 (7%)	5 (5%)
Sterility	7 (12%)	5 (5%)
Other[a]	11 (18%)	21 (23%)
Total	60 (100%)	95 (100%)

[a] 'Other' includes dissolution, physical defects, observed differences, variable content, diagnostic inaccuracy and wrong product, disintegration/dissolution, GMP non-compliance, transport/storage, bioavailability, preservative efficacy and therapeutic inefficiency.

13.2. Medical device recalls

Table 69 Medical device (including IVDs) recalls by reason for recall

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse incidents	6 (1%)	1 (<1%)
Diagnostic inaccuracy	70 (11%)	40 (6%)
Electrical defect	28 (5%)	34 (5%)
Illegal supply	2 (0.1%)	2 (<1%)
Labelling and packaging	136 (22%)	132 (20%)
Mechanical and physical defects	182 (30%)	226 (34%)
Software defects	151 (25%)	166 (25%)
Sterility	3 (0.1%)	25 (4%)
Other[a]	36 (6%)	39 (6%)
Total	614 (100%)	665 (100%)

[a.] 'Other' includes bioavailability, disintegration/dissolution, microbial contamination, variable content, foreign matter, impurity, wrong product, therapeutic inefficiency and observed differences.

13.3. Blood and Biological recalls

Table 70 Blood recalls

	2019-20	2020-21
	July to June	
Recalls to hospital level	100	101

Table 71 Biological recalls

	2019-20	2020-21
	July to June	
Recalls to hospital level	16	18

14. Laboratory Testing

The TGA 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 identify 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.

Laboratory testing results are made available through the *Database of TGA Laboratory Testing Results*. In addition to the routine publication of testing outcomes, we are increasingly publishing more detailed reports related to specific testing projects undertaken within our testing program.

A significant rise in the number of Medical Devices tested was observed during the reporting period. This was predominantly due to the testing of face masks and respirators included on the ARTG. Further information regarding this testing can be found on the testing of face masks and respirators webpage.

An increase in the failure rate of Complementary Medicines was also observed in this period when compared to 2019-20, however this result is affected by the lower number of samples tested over the reporting period due to the pandemic. Similarly, an increase in the failure rate of Pacific Medicines Testing Program samples was observed in 2020-21 as compared to 2019-20, and this is most likely due to the specific targeting of testing, as well as the inclusion of testing of face masks.

The significant increase in workloads due to the COVID-19 pandemic have affected compliance with usual timeframe targets.

Table 72 Samples and products tested by type of therapeutic good and percentage which failed

		2019-20	2020-21
		July to June	
Therapeutic good type			
Prescription medicines	Total	1,268	869
	% fail	9%	2%
OTC medicines	Total	42	81
	% fail	21%	6%
Complementary medicines[a]	Total	137	18
	% fail	4%	39%
Medical devices	Total	128	827
	% fail	44%	52%
External[a]	Total	15	22
	% fail	13%	9%
Pacific Medicines Testing Program	Total	92	53
	% Fail	16%	43%
Unregistered[b]	Total	472	230
	% fail	21%	32%
Total samples (excluding AHQ samples)		2,154	2,100
Total samples[c]		2668	2,684
Percentage fail		14%	27%
Total number of products tested[d]		1,044	1,003

[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 73 Samples that failed laboratory testing by reason for July 2020 to June 2021

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Contamination	0	0	0	0	0	0	1	1 (0.1%)
Formulation	1	1	21	45	6	2	10	86 (3%)
Label and packaging deficiencies	214	0	0	0	1	0	0	215 (10%)
Performance[a]	212	4	0	0	0	0	10	226 (10%)
Physical or mechanical properties	2	0	0	0	0	0	2	4 (0.2%)
Unregistered	0	0	0	28	0	0	0	28 (1%)
Total	429	5	21	73	7	2	23	560

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

Table 74 Batch release and export certification

	2019-20	2020-21
	July to June	
Batch releases and certifications		
Batch release[a]	426	656
Export certification[b]	84	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-approved certificates for batches of biological products to be exported by Australian manufacturers to overseas markets.

Table 75 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 76 Compliance with testing timeframes[a] for July 2020 to June 2021

	Priority	Number (% of Total)
Therapeutic good type[b]		
Medical devices	Routine	786 (27%)
	Priority	40 (100%)
	Urgent	1 (100%)
OTC medicines	Routine	59 (75%)
	Priority	22 (14%)
	Urgent	0 (N/A)
Prescription medicines	Routine	58 (24%)
	Priority	68 (100%)
	Urgent	1 (100%)
Complementary Medicines	Routine	14 (57%)
	Priority	4 (25%)
	Urgent	0 (N/A)
Unregistered products	Routine	45 (33%)
	Priority	153 (35%)
	Urgent	32 (56%)

[a] Samples involving complex biological assays are excluded from the target turnaround timeframes.

[b] Low numbers of samples within categories may affect compliance percentages.

15. Regulatory Compliance

The TGA conducts compliance and enforcement activities against a risk-based compliance framework. A range of tools are utilised 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 77 Number of compliance actions taken against completed investigations

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Completed investigations		
No offence identified	522 (11%)	508 (12%)
Goods released under Personal Import Scheme	338 (7%)	290 (7%)
Referred internally	77 (2%)	22 (0.5%)
Referred to external agency	100 (2%)	95 (2%)
Warning letters issued[a]	3,669 (77%)	3,072 (75%)
Infringement notices[b]	35 (1%)	89 (2%)
Referred to the Commonwealth Director of Public Prosecutions	5 (0.1%)	2 (0.1%)
Criminal prosecution	0 (0%)	2 (0.1%)
Total [c]	4,706 (100%)	4,088 (100%)
Units of goods referred to ABF for destruction[b]	753,897	1,197,3

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

[b] For infringement notices issued for advertising contraventions please refer to the Therapeutic Goods Advertising Compliance Annual Report 2020-21.

[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

	2019-20	2020-21
	July to June	
Compliance cases[a]		
Cases received	4,983	4,215
Cases active	1,684	919
Cases finalised	3,299	4,049

[a] These figures are based on case numbers and not actions taken or offence types.

Table 79 Number of different products investigated

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Therapeutic good type		
Prescription medicines (Schedule 4 and Schedule 8)	3,233 (72%)	4,795 (73%)
Schedule 9 medicines	43 (0.9%)	12 (0.2%)
Schedule 10 medicines	37 (0.8%)	47 (0.7%)
Medical devices	753 (17%)	421 (6%)
Complementary and homoeopathic medicines	222 (5%)	430 (7%)
OTC medicines	62 (1%)	58 (0.9%)
Biological and blood products	14 (0.3%)	3 (0.1%)
Other[a]	123 (3%)	846 (13%)
Total[b]	4,487 (100%)	6,612 (100%)

[a] Due to system technical issues, some investigations were unable to be categorised by therapeutic good type.
[b] Multiple therapeutic goods types may appear in a single case.

Table 80 Regulatory compliance investigations by special interest categories

	2019-20	2020-21
	July to June	
	Number (% of Total)	
Compliance investigation category		
Unregistered	4,895 (97%)	9,582 (98%)
Registered	40 (1%)	186 (1.8%)
Counterfeit product	87 (2%)	22 (0.2%)
Other	1 (0.1%)	0 (0.0%)
Total[a]	5,023 (100%)	9,790 (100%)

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

Table 81 Number of offence types related to completed cases

	2019-20	2020-21
	July to June	
	Number (% of total)	
Offence type		
Import	4,938 (91%)	4,278 (97%)
Export	28 (0.5%)	11 (0.2%)
Manufacture	58 (1%)	4 (0.1%)
Supply	428 (8%)	137 (3%)
Total completed[a]	5,452 (100%)	4,430 (100.0%)

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

16. Pharmacovigilance Inspection Program

Table 82 Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified

	2019-20	2020-21
	July to June	
Compliance investigation category		
Total inspections completed	8	6
Total with completed findings	8	6
Critical deficiencies[a]	1	3
Major deficiencies[b]	35	27
Minor deficiencies[c]	23	15
Average deficiencies per inspection	0 critical 4 major 3 minor	0.5 critical 4.5 major 2.5 minor

[a] A deficiency in pharmacovigilance systems, practices or processes that adversely affects the rights, safety or well-being of patients or that poses a potential risk to public health or that represents a serious violation of applicable legislation and guidelines. Deficiencies classified as critical may include a pattern of deviations classified as major. A critical deficiency also occurs when a sponsor is observed to have engaged in fraud, misrepresentation or falsification of data.

[b] A deficiency in pharmacovigilance systems, practices or processes that could potentially adversely affect the rights, safety or well-being of patients or that could potentially pose a risk to public health or that represents a violation of applicable legislation and guidelines. Deficiencies classified as major may include a pattern of deviations classified as minor.

[c] A deficiency in pharmacovigilance systems, practices or processes that would not be expected to adversely affect the rights, safety or well-being of patients. A deficiency may be minor either because it is judged as minor or because there is insufficient information to classify it as major or critical.

17. Reporting of Medicine Shortages

Table 83 Number of medicine shortage reports[a] by shortage reason

	2019-20	2020-21
	July-June	
	Number (% of Total)	
Shortages Reported		
New – Commercial changes	47 (3%)	36 (3%)
New - Discontinuation	186 (11%)	135 (11%)
New – Manufacturing related	650 (40%)	445 (36l%)
New – Other[b]	422 (26%)	416 (33%)
New – Product recall	10 (1%)	2 (0.2%)
New – Unexpected increase in demand	329 (20%)	202 (16%)
New – Unexpected increase in demand due to other sponsors unable to supply[c]	N/A	3 (0.2%)
New – Transport / Logistic issues / Storage capacity issues[c]	N/A	8 (0.6%)
Total	1,644 (100%)	1,247 (100%)

[a] New reports only, does not include updates of previously reported shortages.
[b] 'Other' was removed as a shortage reason from 1 June 2021.
[c] New shortage reason commencing 1 June 2021.

Table 84 Number of medicine shortage notifications processed

	2019-20	2020-21
	July-June	
Notifications processed		
New	1,644	1,247
Update[a]	4,477	3,978
Total	6,121	5,225

[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.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Reporting and Collaboration Services	October 2021

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D21-3027942