Australian Government

Department of Health

Therapeutic Goods Administration

TGA Half-yearly Performance Snapshot

1 July – 31 December 2021

Contents

About the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA), as part of the Australian Government Department of Health, is responsible for enabling therapeutic goods available for supply in Australia to be safe and fit for their intended purpose. These include goods Australians rely on every day, such as analgesics, disinfectants and sunscreens, through to goods used to treat and prevent serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

The TGA regulates the supply of:

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

The TGA also regulates the manufacturing and advertising of these products.

More information about how therapeutic goods are regulated can be found on the TGA website at www.tga.gov.au.

Executive Summary

The TGA prepares and publishes an annual Business Plan which identifies the priority activities to be undertaken over the course of each financial year. This Half Yearly Performance Snapshot provides statistical information for the period 1 July to 31 December 2021 in relation to our regulation of therapeutic goods and tracking our progress against some of the priorities we have identified for the year. This data will be incorporated into our Annual Performance Statistics Report for the 2021-22 financial year.

We continue to contribute to the Australian Government response to the COVID-19 Pandemic. The TGA plays a critical role as the regulator of medicines and medical devices, and blood, cell, and tissue products. The emergence of this major health pandemic has necessarily influenced our future priorities.

Performance highlights

The TGA has maintained a high level of activity over the reporting period, while also responding to the COVID-19 pandemic and implementing regulatory reforms. Highlights are as follows:

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. Expedited applications underwent full regulatory assessments, with some being approved with specific conditions.
- There were 2,718[1] medical device inclusions in the ARTG approved for supply in Australia from 1 July to 31 December 2021.
- 44 COVID-19 tests were approved for supply during the 1 July to 31 December 2021 period. Of these, 18 tests were COVID-19 self-tests, which have been available for supply to consumers through retail outlets and online since 1 November 2021. A list of all approved COVID-19 tests is published on the TGA website. All COVID-19 tests were approved with conditions and are subject to a post-market review to ensure their continued performance with the emergence of the COVID-19 viral variants.
- Protection for front line health care workers is critical. As of 31 December 2021, there were 2,275 face mask entries included in the post-market review to verify the quality, performance and protection of face masks and respirators being used. The post-market review includes a desktop audit of documentation, visual assessment, and testing by the TGA Laboratories.
- An expedited process to recall products, where there was a potential impact on public health connected to the COVID-19 pandemic, was implemented by the TGA. All recalls were initiated within 24 hours with TGA notifications provided on the website and via letter.
- In the reporting period, the Medical Devices Information Unit managed 22,787 enquiries, an increase of 45 per cent compared with the 1 July to 31 December 2020 period (15,731 enquiries). This is an increase of 309 percent on pre-COVID enquiry levels (5,597 enquiries for 1 July to 31 December 2019).
- To ensure up-to-date information on face masks, personal protective equipment (PPE), ventilators, test kits and other medical devices important to the COVID-19 pandemic response was readily available, over 30 webpages were published on the TGA's COVID-19 hub in the reporting period.

Laboratory testing

- The six months between 1 July and 31 December 2021 saw a continuation of the increased medical device testing observed in 2020. This was a result of the continued testing of PPE, particularly face masks and respirators, in response to the COVID 19 pandemic.

[1] Approved inclusions exclude device change requests, manufacturer's evidence, and Other Therapeutic Goods (OTG's).

Medicines

Provisional determinations and approvals

- During the 1 July to 31 December 2021 period, provisional determinations were made for six COVID-19 treatments and four COVID-19 vaccines. Two provisional approvals were granted for COVID-19 vaccines and four for COVID-19 treatments. One new COVID-19 vaccine was provisionally approved along with multiple extensions of indications. Multiple extensions of indications were also provisionally approved for a COVID-19 vaccine.

Medicine shortages/discontinuations

- The TGA continued to work with state and territory health departments to monitor supply and demand of important medicines used in the treatment of COVID-19 patients, particularly those in Intensive Care Units.
- Some existing medicines were recommended by the National COVID-19 Clinical Evidence Taskforce or had an extension of indications to include treatment of COVID-19. The TGA closely monitored supply of these medicines and has worked with a range of stakeholders including medicine sponsors, wholesalers, health professionals and patient groups to mitigate impacts on patients while ensuring access for use as a COVID treatment.
- To prevent or resolve critical medicine shortages including those caused by COVID-19 related supply chain disruptions and increased demand for medicines used in treatment of COVID-19 patients, the TGA prioritised the evaluation of 13 Category 1 (new medicine) applications and 20 Category 3 applications to vary the manufacturing, quality controls, packaging or labelling of prescription medicines. The TGA also prioritised 18 applications for consent to import or supply prescription medicines that do not conform with Standards.

Over-the-Counter (OTC) Medicines

- The supply of some OTC medicines, such as paediatric paracetamol preparations and TGA-approved hand sanitiser products, continued to be adversely affected by the COVID-19 pandemic due to increased demand, impacts on overseas manufacturers, and shortages of ingredients and packaging materials.
- The redirection of resources to expedite applications for products affected by supply issues and to high priority COVID-19 work impacted the review times for some OTC medicine applications. For N1, N3, N4 and N5 applications (see application types detailed in 'Over-the-Counter medicines' p. 24), the percentage of applications processed within the target time was below 80%.

Listed Medicines

- The number of compliance reviews of listed medicines that were completed in the period 1 July to 31 December 2021 (20) was lower than the same period last year (42). This decrease is partly due to the diversion of resources to respond to the COVID-19 pandemic.

Manufacturing

- In response to the COVID-19 pandemic the TGA adapted procedures to allow continued and flexible oversight of Good Manufacturing Practice (GMP) at domestic and international manufacturing sites. The principal ongoing changes have been a shift to performing inspections remotely (or undertaking 'hybrid' inspections that combine on-site and remote approaches) and modifying the requirements for GMP Clearance applications.
- Medical Device Quality Management System (QMS) audits were performed using a mix of remote and on-site approaches. The TGA also used audit reports from Medical Device Single Audit Program (MDSAP) organisations (if available) to conduct QMS Desk-Top Assessments. There were 13 domestic audits conducted between 1 July and 31 December 2021, compared to eight over the same period in 2020. There was one audit of an overseas manufacturer, which was conducted remotely.

International collaborations

- The International Coalition of Medicines Regulatory Authorities (ICMRA) held over 35 meetings of its 30-country member base to support mutual awareness, and to consider potential alignment on policy approaches and guidance to industry to address aspects of the impact of the COVID-19 pandemic. As well as the TGA continuing as the vice-Chair of ICMRA, TGA-led activities included the development of an ICMRA statement on COVID-19 vaccines confidence targeted at health care professionals, and the establishment of a COVID-19 vaccines pharmacovigilance network of 17 member regulators. This network met fortnightly to share information on potential emerging adverse events of significant interest.
- The member countries of the International Medical Devices Regulators Forum continued to meet regularly to progress working group items, including the harmonisation of terminology for reporting adverse events. In addition, a number of regulators continued to meet to discuss global safety concerns and COVID-19 related issues, and share information, assessments and concerns in relation to the performance of medical devices used in the COVID-19 pandemic response, including COVID-19 tests, and PPE.

Regulatory compliance

- The TGA has received 2,977 referrals about suspected non-compliance regarding the importation of goods since the COVID-19 pandemic was declared, an increase of 65%. Referrals were predominantly from the Australian Border Force and related to the importation of PPE, and unapproved medicines purported to prevent, treat, or cure COVID-19.
- Education was provided to a large number of importers new to the regulatory scheme about their compliance obligations in relation to COVID-19 medications and medical devices.

Reforms and updates

Regulatory reforms

- The TGA continues to implement reforms to medicinal cannabis manufacturing, labelling and packaging requirements for products not registered on the ARTG. These reforms will:
  - better protect patients by introducing GMP requirements for imported medicinal cannabis products, equivalent to those that already apply to products manufactured domestically
  - improve the safe presentation of medicinal cannabis products by introducing new labelling and packaging requirements
  - strengthen regulatory oversight by requiring Special Access Scheme approval in advance of the extemporaneous compounding of medicinal cannabis products.
- Amendment to the *Therapeutic Goods Regulations 1990* will include a new exemption permitting hospital pharmacists to extemporaneously compound certain medicines, prior to the identification of a patient and without the requirement for the medicine to be included on the ARTG. The aim is to:
  - permit the extemporaneous compounding of emergency hospital medicines in advance, to meet critical patient needs
  - give access to critical medicines of a suitable quality without unnecessary delays that may otherwise negatively affect patient outcomes.
- The *Therapeutic Goods (Prescription Medicines—Information Accompanying Applications for Registration) Determination 2021* was registered on 27 October 2021. The instrument enables the TGA to mandate the format of application dossiers that are submitted for prescription medicines in line with international regulators.
- Continued implementation of *An Action Plan for Medical Devices* further strengthened the regulation of medical devices in Australia. The reforms aim to further enhance the safety, performance, and quality of medical devices in Australia, and improve health outcomes for patients.
- Five legislative amendments were introduced to support the implementation of changes to the medical devices' regulatory requirements, including the *Therapeutic Goods (Medical Devices—Excluded Purposes) Specification 2020*, and an amendment to the *Therapeutic Goods (Medical Devices) Regulations 2002*.
- The *Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021* was registered in the Federal Register of Legislation on 5 October 2021 allowing for the submission of COVID-19 Rapid Antigen Self-Test applications from 1 November 2021. Section 42DK advertising permissions were also published to support the advertising of Rapid Antigen Point of Care Tests and Rapid Antigen Self-Tests.
- The TGA conducted a public consultation on potential regulatory options for export only biologicals (and not for supply in Australia).
- Updated standards for human cell and tissue products were implemented in September 2021, covering requirements for donor selection and testing, labelling and general manufacturing and quality requirements.

Medical Devices

- A number of *Therapeutic Goods (Medical Device) Regulations 2002* amendments came into effect in relation to patient information materials, the reclassification of categories of medical devices including spinal implants and active implantable medical devices and all surgical mesh devices to require more clinical evidence to support their ongoing supply in Australia.
- From 1 December 2021, suppliers of implantable medical devices are now required to have patient information materials available in the form of Patient Information Cards and Patient Information Leaflets. These information materials provide patients and medical practitioners with important information about specific implantable medical devices.
- The TGA undertook targeted discussions and public consultations on a broad range of medical device reforms including the potential for mandatory reporting of adverse events by hospitals, the potential exclusion of certain assistive technologies, refinements to the personalised medical devices framework and a proposal to allow patient information materials to be provided in electronic formats.
- We completed 3,463 medical device incident reports from 1 July to 31 December 2021, a small decrease on the 3,520 completed during 1 July to 31 December 2020. The average TGA processing time (56 days) was below the target timeframe (90 days).

Medicines

Prescription medicines

- With the additional prioritised workload of COVID-19 submissions the median assessment time across Category 1 applications has risen from 152 to 162 working days. The number remains similar at 182 registrations between 1 July to 31 December 2021 and well below the legislated timeframes.
- Variations to prescription medicines have continued to be prioritised to prevent or resolve critical medicine shortages. In this reporting period, five variations were approved in 10 working days or less.
- The TGA implemented enhancements to medicine shortages reporting and monitoring including:
    - an upgrade to the Medicine Shortage Reports Database so that information is easier to find and understand, including a new .csv download of current shortages
    - streamlining of the medicine shortage notification e-form
    - new guidance documents to support sponsors.
- Serious Scarcity Substitution Instruments (SSSIs) were introduced to mitigate the impact of shortages by allowing community pharmacists to substitute specific medicines without prior approval from the prescriber so long as the permitted circumstances within the SSSI are met.

Over-the-Counter medicines

- The TGA approved a similar number of new over-the-counter medicine applications from 1 July to 31 December 2021 (99), compared with 1 July to 31 December 2020 (97).
- The TGA approved 306 applications to change the registered details of existing medicines from 1 July to 31 December 2021, compared with 283 in the same period last year.
- For N2, C1, C2 and C3 application types, more than 80% were completed within target times, while 60% or more of N1, N3 and N4 application types were completed within target times.
- The *Therapeutic Goods (Medicines Advisory Statements) Specification 2021* was updated to include an updated version of the Required Advisory Statements for Medicine Labels (RASML). RASML specifies the advisory statements that are required to be included on the labels of some over-the-counter and complementary medicines.

Listed and Complementary medicines

- The number of new listed medicine applications in the 1 July to 31 December 2021 period (1,055) was on par with 1 July to 31 December 2020 (1,079).
- The TGA scanned 971 newly listed medicines on the ARTG and investigated 124 of these medicines due to risk of non-compliance.
- From 1 July 2021 to 31 December 2021, the TGA issued two Infringement Notices totalling $26,640 to a sponsor for alleged unlawful advertising of a listed medicine in relation to COVID-19. Over the same period, four Infringement Notices totalling $53,280 were issued to another sponsor for alleged failure to inform the Secretary of a new manufacturer and alleged failure to comply with a notice issued under section 31 of the Act.
- Out of six completed applications, we approved four new registered complementary medicine applications from 1 July to 31 December 2021.

Exports

- From 1 July to 31 December 2021, the TGA:
    - approved 185 new application for export-only medicine compared with 227 in the 1 July to 31 December 2020 period
    - approved 95 variation and grouping applications for export-only medicine, the same number of approvals as the equivalent period in 2020.

Access to unapproved therapeutic goods

- In the period 1 July to 31 December 2021, the TGA:
    - approved 2,021 Authorised Prescriber applications, including 6,629 applications for medicines, 5,814 for unapproved medicinal cannabis products, and 243 applications for medical devices
    - processed 106,885 applications and notifications through the Special Access Scheme (SAS) for medicines, including 72,482 for unapproved medicinal cannabis products, 5,281 for medical devices, and 468 for biologicals
    - This is mainly attributed to increases in applications for unapproved medicinal cannabis products.

Medicine and vaccine adverse event reports

- The TGA received 81,417 adverse event report cases between 1 July and 31 December 2021. The number of reports received was over 6-times higher than that in the same period in 2020. This was due to the adverse event reports received for COVID-19 vaccines (>67,000 reports), accounting for more than 80% of all reports. Over half of all reports were submitted by state and territory health departments, and the next largest reporter being consumers.
- Excluding reports for COVID-19 vaccines, 67% of reports were received from sponsors. Health professionals reported 12% of reports, with pharmacists being the most common health professional reporters.

Pharmacovigilance Inspection Program

- Between 1 July and 31 December 2021, the TGA inspected six medicine sponsors to assess their compliance with Australian pharmacovigilance legislation and guidelines. Inspections were scheduled using a risk-based approach that included assessment of the sponsor's pharmacovigilance system, product portfolio, and regulatory compliance history. Deficiencies were identified in each inspection, with a total of one critical deficiency, 24 major deficiencies and nine minor deficiencies.

Laboratory testing

- During the second half of 2021 the TGA Laboratories undertook a survey of nicotine vaping products in response to legislative changes introduced at the start of October. This resulted in an increase in the number of unregistered medicines tested (242 samples tested in this period, compared with 92 samples in the same period in 2020).
- COVID-19 vaccine batch release continued during the second half of 2021 with 155 batches covering 69.95 million doses being assessed for release with 98% of batch release requests completed in 2 days or less. The period included the first batches of Moderna's Spikevax and Pfizer's Comirnaty paediatric presentation.

Clinical trials

- From 1 July to 31 December 2021, there were 654 notifications for new clinical trials through the CTN scheme, which is comparable to the 1 July to 31 December 2020 figure of 585.

Recalls

- In consultation with stakeholders the TGA commenced planning comprehensive reforms to our management of recalls of therapeutic goods. The reforms will modernise processes for notifying and communicating recall information across supply chains and will provide health professionals, patients, and consumers with better access to the information they need.

Processing and approval times

Processing and approval times are defined as the number of working days from the acceptance of an application until the formal notification of decision, unless otherwise specified. These exclude times where we were unable to progress the application until the sponsor provides additional information or completes payment of fees, unless otherwise specified. Under the *Therapeutic Goods Act 1989*, the TGA working days exclude public holidays and weekends.

The timeframes applicable to many of our activities are mandated by legislation. For non-mandated activities, we self-impose target timeframes to ensure that we perform our functions efficiently and in a timely manner.

1. Prescription medicines

Applications to register new prescription medicines, or vary existing ones, 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:

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. The priority review pathway (applicable to Category 1 applications only) has the same statutory timeframe as other Category 1 applications, but the target timeframe is 150 working days.
Category 2	An application accompanied by two independent evaluation reports from comparable overseas regulators in whose jurisdiction the product is approved for the same indication	Legislated timeframe: 20 working days for notification of whether the application has passed preliminary assessment, and 175 working days to notify the applicant of the decision.
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 to notify the applicant of the decision depends on the COR pathway: COR-A[a]: 120 working days COR-B[a]: 175 working days

Application category	Description	Timeframe in 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.
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 an 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 is 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.

[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. The amount and type of additional data requiring evaluation will determine whether the application is best processed under the COR-B approach, or as a Category 1 application.

Prescription medicine submissions may include a number of applications submitted at the one time. The data presented on the following page relates to the number of submissions as this best reflects the evaluation and decision-making processes.

1.1. Submission outcomes

Table 1 Completed prescription medicines submissions by type and outcome for 1 July to 31 December 2021

	Number			
Submission Type	Approved	Withdrawn	Rejected	Total (% approved)
Category 1				
A: New chemical entity/New biological entity/ Biosimilar [a]	29	2	0	31 (94%)
B: New fixed-dose combination	1	0	0	1 (100%)
C: Extension of indication[a]	30	2	0	32 (94%)
D: New generic medicine	41	11	0	52 (79%)
F: Major variation	17	1	0	18 (94%)
G: Minor variation[b]	2	0	0	2 (100%)
H: Minor variation[c]	4	0	0	4 (100%)
J: Changes to Product Information	48	0	0	48 (100%)
S: Provisional to Full Registration	2	0	0	2 (100%)
Comparable Overseas Regulator (COR) – A				
C: Extension of indication	1	0	0	1 (100%)
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/ Biosimilar	1	0	0	1 (100%)
D: New generic medicine	2	0	0	2 (100%)
F: Major variation	1	0	0	1 (100%)
Minor Variations				
Category 3				
G: Minor variation[b]	30	2	0	32 (94%)
H: Minor variation[c]	823	12	0	835 (99%)
Correction [9D(1)]	143	8	0	151 (95%)
Additional Trade Name [ATN]	18	0	0	18 (100%)
Extension of Indication – Generic	12	1	0	13 (92%)
Internal Review	2	0	0	2 (100%)
Minor editorial change [MEC]	85	5	0	90 (94%)
Notification	846	6	0	852 (99%)
S.14 Exemption	60	2	0	62 (97%)
Self-assessable request [SAR]	332	8	0	340 (98%)
Safety-related request [SRR]	455	9	0	464 (98%)
Total	2,985	69	0	3,054 (98%)

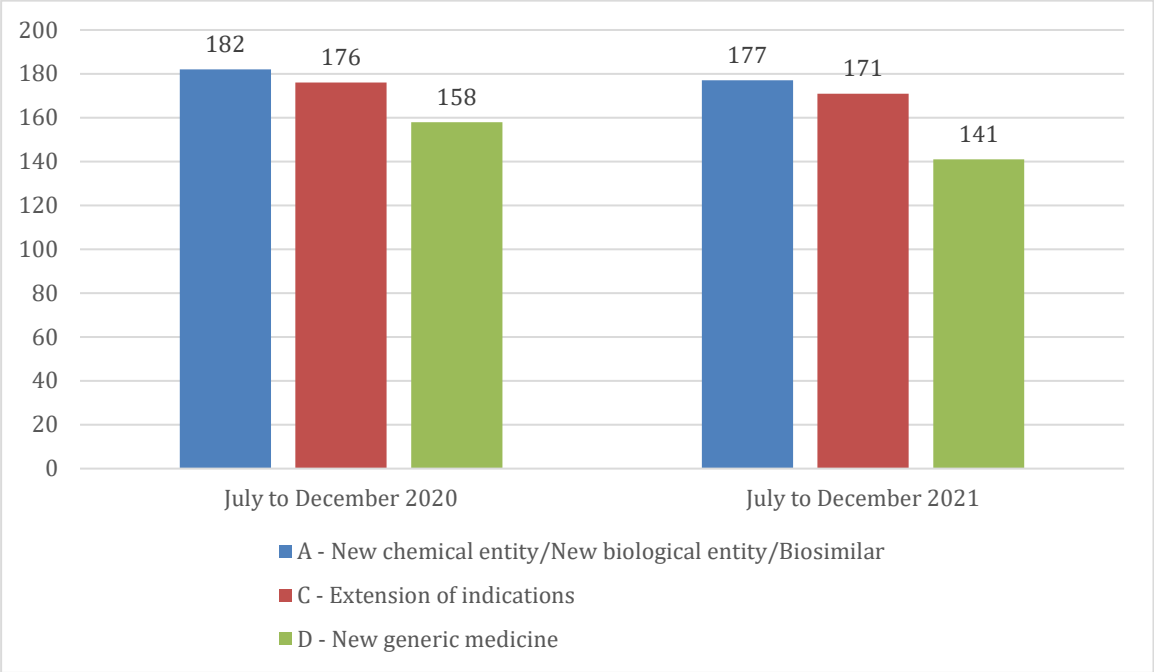
[a] Includes submissions processed via the priority review.

[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) included in the table above refer to applications to change the formulation, composition or design specification or the

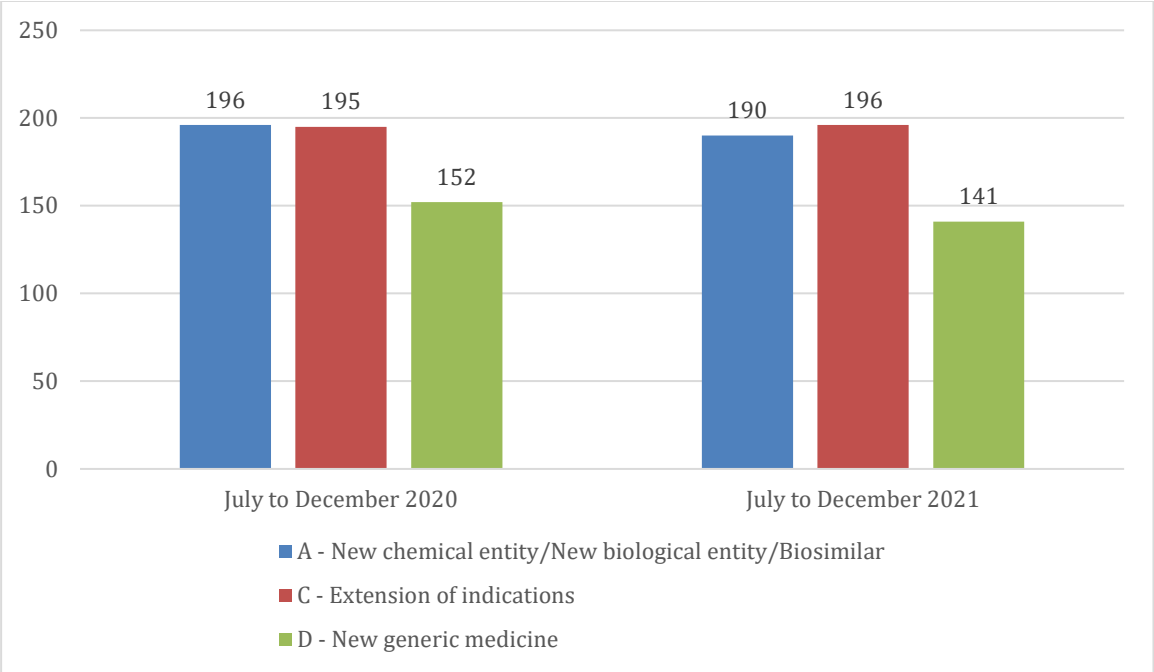
container for the goods or any other attribute that results in the goods being separate and distinct. These applications are typically 'Category 3' changes, unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

Figure 2 Prescription medicine standard registration[a] mean approval times for 1 July to 31 December



[a] Does not include submissions processed via the priority review, COR-A or COR-B pathways

Figure 3 Prescription medicine standard registration[a] median approval times for 1 July to 31 December



[a] Does not include submissions processed via the priority review, COR-A or COR-B pathways.

1.2. Approval times

Table 2 Prescription medicine standard registration application approval time for 1 July to 31 December 2021

Application type	Submissions approved	Legislated timeframe	Approval time (working days) 1 July to 31 December		
			Mean	Median	Range
Category 1					
A: New chemical entity/New biological entity/Biosimilar[a]	25	255	177	190	23 – 251
B: New fixed-dose combination	1	255	196	196	196 – 196
C: Extension of indication[b]	28	255	171	196	1 – 253
D: New generic medicine	41	255	141	141	108 – 186
F: Major variation	17	255	136	147	8 – 194
G: Minor variation	2	255	172	172	161 – 184
H: Minor variation	4	255	208	215	166 – 236
J: Changes to Product Information requiring the evaluation of data	48	255	141	156	18 – 240
S: Provisional to full registration	2	255	216	216	179 – 254
T: Provisional registration extension	1	255	121	121	121 – 121

[a] Application type A figures do not include 4 submissions processed via the priority review pathway.

[b] Application type C figures do not include 2 submissions processed via the priority review pathway.

1.3. Other applications

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 to supply a product when it does not meet a particular standard may be granted.

Table 3 Other prescription medicine submissions for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Exemptions to comply with a standard (S.14)	Number (% of total)	
Approved	97 (90%)	60(97%)
Rejected/Withdrawn	11 (10%)	2 (3%)
Total	108 (100%)	62 (100%)

Table 4 Prescription medicine median approval time comparisons for 1 July to 31 December

Application Type	Legislated timeframe	Median approval time (TGA working Days 1 July to 31 December	
		2020	2021 (% Change)
Category 1			
A: New chemical entity/New biological entity/Biosimilar[a]	255	196	190 (▼ 3%)
B: New fixed-dose combination	255	194	196 (▲ 1%)
C: Extension of indication[a]	255	194	195 (▲ 1%)
D: New generic medicine	255	152	141 (▼ 7%)
F: Major variation	255	182	147 (▼ 19%)
G: Minor variation[b]	255	95	172 (▲ 81%)
H: Minor variation[c]	255	137	215 (▲ 57%)
J: Changes to Product Information requiring the evaluation of data	255	118	156 (▲ 32%)
S: Provisional to full registration	0	0	216 (N/A)
T: Provisional registration extension	0	0	121 (N/A)
Comparable Overseas Regulator (COR-B)			
A: New chemical entity/New biological entity/ Biosimilar	175	0	166 (N/A)
D: New generic medicine	175	122	125 (▲ 2%)
F: Major variation	175	0	174 (N/A)
Minor Variations			
Category 3			
G: Minor variation[b]	45	39	39 (▲ 0%)
H: Minor variation[c]	45	35	34 (▼ 3%)
Correction [9D(1)]	N/A	187	69 (▼ 63%)
Additional Trade Name [ATN]	45	15	27 (▲ 80%)
Extension of Indication Generic	45	49	36 (▼ 27%)
Minor editorial change [MEC]	45	30	32 (▲ 7%)
Notification	N/A	2	1 (▼ 50%)
S.14 Exemption	45	20	30 (▲ 50%)
Self-assessable request [SAR]	45	39	32 (▼ 18%)
Safety-related request [SRR]	45	32	33 (▲ 3%)

[a] Median working days does not include submission processed via the priority review pathway.

[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) included in the table above 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.

1.4. Orphan drug program

The objective of the orphan drug program is to provide an incentive to sponsors to bring medicines for a small population to market, and to 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 Orphan drug designations granted for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Application Type (proposed)	Number (% of total)	
A: New chemical entity/New biological entity/Fixed dose combination	12 (71%)	5 (42%)
C: Extension of Indications	4 (23%)	3 (25%)
F: Major Variation	1 (6%)	4 (33%)
Total	17 (100%)	12 (100%)

Table 6 Orphan drug registrations for 1 July to 31 December

	2020		2021	
	1 July to 31 December			
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	6 (55%)	142	10 (77%)	178
C: Extension of Indications	2 (18%)	110	1 (8%)	149
D: New generic medicine	1 (9%)	172	0	0
F: Major Variation	2 (18%)	193	1 (8%)	174
S: Provisional to full registration	0	0	1 (8%)	254
Total	11 (100%)	0	13 (100%)	0

1.5. 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 Priority determinations granted for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	4 (36%)	2 (25%)
C: Extension of indications	7 (64%)	6 (75%)
Total	11 (100%)	8 (100%)

Table 8 Medicines approved through the priority review pathway[a] for 1 July to 31 December

	2020		2021	
	1 July to 31 December			
Application Type	Number Approved (% of total)	Median approval time (TGA working days)	Number Approved (% of total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	3 (50%)	123	4 (67%)	124
C: Extension of Indications	2 (33%)	110	2 (33%)	148
S: Provisional to full registration	1 (17%)	99	0 (0%)	0
Total	6 (100%)		6 (100%)	

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

1.6. 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 on the basis of the evaluation of preliminary clinical data where there is the potential for a substantial benefit to Australian patients. 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 is 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 does not necessarily mean that the medicine will be approved after evaluation and provisionally registered on the ARTG.

Table 9 Provisional determinations granted for 1 July to 31 December

	2020	2021
	1 July to 31 December number (% of total)	
Application Type (proposed)	Granted	
A: New chemical entity/New biological entity/Fixed dose combination	7 (100%)	10(59%)
C: Extension of Indications	0 (0%)	7 (41%)
Total	7 (100%)	17 (100%)[a]

[a] There has been marked increase since the outbreak of COVID-19.

Table 10 Provisional approval registrations for 1 July to 31 December

	2020		2021	
	1 July to 31 December number (% of total)			
Application Type (proposed)	Number Approved (% of total)	Median approval time (TGA working days	Number Approved (% of total)	Median approval time (TGA working days
A: New chemical entity/New biological entity/Biosimilar	3 (75%)	195	8 (47%)	109
C: Extension of Indications	0	0	7 (41%)	43
F: Major variation	0	0	2 (12%)	15
Total	3		17 (100%)	

2. Over-the-Counter medicines

Over-the-counter (OTC) medicine applications are categorised as new medicine (N) or change (C) applications and are further categorised by risk (N1 and C1 are lowest risk, N5 and C4 are highest risk).

Application category	Definition
N1	An application submitted as a 'Clone'.
N2	An application that complies with an OTC medicine monograph.
N3	New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2, or N4.
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.
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.
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'.
C1	Quality and non-quality changes classified as 'negligible risk'.
C2	Quality and non-quality changes classified as 'low risk' – no safety and/or efficacy data required. Quality data may be required.
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.
C4	Non-quality changes classified as 'moderate risk' – safety and/or efficacy data required unless justified.
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.
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.
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.

Table 11 OTC medicine application processing time for approved applications for 1 July to 31 December 2021

Application type	Number completed (% of total)	Target Approval time (days)	Range	Mean	Median	% within target
New medicine applications						
N1 Lower risk	30 (30%)	45	0-74	37	44	63%
N2	4 (4%)	55	2-46	13	2	100%
N3	40 (40%)	150	26-177	120	123	70%
N4	15 (15%)	170	63-256	160	154	60%
N5 Higher risk	10 (10%)	210	134-289	263	289	20%
Total	99 (100%)					
C1 Lower risk	135 (44%)	20	0-86	17	14	81%
C2	157 (51%)	64	0-156	34	23	86%
C3	14 (5%)	120	2-116	57	50	100%
C4 Higher risk	0 (0%)	170	0	0	0	0%
Total	306 (100%)					

Table 12 Other OTC medicine applications processed for 1 July to 31 December

Other application types that we process include notification changes where their implementation would not impact the quality, safety, or efficacy of a medicine, and 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.

	2020	2021
	1 July to 31 December number (% of total)	
Notification changes, where their implementation would not impact the quality, safety or efficacy of a medicine		
CN	66	99
Request for advice for the purpose of listing a medicine as a pharmaceutical benefit		
B1	0	1
B3	0	0
Total	0	1
Requests for consent under section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard		
Approved	70 (100%)	5 (100%)
Rejected	0 (0%)	0 (0%)
Total	70 (100%)	5 (100%)

3. Listed and Complementary medicine

3.1. Registered complementary medicines

Table 13 Approved registered complementary medicine applications for 1 July to 31 December

	2020	2021
	1 July to 31 December	
New registered medicines	6	4
Variation to registered medicines	23	1

3.2. Listed medicines

Table 14 Approved applications for evaluation of an ingredient for use in listed medicines for 1 July to 31 December

	2020	2021
	1 July to 31 December	
New permitted ingredients	2	5

Table 15 New listed medicines for 1 July to 31 December

	2020	2021
	1 July to 31 December	
New listed medicines	1,079	1,055

Table 16 Listed medicine reviews by type for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Reviews initiated		
Random reviews	2 (4%)	3 (18%)
Targeted reviews	54 (96%)	14 (82%)
Total	56 (100%)	17 (100%)
Reviews completed		
Random reviews	5 (12%)	1 (5%)
Targeted reviews	37 (88%)	19 (95%)
Total	42 (100%)	20 (100%)

Table 17 Completed listed medicine reviews by outcome for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Compliance status determined		
Medicines with no compliance breaches	7 (23%)	6 (30%)
Medicines with verified compliance breaches	23 (77%)	14 (70%)
Subtotal	30 (100%)	20 (100%)
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	12 (100%)	0 (0%)
Medicines not yet manufactured or information unavailable	0 (0%)	0 (0%)
Subtotal	12 (100%)	0 (0%)
Product not a therapeutic good	0	0
Total completed	42 (100%)	20 (100%)

Table 18 Number of TGA cancelled listed medicines for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Cancelled listed medicines	25	2

Table 19 Initiated and completed signal investigations for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Initiated Investigation		
Complaints and referrals[a]	51 (58%)	55 (46%)
Internal analysis[b]	16 (18%)	41 (35%)
Food/Cosmetic-Medicine Interface (FMI/CMI)	21 (24%)	23 (19%)
Total	88 (100%)	119 (100%)
Completed investigations		
Complaints and referrals	33 (52%)	43 (52%)
Internal analysis	10 (16%)	17 (20%)
FMI/CMI	21 (33%)	23 (28%)
Total	64 (100%)	83 (100%)

[a] Sources may include adverse events, consumers, listed medicines industry, internal business areas, other agencies, etc.

[b] Sources may include ARTG scanning, internal investigations

Table 20 Infringement Notices issued for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Infringement Notices	3	6

Table 21 Applications received and completed for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Applications received		
Aristolochic Acid clearances	17 (42%)	29 (85%)
Consents under s14/14A of the Act[a]	21 (51%)	3 (9%)
New permitted indications	3 (7%)	2 (6%)
Total	41 (100%)	34 (100%)
Applications Completed		
Aristolochic Acid clearances	19 (38%)	26 (86%)
Consents under s14/14A of the Act	29 (58%)	2[b] (7%)
New permitted indications	2 (4%)	2 (7%)
Total	50 (100%)	30 (100%)

[a] Consent to import, supply or export therapeutic goods that do not comply with standards

[b] Extensions were given to a further 18 sponsors covering 582 products who had exemptions regarding Section 9(2) of TGO 92

3.2. Assessed listed medicines

Table 22 Approved Assessed listed (L(A)) medicine applications for 1 July to 31 December

	2020	2021
	1 July to 31 December	
New Assessed listed medicines	1	0

4. Biologicals and blood components

Blood, blood components, plasma derivatives, tissue and cellular products, tissue and cell-based derivatives, and other emerging biological therapies are regulated under the Act.

Table 23 Completed biological applications for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Applications received		
Technical Master File (TMF) new	0 (0%)	0 (0%)
TMF annual updates	2 (5%)	2 (10%)
TMF variations	7 (17%)	1 (5%)
TMF notifications	6 (15%)	1 (5%)
Plasma Master File annual updates	7 (17%)	7 (35%)
Biological Class 1 – new applications	0 (0%)	1 (5%)
Biological Class 2 – new applications	1 (2%)	2 (10%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	0 (0%)	1 (5%)
Biological Class 2 – variations	8 (20%)	2 (10%)
Biological Class 3 – variations	2 (5%)	0 (0%)
Biological Class 4 - variations	8 (20%)	3 (15%)
Total completed	41 (100%)	20 (100%)

5. Medical devices

The regulatory framework for medical devices spans the life cycle of these products, including conformity assessment, inclusion on the ARTG, and post-market monitoring and regulatory response if required.

5.1. Priority review pathway

Priority review involves faster assessment times for medical devices that offer major clinical or, in the case of IVD medical devices, public health advantages over existing technology. Medical devices that are granted priority review determinations are allocated 'front-of-queue' priority through the relevant medical device assessment process - conformity assessment or ARTG inclusion. The priority review determination step precedes lodgment of the conformity assessment or ARTG inclusion application, and the granting of priority designation does not guarantee approval of the application itself.

The TGA received no priority review applications for medical devices in the period and approved two priority review applications received in previous periods.

Table 24 Number of medical devices approved through the priority review pathway for 1 July to 31 December 2021

Application Type	Number Approved (% of Total)	Median approval time (TGA working days)
A: Conformity Assessment	2 (100%)	117
B: Medical Devices (ARTG inclusion)	0 (0%)	0
Total	2[a] (100%)	

5.2. Conformity assessment certification

All conformity assessment applications were processed within legislated timeframes noting that there were some delays due to the significant increase in medical device applications for COVID-19 related medical devices.

Table 25 Completed applications and processing time for conformity assessments of medical devices (including IVDs) for 1 July to 31 December

	2020		2021	
	1 July to 31 December Number (% of total)			
New Devices	New		New	
	Devices	IVDs	Devices	IVDs
Total completed	29	9	46	4
Percentage processed within legislated timeframe for Conformity Assessment	100%	100%	100%	100%
Mean TGA processing time (working days)	103	104	137	152
Median TGA processing time (working days)	53	142	156	182
Changes to recertification	Devices	IVDs	Devices	IVDs
Total completed	93	29	96	7
Percentage processed within legislated timeframe for Conformity Assessment	100%	100%	100%	100%
Mean TGA processing time (working days)	117	102	141	141
Median TGA processing time (working days)	94	85	161	188

Note: The TGA is required to complete conformity assessment applications within 255 working days. This year, the table reports statistics for Medical Device and IVD applications separately. Processing time for conformity assessments for 1 July to 31 December 2020 were impacted by a significant increase in the number of incorrectly submitted applications which were quickly completed, and this reduced the mean and median timeframes in that period.

5.3. Applications to include medical devices and IVDs on the ARTG

Table 26 Completed applications for inclusion of medical devices and IVDs on the ARTG for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Class I medical devices	2,283 (56%)	957 (38%)
Class I measuring medical devices	34 (1%)	17 (0.7%)
Class I sterile medical devices	160 (4%)	144 (6%)
Class IIa medical devices	750 (19%)	725 (28%)
Class IIb medical devices	332 (8%)	309 (12%)
Class III medical devices	219 (5%)	256 (10%)
Active Implantable Medical Devices (AIMD)	41 (1%)	6 (0.2%)
Class 1 IVDs	62 (2%)	44 (2%)
Class 2 IVDs	39 (1%)	26 (1%)
Class 3 IVDs	120 (3%)	63 (2%)
Class 4 IVDs	9 (1%)	3 (0.1%)
Total	4,049 (100%)	2,550 (100%)

Table 27 Application audits completed and processing time for medical devices and IVDs 1 July to 31 December 2021

	Total completed	Processing times (TGA days)	
		Mean	**Median**
Medical devices			
Class I applications completed without audit	781	3	1
Class I applications completed with audit	176	31	11
Non class I applications completed without audit	1,166	10	9
Non-compulsory audits (Non class I)	52	115	60
Level 1 compulsory audits	24	27	14
Level 2 compulsory audits	124	174	161
IVDs			
Class I IVD applications completed without audit	33	2	1
Class I IVD applications completed with audit	10	9	4
Non class I IVD applications completed without audit	27	5	4
IVD non-compulsory audit	1	41	41
IVD compulsory audit	32	64	61

6. Listed Other Therapeutic Goods (Disinfectants)

Disinfectants that make 'specific' claims to kill micro-organisms such as viruses, spores, tuberculosis bacteria, and fungi are regulated as listed other therapeutic goods.

Table 28 Completed applications for listing of disinfectants in the ARTG for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Listed OTG (Disinfectants)		
Applications completed	221	78

Table 29 Outcomes of listed disinfectant 1 July to 31 December

	2020	2021
	1 July to 31 December	
Listed OTG (Disinfectants)		
Approved/ Accepted	101	48
Rejected/ Lapsed	31	1
Withdrawn	89	28

7. Exports

Table 30 Approved applications for export-only medicines and export certifications and processing time for 1 July to 31 December

	Total approved	Target processing time (days)	2020	2021
			Average processing time (days)	
Export only medicines				
New applications	185	30	24	23
Variation and grouping applications	9,595	30	24	23
Export certification				
Medicines	1,569	15	12	13
Medical devices	327	10	9	4

The TGA issues permits for the export of human substances under regulation 8 of the *Customs (Prohibited Exports) Regulations 1958*. 'Human substances' refers to goods of human origin that are human body fluids, organs, and other tissues or substances derived from human blood.

Table 31 Number of issued permits for the export of human substances for 1 July to 31 December

	2020	2021
	1 July to 31 December Total issued	
Permit Type		
Annual permit	13	16
Bone and tissue permit	38	26
Blood fraction permits	21	21

8. Access to unapproved therapeutic goods

8.1. Special Access Scheme

Table 32 Completed applications and notifications for the Special Access Scheme for 1 July to 31 December

	2020	2021[a]
	1 July to 31 December Number (% of total)	
Medicines		
Category A	22,852 (31%)	15,918 (15%)
Category B[b]	45,820 (61%)	80,062 (75%)
Category C	6,288 (8%)	10,905 (10%)
Total	75,140 (100%)	106,885 (100%)
Medical devices		
Category A	2,397 (42%)	2,344 (44%)
Category B	2,922 (52%)	2,424 (46%)
Category C	330 (6%)	513 (10%)
Total	5,649 (100%)	5,281 (100%)
Biologicals		
Category A	43 (9%)	40 (9%)
Category B	303 (62%)	147 (31%)
Category C	144 (29%)	281 (60%)
Total	490 (100%)	468 (100%)

[a] 12,584 additional SAS Category C notifications received from 1 July to 31 December 2021 and earlier are yet to be processed by the TGA.

[b] The increase in SAS Category B applications for medicines in 2021, when compared with the 1 July to 31 December 2020 period, is attributable to increases in applications for unapproved medicinal cannabis products.

8.2. Authorised prescribers

Table 33 Authorised prescriber approvals for medicines and medical devices for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Medicines[a]	1,832 (90%)	6,629 (96%)
Medical devices	196 (10%)	243 (4%)
Total	2,028 (100%)	6,872 (100%)

[a] The increase in Authorised Prescriber applications for medicines in 2021, when compared with 1 July to 1 December 2020, is attributable to increases in applications for unapproved medicinal cannabis products.

8.3. Clinical trials

Table 34 Notifications for new clinical trials received by therapeutic good type for 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Medicine only	245 (42%)	281 (43%)
Medical device only	93 (16%)	84 (13%)
Biological only	2 (1%)	6 (0.9%)
Medicine and medical device	245 (42%)	276 (42%)
Medical device and biological	0 (0%)	1 (0.2%)
Medicine and biological	0 (0%)	3 (0.5%)
Medicine, medical device and biological	0 (0%)	3 (0.5%)
Total	585 (100%)	654 (100%)

Table 35 Notifications for new clinical trials received by phases for 1 July to 31 December[a]

	2020	2021
	1 July to 31 December	
Phase 1	131	149
Phase 1 and 2 in combination	33	46
Phase 2	128	173
Phase 2 and 3 in combination	9	10
Phase 3	148	147
Phase 4	28	34
Bioavailability / equivalence	4	2
Other phases in combination	14	5
Device only	90	88

A trial may be notified with more than one phase type and not all trials are notified to the TGA by phase, so there may be a discrepancy between the numbers presented in Tables 31 and 32.

One variation to a clinical trial approval (CTA) was approved by the TGA between 1 July and 31 December 2021.

9. Licensing and manufacturing

Number of manufacturing inspections by outcome

Applicants often submit applications for GMP licences and certifications before finalising all of their systems and processes. The TGA works with the applicant to ensure an inspection is not conducted before the manufacturing facility is ready. It is therefore not uncommon for inspections to be conducted later than the target dates.

Table 36 Medicines and blood, tissue and cellular therapies for 1 July to 31 December

	2020 [a]	2021
	1 July to 31 December	
Outcomes of inspections of Australian manufacturers		
Number of inspections conducted	127	73
Satisfactory compliance (of completed inspections)	93 (73%)	53 (73%)
Marginal compliance (of completed inspections)	25 (20%)	10 (14%)
Unacceptable (of completed inspections)	5 (4%)	1 (1%)
Compliance under assessment at period end	4 (3%)	9 (12%)
Processing time		
Initial inspections conducted within 3 months of application	6 of 8 (75%)	3 of 6 (50%)[b]
Re-inspections conducted within 6 months of due date	76 of 106 (72%)	27 of 51 (53%)[b]
Outcomes of inspections of overseas manufacturers		
Number of inspections conducted	26	52
Satisfactory compliance (of completed inspections)	22 (85%)	38 (73%)
Marginal compliance (of completed inspections)	1 (4%)	3 (6%)
Unacceptable (of completed inspections)	0 (0%)	2 (4%)
Compliance under assessment at period end	3 (12%)	9 (17%)
Processing time		
Initial certification inspections conducted within 6 months of application	2 of 6 (33%)[b]	0 of 11 (0%)[b]
Certification re-inspections conducted within 6 months of due date	3 of 15 (20%)[b]	1 of 41 (2%)[b]

[a] The number of inspections conducted in 2020-21 has been revised since the previous Half Yearly Performance Snapshot.

[b] The timeliness of GMP inspections has been impacted by travel restrictions associated with the COVID-19 pandemic. Inspections have also been delayed by manufacturers not being ready for scheduled inspections and by inspector resources being diverted to COVID-19 related work.

Table 37 Medical Device Audits for 1 July to 31 December

We conduct assessments of applications received for Conformity Assessment Certification. It may be determined that an audit of one or more manufacturers included in the Conformity Assessment Application is required. The timeframes used below for calculation of conducted audits are from the date of notification of this requirement.

The implementation of the Medical Device Single Audit Program (MDSAP) has enabled a reduction in the overall number of internal on-site audits required, substituted by a desktop assessment based on the MDSAP audit report.

	2020	2021
	1 July to 31 December	
Quality Management System (QMS) Audits (domestic manufacturers)		
Number of audits conducted	8	13
Satisfactory compliance (of completed audits)	13%	23%
Marginal compliance (of completed audits)	0%	8%
Unacceptable (of completed audits)	0%	0%
Close-out in progress	88%	69%
Processing time		
Initial audits conducted within 3 months of application	100%	0%
Re-audits conducted within 6 months of due date	0%	0%
QMS Audits (overseas manufacturers)		
Number of audits conducted	0 [a]	1 [a]
Satisfactory compliance (of completed audits)	0% [a]	0% [a]
Marginal compliance (of completed audits)	0% [a]	0% [a]
Unacceptable (of completed audits)	0% [a]	0% [a]
Close-out in progress	0% [a]	0% [a]
Processing time		
Initial certification audits conducted within 6 months of application	0% [a]	0% [a]
Certification re-audits conducted within 6 months of due date	0% [a]	0% [a]

[a] There was 1 "remote audit" of an overseas manufacturer. COVID-19 travel restrictions prevented QMS Audits of overseas manufacturers from 1 July to 31 December 2020 and 2021. However, changed arrangements were implemented, including delaying on-site audits where appropriate, completing desktop assessment of the comparable regulator evidence, and undertaking the remote audit. All TGA Conformity Assessments requiring audit have met statutory timeframes.

Table 38 GMP clearance application status for 1 July to 31 December

GMP clearance is required for all medicines supplied in Australia (unless exempt), including for products supplied to sponsors by overseas manufacturers.

	2020	2021 [a]
	1 July to 31 December Numbers (% of total)	
Applications received	3,783	4,441 [a]
Applications completed		
Approved	3,317 (93%)	3,945 (91%)
Rejected	256 (7%)	378 (9%)
Total completed	3,573 (100%)	4,323 (100%)

[a] Total excludes re-instatement application requests which are received via email.

Table 39 Number of GMP Clearance applications received and completed by type for 1 July to 31 December 2021

Application Category	Applications received	Applications completed
Cancel	1	1
Extend	1,674	1,667
New	850	879
Variation	1,916	1,776
Reinstatement	19	19

[a] The additional application types identified in table 29 are accounted for across all the above application categories with the exception of Cancel.

Table 40 Number of Compliance Verification and Mutual Recognition Agreement applications actioned by pathway for 1 July to 31 December 2021

Pathway	Applications received	Applications completed [b]	Applications approved	Applications not approved
Compliance Verification[a]	812	736	712	24
Mutual Recognition Agreement[a]	1,609	1,561	1,506	55

[a] The figures shown in the table represent the number of normal Compliance Verification and Mutual Recognition Agreement applications. They do not account for extensions.

[b] The number of applications completed account for more outcomes than approval and rejection, such as withdrawals.

10. Laboratory testing

Table 41 Samples and products tested by type of therapeutic good and percentage which failed for 1 July to 31 December

	2020		2021	
	1 July to 31 December			
Product type	Total	% fail	Total	% fail
Prescription medicines	347	6%	368	0.3%
OTC medicines	10	10%	0	N/A
Complementary medicines	7	57%	38	13%
Medical devices	457	63%	811	46%
External/contract[a]	18	11%	7	14%
Pacific Medicines Testing Program[b]	37	68%	23	35%
Unregistered[c]	92	35%	242	84%
Total samples (excluding AHQ samples)[c]	1,438	43%	1,489	40%
Total samples (including AHQ samples)[d]	1,730	36%	1,596	37%
Total number of products tested[e]	584	N/A	921	N/A

[a] Performed on request for overseas regulators or aid agencies, and encompasses medicines and medical devices.

[b] The Pacific Medicines Testing Program is a joint program between the Department of Foreign Affairs and Trade and the Therapeutic Goods Administration. More information is available at www.tga.gov.au/laboratories0branch0international0affiliations

[c] '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.

[d] Accreditation, harmonisation, and quality control (AHQ) samples.

[e] The TGA may test a number of samples of each product per reporting period.

11. Medicine and vaccine adverse event reporting

Table 42 Source of notifications of medicine and vaccine adverse reaction for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Accepted cases total	12,340 (96%)	78,544 (96%)
Reports by health professionals (total)	2,445	6,706
Medical practitioners	*569*	*2,850*
Pharmacists	*1,329*	*1,434*
Nurses	*363*	*1,280*
Others	*113*	*328*
Unknown	*71*	*814*
Patients/consumers	462	19,769
Pharmaceutical companies	7,978	9,514
State and Territory health departments	1,406	42,456
Other source	49	99
Rejected/withdrawn cases	475 (4%)	2,873 (4%)
Total received	12,815	81,417
Average number of reports received weekly	493	3,131
Vaccine reports included in this table	1,727	73,238

12. Medical device incident reports

Processing time is defined as the number of working days from receipt of the notification until the incident has been investigated and resolved.

The target timeframe for processing of medical device incident reports is 90 working days. The doubling of the mean processing time is due to the length of time taken to close several investigations that required complex testing in the laboratories, and many rounds of expert advice.

Table 43 Completed medical device incident reports and processing time for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Reports completed	3,520	3,463
Mean TGA processing time	59	56
Percentage processed within target timeframe	74%	76%

13. Regulatory compliance

In October 2020, a new case management system was implemented providing enhanced access to compliance case data. As a result, 2020 comparative data has been adjusted where appropriate.

Table 44 Different Products investigated 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Complementary and homeopathic medicines	156 (6%)	78 (1%)
OTC medicines	22 (1%)	28 (<1%)
Prescription medicines	2,388 (90%)	6,199 (94%)
Schedule 9 medicines	5 (1%)	3 (<1%)
Schedule 10 medicines	19 (1%)	10 (<1%)
Medical devices	66 (2%)	246 (4%)
Biological products	2 (1%)	1 (<1%)
Total[a]	2,658 (100%)	6,565 (100%)

[a] The total number of products is higher than the number of compliance cases managed. One compliance case can include multiple products.

Table 45 Number of compliance actions taken for completed investigations 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
No offence identified[a]	80 (2%)	390 (6%)
Referred to external entity	27 (1%)	118 (2%)
Goods released under the Personal Importation Scheme	687 (16%)	452 (7%)
Warning letters issued[b]	1,780 (42%)	2,989 (46%)
Destruction certificates issued	1,549 (37%)	2,471 (38%)
Infringement notices issued	100 (2%)	27 (<1%)
Referrals to Commonwealth Department of Public Prosecutions	2 (1%)	1 (<1%)
Criminal prosecution	2 (1%)	0 (0%)
Total completed [c]	4,227 (100%)	6,448 (100%)

[a] A compliance case may be finalised as 'no offence identified' where evidence is provided to demonstrate a product is recorded on the ARTG, or where the allegation does not fall within the TGA's regulatory jurisdiction.

[b] The category 'warning letters issued' can also include goods destroyed as prohibited imports and goods re0exported.

[c] The total number of actions is higher than the number of compliance cases managed. One compliance case can include multiple actions.

Table 46 Offence types related to completed cases for 1 July to 31 December

	2020	
Import	2,493 (98%)	4,274 (98%)
Supply	19 (<1%)	46 (1%)
Counterfeit [a]	14 (<1%)	41 (<1%)
Manufacture	2 (<1%)	5 (<1%)
Export	7 (<1%)	5 (<1%)
Total completed [a b]	2,535 (100%)	

[a] Ongoing case resolution has identified counterfeit offences in the period 1 July to 31 December 2020. The Counterfeit and Total completed rows for this period have been adjusted accordingly.

[b] A single compliance case can include multiple offence types.

14. Recalls

Table 47 Therapeutic goods recalls for 1 July to 31 December

	2020	2021
	1 July to 31 December	
Medicines	47 (12%)	42 (9%)
Medical devices (including IVDs)	286 (73%)	376 (81%)[a]
Biologicals	11 (3%)	2 (<1%)[b]
Bloods	50 (13%)	44 (9%)
Total recalls	394 (100%)	464 (100%)[c]

[a] The increase in medical device recalls was partly a result of the post-market review of face masks.

[b] The decline in biological recalls may have been influenced by COVID lockdowns and restrictions on elective surgery during the latter half of 2021.

[c] Total recalls activity increased by about 18% when comparing 2020 to the corresponding period in 2021.

15. Pharmacovigilance Inspection Program

Table 48 Pharmacovigilance Inspection Program inspections undertaken, and deficiencies identified from 1 July to 31 December

	2020	2021
	1 July to 31 December	
Total completed	3	6
Total with completed findings	3	6
Critical deficiencies [a]	1	1
Major deficiencies [b]	13	24
Minor deficiencies [c]	10	9
Average deficiencies per inspection	0.3 critical 4.3 major 3.3 minor	0.2 critical 4 major 1.5 minor

[a] A deficiency in pharmacovigilance systems, practices or processes that adversely affects the rights, safety, or wellbeing 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 wellbeing 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 wellbeing 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.

16. Reporting of medicine shortages

Table 49 New medicine shortage reports by month for July to December [a]

	2020	2021
	1 July to 31 December	
July	112	104
August	120	82
September	111	95
October	82	94
November	123	89
December	110	103
Total reports	658	567

[a] New reports only. Does not include updates of previously reported shortages. Mandatory reporting of all shortages of prescription medicines and certain over-the-counter medicines commenced on 1 January 2019.

Table 50 Number of medicine shortage reports[a] by shortage reason 1 July to 31 December

	2020	2021
	1 July to 31 December Number (% of total)	
Shortages Reported		
Commercial changes	50 (8%)	107 (19%)
Manufacturer related	249 (38%)	322 (57%)
Other [c]	237 (36%)	0 (0%)
Product Recall	1 (<1%)	0 (0%)
Unexpected increase in demand	121 (18%)	93 (16%)
New - Freight or logistics issues [d]	0 (0%)	43 (8%)
New - Seasonal depletion of stock [d]	0 (0%)	2 (1%)
Total	658 (100%)	567 (100%)

[a] New reports only. Does not include updates of previously reported shortages. Mandatory reporting of all shortages of prescription medicines and select over-the-counter medicines commenced on 1 January 2019.

[b] Shortage reasons commenced being collected in 2020.

[c] From 1 June 2021, the option to choose shortage reason 'other' was removed.

[d] From 1 June 2021, 2 new options for shortage reason were introduced.

Version	Description of change	Author	Effective date
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