Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration

Half Yearly Performance Snapshot

1 July to 31 December 2020

Contents

About the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is part of the Department of Health and is responsible for assessing whether therapeutic goods available for supply in Australia are safe and fit for their intended purpose. Approved therapeutic goods can be lawfully manufactured and supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices.

Products for which therapeutic claims are made are entered on the Australian Register of Therapeutic Goods (ARTG).

Some examples of goods that the TGA regulates the supply of include:

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

We also play a regulatory role in overseeing the manufacturing process and advertising of therapeutic goods.

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

Introduction

The TGA prepares an annual TGA Business Plan, which identifies the priority activities being undertaken over the financial year and is available on the TGA website. This Half Yearly Performance Snapshot provides statistical information for the period 1 July 2020 to 31 December 2020 in relation to our regulation of therapeutic goods, 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 2020-21 financial year, to be published on the TGA website in the second half of 2021.

As part of our annual Business Plan we continue to implement the Australian Government response to the COVID-19 Pandemic. 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 influenced our future priorities.

Performance highlights

The TGA has maintained a high level of activity over the reporting period 1 July to 31 December 2020, while also responding to the COVID-19 pandemic and implementing regulatory reforms. Highlights are as follows:

Impacts of COVID-19

Medical Devices

- Medical devices were at the forefront of Australia's response to the global COVID-19 pandemic, resulting in 3,829[1] medical device inclusions in the ARTG approved for supply in Australia from 1 July to 31 December 2020. This is a 54% increase when compared to 1 July to 31 December 2019.
- 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.
- To ensure sufficient tests were available, 64 COVID-19 tests were approved for supply during 1 July to 31 December 2020, with a list of approved COVID-19 tests published on the TGA website. All COVID-19 tests were approved with conditions.
- The TGA permitted 2 ventilators for supply to healthcare facilities under a special exemption.
- A significant number of new sponsors and manufacturers sought to supply disinfectants for the first time in response to the COVID-19 pandemic, with the TGA approving 101 applications making specific COVID-19 claims. To help these sponsors meet statutory requirements, the TGA published updated guidance material and developed new fact sheets. The TGA also published an up-to-date list of approved disinfectants for the broader community's use.
- As at 31 December 2020, there were 2,240 face mask entries in the ARTG. To ensure the safety and performance of face masks used in response to the COVID-19 pandemic, these devices are subject to a post-market review, including a desktop audit of documentation, visual assessment and testing by the TGA Laboratories.
- An expedited process to recall products, where there is a potential impact on public health connected to the COVID-19 pandemic, was undertaken by the TGA. All recalls were initiated within 24 hours with notifications provided on the website and via letter.
- In the reporting period the Medical Devices Information Unit managed a total of 15,731 enquiries, which is a 181% increase compared to the 1 July to 31 December 2019 period (5,597 enquiries).
- 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 2020.

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

Laboratory testing

- The 6 months between 1 July and 31 December 2020 saw a large increase in the number of medical devices tested (457 samples tested in this period, compared to 119 samples in the same period in 2019). This was predominantly the result of the testing of PPE, particularly face masks and respirators. Testing of these samples was performed in conjunction with the TGA's post-market review of face masks, and continues into 2021.

Medicines

Provisional determinations

- Three provisional determinations were made for COVID-19 vaccines during 1 July to 31 December 2020. COVID-19 vaccine submissions are being treated with the highest priority and the TGA is accepting rolling data submissions to ensure prompt evaluation.

Medicine shortage/discontinuation

- The TGA worked with state and territory health departments to conduct national supply modelling of important medicines used in the treatment of COVID-19 patients in Intensive Care Units. State and territory health departments also used the Dynamic Model of Medicines Availability, supported by the TGA, to independently monitor their own demand and supply.

Over-the-Counter Medicines

- The supply of some crucial OTC medicines, such as paediatric paracetamol preparations and TGA-approved hand sanitiser products, were adversely affected by the COVID-19 pandemic due to impacts on overseas manufacturers, and shortages of ingredients and packaging materials. Resources were directed to expediting applications for affected products that sought to change the approved details for their products.
- An increase of approximately 30% in enquiries relating to the regulation of over-the–counter (OTC) medicines and the redirection of resources has impacted the review times for some OTC medicine application levels. For N3, N4, N5, C1 and C3 applications (application types detailed in 'Over-the-Counter medicines' p. 27), the percentage of applications processed within the target time was below 80%.
- Due to the challenges posed by the COVID-19 pandemic, some in the pharmaceutical industry experienced difficulty in implementing new medicine labels that complied with TGO 92 (the labelling order for medicines), by 1 September 2020. The TGA established a temporary process for sponsors of OTC medicines to request consent to supply products that do not comply with TGO 92 due to adverse business impacts of the COVID-19 pandemic. 53 applications were received for OTC medicines, 9 of which also pertained to registered complementary medicines and/or listed medicines.

Listed and Registered Complementary Medicines

- As with OTC medicines, the TGA established a temporary expedited process for sponsors of listed and registered complementary medicines to request consent to supply products that do not comply with labelling requirements under TGO 92 due to adverse business impacts of the COVID-19 pandemic. 125 consent to supply applications were received. Of these, 67 were for listed medicines only, 4 for RCMs only, and one pertained to both listed medicines and RCMs.

- The number of compliance reviews that were completed in the period 1 July to 31 December 2020 (42) was lower than the same period last year (105). This decrease is due to the temporary diversion of resources required to respond to the COVID-19 pandemic.

International collaborations

- The International Coalition of Medicines Regulatory Authorities (ICMRA) held over 35 meetings to support, among its 30-country member base, mutual awareness and potential alignment on policy approaches and guidance to industry, to address aspects of the impact of the COVID-19 pandemic. As well as continuing the vice-Chair of ICMRA, TGA-led output included the development of an ICMRA statement on COVID-19 vaccines confidence, targeted at health care professionals and establishing 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 discuss COVID-19 related issues, particularly in relation to performance of COVID-19 tests, PPE and supply issues.

Regulatory compliance

- The TGA received 2,977 referrals about suspected non-compliance regarding the importation of goods since the COVID-19 pandemic was declared, an increase of 65% in referrals. Referrals were predominately from the Australian Border Force and related to the importation of PPE, and the importation of 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 Therapeutic Goods (Prescription Medicines—Transparency Measures) Specification 2020 was registered on 18 December 2020. The instrument enables the earlier publication of certain information about significant, innovative new medicines that have passed preliminary assessment and can be evaluated for their suitability for registration from 1 January 2021.
- The Australian Government, under An Action Plan for Medical Devices, continued to undertake a significant program of reforms to strengthen the regulation of medical devices in Australia. The reforms will continue to improve 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 TGA strengthened the regulation of surgical mesh devices, requiring them to meet the higher regulatory requirements of Class III medical devices. Sponsors with urogynaecological mesh devices that were already included in the ARTG needed to provide evidence that their products met the requirements of a Class III device by 1 December 2020. Four urogynaecological mesh products were granted approval to supply following reclassification to Class III. All other entries were cancelled.
- We clarified that certain sports supplements are medicines rather than food by making a declaration under section 7 of the *Therapeutic Goods Act 1989*. This ensures 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 declaration came into effect on 23 November 2020.

Medical Devices

- All conformity assessment applications were processed within target timeframes despite resources being focused on reviewing the significant increase in medical device applications connected to COVID-19.
- One conformity assessment was approved under the priority review framework. No new priority determinations were granted.
- The number of initial audits for domestic Quality Manufacturing System applications conducted within 3 months of application, increased from 33% in the 1 July to 31 December 2019 period, to 100% in 1 July to 31 December 2020.
- We completed 3,520 medical device incident reports from 1 July to 31 December 2020, this was an increase on the 3,042 completed over the 1 July to 31 December 2019 period. While the average TGA processing time (59 days) was higher than the time for 1 July to 31 December 2019 (47 days), it was still significantly below the target timeframe (90 days).
- Travel restrictions associated with COVID-19 pandemic severely impacted TGA's ability to undertake on-site audits of medical device manufacturers. In response, remote auditing was implemented in accordance with international best practice. This enabled 8 domestic audits to be conducted from 1 July to 31 December 2020, compared to 14 from 1 July to 31 December 2019. These audits were a hybrid of desktop, remote and on-site assessment.

Medicines

Prescription medicines

- Despite a similar number of Category 1 applications (from 181 in the 1 July to 31 December 2019 period to 188 in 1 July to 31 December 2020), there have been improvements in the assessment times for Category 1 applications. From 1 July to 31 December 2020, the median assessment time has fallen from 169 to 152 working days.
- During this reporting period, the TGA:
  - determined 11 medicines were eligible for priority review
  - approved 17 medicines with an orphan drug designation
  - approved 6 medicines with a priority review approval for registration, with a median approval time of 144 working days
  - approved 4 medicines given provisional determination for registration, with a median approval time of 147 working days
  - approved one medicine for registration after undergoing Comparable Overseas Regulator (COR)-B review with an approval time of 122 working days
  - reviewed 8 medicines collaboratively through the United Stated Food and Drug Administration's Project Orbis.
- With input from the Medicine Shortages Working Party, reforms have continued in 4 main areas: enhancements to the Medicine Shortage Information Initiative; Monitoring Medicines Availability; Education and Communication; and Medicine Shortage Mitigation Strategies.

Over-the-Counter medicines

- A data protection scheme for assessed listed medicines was implemented to provide incentives for innovation for industry by preventing competitors from seeking market authorisation of generic forms of an assessed listed medicine by relying on data generated by the originator.
- We approved 97 new over-the-counter medicine applications from 1 July to 31 December 2020, compared to 78 in from 1 July to 31 December 2019.
- For N1, N2, C2 and C4 application types, more than 90% were completed within target times, while more than 70% of N3, N4 and C1 application types were completed within target times.
- We received and processed a significantly higher number of requests (70) for consent to supply under s 14/14A of the Act from 1 July to 31 December 2020 compared with 1 July to 31 December 2019 (4).

Complementary medicines

- The TGA approved the first assessed listed medicine application during this period.
- The number of new listed medicine applications in 1 July to 31 December 2020 (1079) was on par with 1 July to 31 December 2019 (1141).

- We completed processing of a significantly higher number of requests (30) for consent to supply under section 14/14A of the Act from 1 July to 31 December 2020 compared with 1 July to 31 December 2019 (8).
- We approved six new registered complementary medicine applications from 1 July to 31 December 2020, an increase from two applications approved during 1 July to 31 December 2019.

Exports

- From 1 July to 31 December 2020, the TGA:
  - approved 227 new application for export only medicine compared with 70 in 1 July to 31 December 2019
  - approved 95 variation and grouping applications for export only medicine, compared with 44 in the 1 July to 31 December 2019 period.

Access to unapproved therapeutic goods

- In the period 1 July to 31 December 2020, the TGA
  - approved 2020 Authorised Prescriber applications, including 1,832 applications for medicines, 1,682 for unapproved medicinal cannabis products, and 196 applications for medical devices
  - processed a total of 78,308 applications and notifications through the Special Access Scheme (SAS). We processed 72,169 SAS applications and notifications for medicines, including 29,988 for unapproved medicinal cannabis products, 5,649 for medical devices, and 490 for biologicals, and
  - processed large increases in SAS Category B applications for medicines, up 45% compared with the same period in 2019 (45,820 in 1 July to 31 December of 2020, compared with 27,714 from1 July to 31 December 2019). This is mainly attributed to increases in applications for unapproved medicinal cannabis products.

Medicine and vaccine adverse event reports

- The TGA received 12,815 adverse event report cases between 1 July and 31 December 2020. The number of reports received was similar to the same period in 2019. 65% of reports were received from sponsors. Health professionals reported 20% of accepted cases, with pharmacists the most common health professional reporter (54%).

Pharmacovigilance Inspection Program

- Between 1 July and 31 December 2020, the TGA inspected three medicine sponsors. Inspections were scheduled using a risk-based approach that included an 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, 13 major deficiencies and 10 minor deficiencies.

Clinical trials

- From 1 July to 31 December 2020, there were 585 notifications for new clinical trials through the CTN scheme, which is comparable to the 1 July to 31 December 2019 figure of 499.

Work sharing with overseas regulators

- On 14 October 2020, the ACCESS Consortium announced that the United Kingdom's regulator, the Medicines and Healthcare products Regulatory Authority (MHRA), would join the group. The MHRA joined the 4 existing national regulatory authorities—TGA, Health Canada, Health Sciences Authority of Singapore, and the Swiss therapeutic goods regulator, Swissmedic.
- Six submissions were accepted for evaluation during 1 July to 31 December 2020 via the ACCESS Consortium.

Processing and approval times

Processing and approval times are defined as the number of working days from the acceptance of the application until the formal notification of decision, unless otherwise specified. These exclude times where we were unable to progress the application until the sponsor provided additional information or completed 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 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:

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 2 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

[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.

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 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.

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

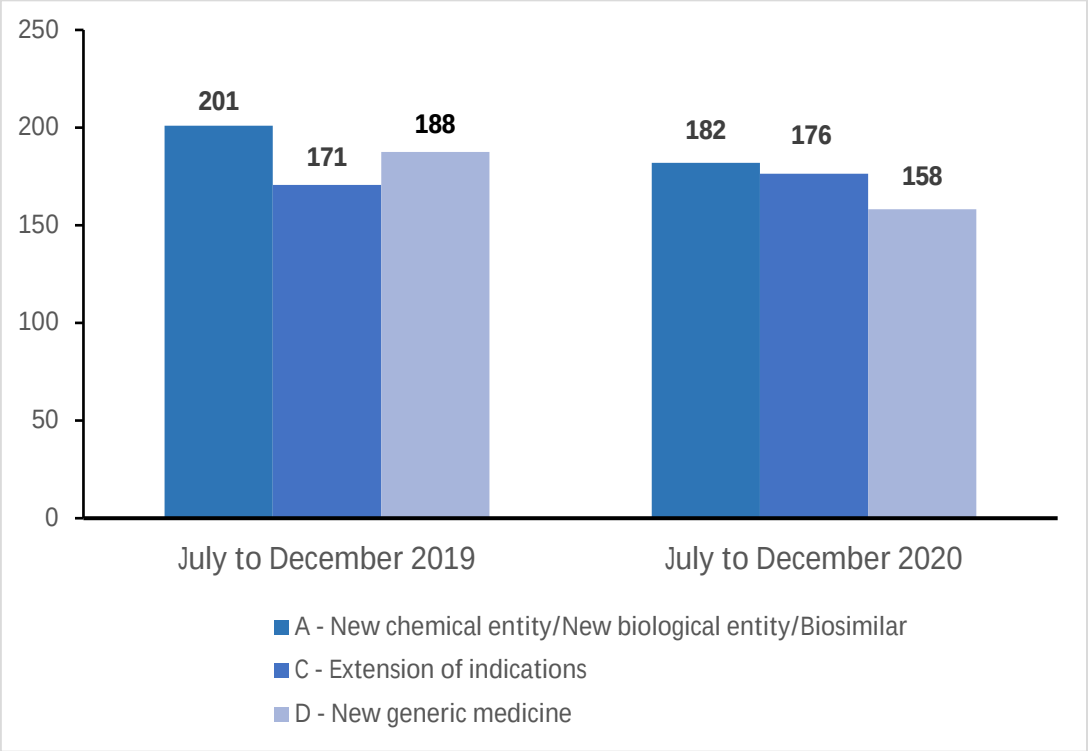
1.1. Submission outcomes

Table 1 Completed prescription medicines submissions by type and outcome for 1 July to 31 December 2020

	Number			
Submission Type	**Approved**	**Withdrawn**	**Rejected**	**Total (% approved)**
Category 1				
A: New chemical entity/New biological entity/ Biosimilar [a]	20	2	1	23 (87%)
B: New fixed-dose combination	3	0	0	3 (100%)
C: Extension of indication[a]	20	3	0	23 (87%)
D: New generic medicine	42	2	0	44 (96%)
F: Major variation	27	1	0	28 (96%)
G: Minor variation[b]	2	0	0	2 (100%)
H: Minor variation[c]	5	2	0	7 (71%)
J: Changes to Product Information	68	2	0	70 (97%)
S: Provisional to Full Registration	1	0	0	1 (100%)
Comparable Overseas Regulator (COR) – A				
A: New chemical entity/New biological entity/ Biosimilar	0	1	0	1 (0%)
Comparable Overseas Regulator (COR) – B				
D: New generic medicine	1	0	0	1 (100%)
Minor Variations				
Category 3				
G: Minor variation[b]	49	3	0	52 (94%)
H: Minor variation[c]	730	7	0	737 (99%)
Additional Trade Name [ATN]	16	0	0	16 (100%)
Extension of Indication - Generic	5	0	0	5 (100%)
Safety-related request [SRR]	569	9	0	578 (98%)
Self-assessable request [SAR]	524	8	0	532 (98%)
Minor editorial change [MEC]	176	2	0	178 (99%)
Correction [9D(1)]	188	13	0	201 (94%)
Notification	871	8	0	879 (100%)
Total	3,317	63	1	3,381 (98%)

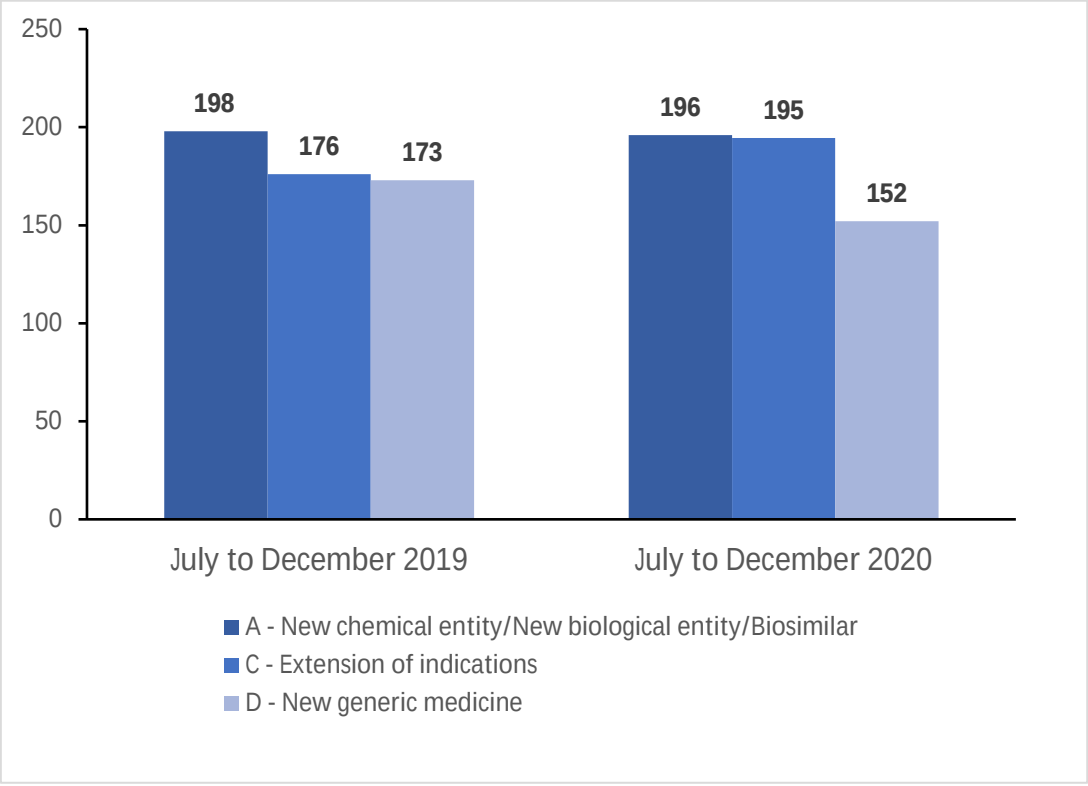
[a] Includes submissions processed via the priority review.
[b] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry.
[c] The minor variations (type H) included in the table above refer to applications to change the formulation, composition or design 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 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 2020

			Approval time (working days) 1 July to 31 December		
Application type	**Submissions approved**	**Legislated timeframe**	**Mean**	**Median**	**Range**
Category 1					
A: New chemical entity/New biological entity/Biosimilar[a]	17	255	182	196	5-223
B: New fixed-dose combination	3	255	202	194	186-226
C: Extension of indication[b]	18	255	176	195	68-223
D: New generic medicine	42	255	158	152	121-253
F: Major variation	27	255	171	182	21-250
G: Minor variation	2	255	95	95	24-166
H: Minor variation	5	255	161	137	137-207
J: Changes to Product Information requiring the evaluation of data	68	255	111	119	11-227
Comparable Overseas Regulator (COR-B)					
D: New generic medicine	1	175	122	122	122-122

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

[b] Application type C figures do not include one submission 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

	2019	2020
	1 July to 31 December	
Exemptions to comply with a standard (S.14)	Number (% of total)	
Approved	50 (86%)	97 (90%)
Rejected	8 (14%)	11 (10%)
Total	58 (100%)	108 (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 2019	2020 (% Change)
Category 1			
A: New chemical entity/New biological entity/Biosimilar[a]	255	198	196 (▼1%)
B: New fixed-dose combination	255	192	194 (▲1%)
C: Extension of indication[a]	255	176	194 (▲10%)
D: New generic medicine	255	173	152 (▼12%)
F: Major variation	255	189	182 (▼4%)
G: Minor variation[b]	255	N/A	95 (N/A)
H: Minor variation[c]	255	126	137 (▲9%)
J: Changes to Product Information requiring the evaluation of data	255	125	118 (▼6%)
Comparable Overseas Regulator (COR-B)			
D: New generic medicine	175	N/A	122 (N/A)
Minor Variations			
Category 3			
G: Minor variation[b]	45	40	39 (▼3%)
H: Minor variation[c]	45	36	35 (▼3%)
Additional trade name [ATN]	45	43	15 (▼65%)
Safety-related request [SRR]	N/A	35	32 (▼9%)
Self-assessable request [SAR]	45	41	39 (▼5%)
Minor editorial change [MEC]	45	27	30 (▲11%)
Correction [9D(1)]	N/A	99	186 (▲88%)

[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

	2019	2020
	1 July to 31 December	
Application Type (proposed)	**Number (% of total)**	
A: New chemical entity/New biological entity/Fixed dose combination	13 (87%)	12 (71%)
C: Extension of Indications	2 (13%)	4 (23%)
F: Major Variation	N/A	1 (6%)
Total	15 (100%)	17 (100%)

Table 6 Orphan drug registrations for 1 July to 31 December

	2019		2020	
	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	5 (56%)	198	6 (55%)	142
C: Extension of Indications	4 (44%)	196	2 (18%)	110
D: New generic medicine	0 (0%)	N/A	1 (9%)	172
F: Major Variation	0 (0%)	N/A	2 (18%)	193
Total	9 (100%)	198	11 (100%)	144

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

	2019	2020
	1 July to 31 December Number (% of total)	
Application Type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	4 (100%)	4 (36%)
C: Extension of indications	0 (0%)	7 (64%)
Total	4 (100%)	11 (100%)

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

	2019		2020	
	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 (75%)	130	3 (50%)	123
C: Extension of Indications	1 (25%)	105	2 (33%)	110
S: Provisional to full registration	0 (0%)	N/A	1 (17%)	99
Total	4 (100%)	125	6 (100%)	118

[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

	2019	2020
	1 July to 31 December Number (% of total)	
Application Type (proposed)	**Granted**	
A: New chemical entity/New biological entity/Fixed dose combination	2 (67%)	7 (100%)
C: Extension of Indications	1 (33%)	0 (0%)
Total	3 (100%)	7 (100%)

Table 10 Provisional approval registrations for 1 July to 31 December

	2019		2020	
	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	2 (33%)	135	3 (75%)	195
C: Extension of Indications	4 (67%)	62	0 (0%)	N/A
S: Provisional registration to full registration on the ARTG (s)	0 (0%)	N/A	1 (25%)	99
Total	6 (100%)	71	4 (100%)	147

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 which 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 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 2020

Application type	Number completed (% of total)	Target Approval time (days)	Range	Mean	Median	% within target
New medicine applications						
N1 Lower risk	50 (52%)	45	1-58	29	30	94%
N2	6 (6%)	55	6-41	23	22	100%
N3	25 (26%)	150	10-218	95	73	72%
N4	12 (12%)	170	63-277	118	80	75%
N5 Higher risk	4 (4%)	210	215-317	244	223	0%
Total	97 (100%)					
C1 Lower risk	112 (40%)	20	0-44	14	11	71%
C2	169 (60%)	64	0-113	35	39	96%
C3	1 (<0.4%)	120	188	188	188	0%
C4 Higher risk	1 (<0.4%)	170	105	105	105	100%
Total	283 (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.

	2019	2020
	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	78	66
Request for advice for the purpose of listing a medicine as a pharmaceutical benefit		
B1	0	0
B3	0	0
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]	4 (100%)	70 (100%)
Rejected	0	0
Total	4 (100%)	70 (100%)

[a] This includes 53 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. Complementary medicines

3.1. Registered complementary medicines

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

	2019	2020
	1 July to 31 December	
New registered medicines	2	6
Variation to registered medicines	27	23

3.2. Listed complementary medicines

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

	2019	2020
	1 July to 31 December	
New permitted ingredients	4	2

Table 15 New listed medicines for 1 July to 31 December

	2019	2020
	1 July to 31 December	
New listed medicines	1,141	1,079

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

	2019	2020
	1 July to 31 December Number (% of total)	
Reviews initiated		
Random reviews	5 (4%)	2 (4%)
Targeted reviews	136 (96%)	54 (96%)
Total	141 (100%)	56 (100%)
Reviews completed		
Random reviews	19 (18%)	5 (12%)
Targeted reviews	86 (82%)	37 (88%)
Total	105 (100%)	42 (100%)

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

	2019	2020
	1 July to 31 December Number (% of total)	
Compliance status determined		
Medicines with no compliance breaches	29 (32%)	7 (23%)
Medicines with verified compliance breaches	63 (68%)	23 (77%)
Sub-total	92 (100%)	30 (100%)
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	9 (69%)	12 (100%)
Medicines not yet manufactured or information unavailable	4 (31%)	0 (0%)
Sub-total	13 (100%)	12 (100%)
Product not a therapeutic good	0	0
Total completed	105 (100%)	42 (100%)

3.2. Assessed listed medicines

Table 18 Approved Assessed listed (L(A)) medicine applications for 1 July to 31 December

	2019	2020
	1 July to 31 December	
New Assessed listed medicines	0	1

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 19 Completed biological applications for 1 July to 31 December

	2019	2020
	1 July to 31 December Number (% of total)	
Applications received		
Technical Master File (TMF) new	0	0
TMF annual updates	1 (3%)	2 (5%)
TMF variations	5 (13%)	7 (17%)
TMF notifications	3 (8%)	6 (15%)
Plasma Master File annual updates	7 (18%)	7 (17%)
Biological Class 2 – new applications	0	1 (2%)
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	0	0
Biological Class 2 – variations	15 (38%)	8 (20%)
Biological Class 3 – variations	4 (10%)	2 (5%)
Biological Class 4 - variations	4 (10%)	8 (20%)
Total completed	39 (100%)	41 (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.

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.

Table 20 Priority review determinations for medical devices granted for 1 July to 31 December 2020

Application type	Granted
ARTG inclusion	0
Conformity assessment	0
Total	0

Table 21 Number of medical devices approved through the priority review pathway for 1 July to 31 December 2020

Application Type	Number Approved (% of Total)	Median approval time (TGA working days)
A: Conformity Assessment	1 (100%)	70
B: Medical Devices (ARTG inclusion)	0	N/A
Total	1 (100%)	N/A

Table 22 Completed applications and processing time for conformity assessments of medical devices (including IVDs) for 1 July to 31 December

	2019	2020
	1 July to 31 December Number (% of total)	
New devices		
Total completed	40	38
Percentage processed within target processing timeframes	100%	100%
Mean TGA processing time (working days)	143	103
Median TGA processing time (working days)	197	62
Changes to recertification		
Total completed	119	122
Percentage processed within target processing timeframes	100%	100%
Mean TGA processing time (working days)	153	114
Median TGA processing time (working days)	181	94

Note: The TGA is required to complete conformity assessment applications within 255 working days. 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 had the effect of reducing the mean and median timeframes.

Table 23 Completed applications for inclusion of medical devices and IVDs on the ARTG for 1 July to 31 December

	2019	2020
	1 July to 31 December Number (% of total)	
Class I medical devices	994 (37%)	2,283 (56%)
Class I measuring medical devices	36 (1%)	34 (1%)
Class I sterile medical devices	160 (6%)	160 (4%)
Class IIa medical devices	794 (30%)	750 (19%)
Class IIb medical devices	361 (14%)	332 (8%)
Class III medical devices	210 (8%)	219 (5%)
Active Implantable Medical Devices (AIMD)	19 (1%)	41 (1%)
Class 1 IVDs	29 (1%)	62 (2%)
Class 2 IVDs	39 (1%)	39 (1%)
Class 3 IVDs	22 (1%)	120 (3%)
Class 4 IVDs	4 (1%)	9 (1%)
Total	2,651 (100%)	4,049 (100%)

Table 24 Application audits completed and processing time for medical devices and IVDs 1 July to 31 December 2020

	Total completed	Processing times	
		Mean	Median
Medical devices			
Auto-included applications[a]	2,283		
Applications completed without audit[b]	1,226	9	8
Non-compulsory audits[c]	73	96	37
Level 1 compulsory audits	24	58	64
Level 2 compulsory audits	165	192	161
IVDs			
Auto-included applications[a]	47		
Applications completed without audit[b]	35	7	2
IVD non-compulsory audit	2	69	69
IVD compulsory audit	102	53	42

[a] Class I and Class 1 IVDs (with some exceptions) are automatically included medical devices and are not subject to audits before inclusion. Separate post-market monitoring is undertaken for these goods.

[b] These figures do not include applications for Class I and Class 1 IVD auto-included devices. These applications are completed within 20 working days.

[c] Non-compulsory audit – estimate for the audit processing time does not include applications for reclassification of joint replacement medical devices received during transitional period (Class III Joint Reclassification medical devices).

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 good (OTGs).

Table 25 Completed applications for listing of disinfectants in the ARTG for 1 July to 31 December

	2019	2020
	1 July to 31 December	
Listed OTG (Disinfectants)		
Applications completed	10	221

Table 26 Outcomes of listed disinfectant 1 July to 31 December

	2019	2020
	1 July to 31 December	
Listed OTG (Disinfectants)		
Approved/ Accepted	0	101
Rejected/ Lapsed	2	31
Withdrawn	8	89

7. Exports

Table 27 Approved applications for export-only medicines and export certifications and processing time for 1 July to 31 December

	Total approved	Target processing time (days)	2019	2020
			Average processing time (days)	
Export-only medicines				
New applications	227	30	18	24
Variation and grouping applications	95	30	14	24
Export certification				
Medicines	720	15	12	12
Medical devices	452	10	4	9

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 which are human body fluids, organs and other tissues or substances derived from human blood.

Table 28 Number of issued permits for the export of human substances for 1 July to 31 December

	2019	2020
	1 July to 31 December Total issued	
Permit Type		
Annual permit	29	13
Bone and tissue permit	23	38
Blood fraction permits	100	21

8. Access to unapproved therapeutic goods

8.1. Special Access Scheme

Table 29 Completed applications and notifications for the Special Access Scheme for 1 July to 31 December

	2019	2020[a]
	1 July to 31 December Number (% of total)	
Medicines		
Category A	23,859 (40%)	22,852 (31%)
Category B[b]	27,714 (46%)	45,820 (61%)
Category C	8,654 (14%)	6,288 (8%)
Total	60,227 (100%)	75,140 (100%)
Medical devices		
Category A	2,763 (57%)	2,397 (42%)
Category B	1,593 (33%)	2,922 (52%)
Category C	494 (10%)	330 (6%)
Total	4,850 (100%)	5,649 (100%)
Biologicals		
Category A	40 (5%)	43 (9%)
Category B	613 (77%)	303 (62%)
Category C	142 (18%)	144 (29%)
Total	795 (100%)	490 (100%)

[a] 16,535 additional SAS Category C notifications received from 1 July to 31 December 2020 and earlier are yet to be processed by the TGA.

[b] The increase in SAS Category B applications for medicines in 2020, when compared to 1 July to 31 December 2019, is attributable to increases in applications for unapproved medicinal cannabis products.

8.2. Authorised prescribers

Table 30 Authorised prescriber approvals for medicines and medical devices for 1 July to 31 December

	2019	2020
	1 July to 31 December Number (% of total)	
Medicines[a]	446 (64%)	1,832 (90%)
Medical devices	253 (36%)	196 (10%)
Total	699 (100%)	2,028 (100%)

[a] The increase in Authorised Prescriber applications for medicines in 2020, when compared with 1 July to 1 December 2019, is attributable to increases in applications for unapproved medicinal cannabis products.

8.3. Clinical trials

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

	2019	2020
	1 July to 31 December Number (% of total)	
Medicine only	205 (41%)	245 (42%)
Medical device only	91 (18%)	93 (16%)
Biological only	6 (1%)	2 (1%)
Medicine and medical device	197 (40%)	245 (42%)
Medical device and biological	0	0
Medicine and biological	0	0
Medicine, medical device and biological	0	0
Total	499 (100%)	585 (100%)

A trial may be notified with more than one phase type and not all trials are notified to the TGA by phase, therefore there may be a discrepancy between the numbers in Tables 24 and 25.

Table 32 Notifications for new clinical trials received by phases for 1 July to 31 December[a]

	2019	2020
	1 July to 31 December	
Phase 1	110	131
Phase 1 and 2 in combination	24	33
Phase 2	104	128
Phase 2 and 3 in combination	3	9
Phase 3	116	148
Phase 4	32	28
Bioavailability / equivalence	6	4
Other phases in combination	9	14
Device only	95	90

[a] No clinical trials applications (CTX) were approved during 1 July to 31 December 2020.

A trial may be notified with more than one phase type and not all trials are notified to the TGA by phase, as such there may be a discrepancy between the numbers in Tables 26 and 27

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

	2019	2020
	1 July to 31 December	
Outcomes of inspections of Australian manufacturers		
Number of inspections conducted	80	64
Satisfactory compliance (of completed inspections)	47 (59%)	44 (69%)
Marginal compliance (of completed inspections)	14 (18%)	7 (11%)
Unacceptable (of completed inspections)	5 (6%)	2 (3%)
Compliance under assessment at period end	14 (18%)	11 (17%)
Processing time		
Initial inspections conducted within 3 months of application	11 of 13 (85%)	0 of 0 (0%)
Re-inspections conducted within 6 months of due date	31 of 46 (67%)	36 of 63 (57%)[a]
Outcomes of inspections of overseas manufacturers		
Number of inspections conducted	41 (100%)	15[b]
Satisfactory compliance (of completed inspections)	26 (63%)	13 (7%)
Marginal compliance (of completed inspections)	11 (27%)	1 (7%)
Unacceptable (of completed inspections)	0 (0%)	0 (0%)
Compliance under assessment at period end	4 (10%)	1 (7%)
Processing time		
Initial certification inspections conducted within 6 months of application	8 of 14 (57%)	0 of 1 (0%)[a]
Certification re-inspections conducted within 6 months of due date	17 of 22 (77%)	1 of 12 (8%)[a]

[a] In the first 6 months of 2020 travel restrictions in response to the COVID-19 pandemic required the reprioritisation of all scheduled inspections, which resulted in delays of domestic re-inspections and overseas initial and re-inspections.

[b] The decline in the number of overseas inspections conducted is attributed to COVID-19 pandemic travel restrictions. Implementation of remote inspection processes following a short suspension of the overseas program has enables overseas inspections to continue.

Table 34 Medical Devices 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.

	2019	2020
	1 July to 31 December	
Quality Management System (QMS) Audits (domestic manufacturers)		
Number of audits conducted	14	8
Satisfactory compliance (of completed audits)	28%	13%
Marginal compliance (of completed audits)	0%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in progress	50%	88%
Processing time		
Initial audits conducted within 3 months of application	33%[a]	100%
Re-audits conducted within 6 months of due date	27%	0%
QMS Audits (overseas manufacturers)		
Number of audits conducted	9	0[a]
Satisfactory compliance (of completed audits)	11%	0%[a]
Marginal compliance (of completed audits)	0%	0%[a]
Unacceptable (of completed audits)	0%	0%[a]
Close-out in progress	11%	0%[a]
Processing time		
Initial certification audits conducted within 6 months of application	50%	0%
Certification re-audits conducted within 6 months of due date	50%	0%

[a] COVID-19 travel restrictions prevented QMS Audits of overseas manufacturers from 1 July to 31 December 2020. However, changed arrangements were implemented, including delaying on-site audits where appropriate, and completing desktop assessment of the comparable regulator evidence, and undertaking remote audit.

Table 35 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.

	2019	2020[a]
	1 July to 31 December Number (% of total)	
Applications received	2,948	3,783
Applications completed		
Approved	2,874 (90%)	3,317 (93%)
Rejected	309 (10%)	256 (7%)
Total completed	3,183 (100%)	3,573 (100%)

[a] The July to December data for 2020 includes additional application types that were not reported on in 2019 such as transfers of sponsorship, name changes and GMP Clearances issued from TGA certificates. These additional application types account for an increase of almost 400 across both received and completed categories. In addition to this, as a result of the COVID-19 pandemic, we have seen significant increases in the number of extension and renewal applications.

Table 36 Number of GMP Clearance applications received and completed by type for 1 July to 31 December 2020

Application Category	Applications received	Applications completed
Cancel	2	2
Extend	1,230	1,211
New	1,070	953
Variation	1,460	1,387
Reinstatement	21	20

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

Table 37 Number of Compliance Verification and Mutual Recognition Agreement applications actioned by pathway for 1 July to 31 December 2020

Pathway	Applications received	Applications completed[b]	Applications approved	Applications not approved
Compliance Verification[a]	745	678	629	47
Mutual Recognition Agreement[a]	1,436	1,319	1,251	66

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

	2019		2020	
	1 July to 31 December			
Product type	**Total**	**% fail**	**Total**	**% fail**
Prescription medicines	665	16%	347	6%
OTC medicines	14	57%	10	10%
Complementary medicines	121	4%	7	57%
Medical devices	119	50%	457	63%
External/contract[a]	8	13%	18	11%
Pacific Medicines Testing Program[b]	27	0%	37	68%
Unregistered[c]	236	16%	92	35%
Total samples (excluding AHQ samples)[c]	1,190	18%	1,438	43%
Total samples (including AHQ samples)[d]	1,435	15%	1,730	36%
Total number of products tested[e]	622	N/A	584	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 https://www.tga.gov.au/laboratories-branch-international-affiliations

[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 39 Source of notifications of medicine and vaccine adverse reaction for 1 July to 31 December

	2019	2020[a]
	1 July to 31 December	
Accepted cases total	**11,662 (95%)**	**12,340 (96%)**
Reports by health professionals (total)	2,327	2,445
Medical practitioners	537	569
Pharmacists	1,123	1,329
Nurses	221	363
Others	249	113
Unknown	197	71
Patients/consumers	395	462
Pharmaceutical companies	7,484	7,978
Other source	1,456	1,455
Rejected/withdrawn cases	**633 (5%)**	**475 (4%)**
Total received	12,295	12,815
Average number of reports received weekly	473	493
Vaccine reports included in this table	1,706	1,727

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

	2019	2020[a]
	1 July to 31 December	
Reports completed	3,042	3,520
Mean TGA processing time	47	59
Percentage processed within target timeframe	93%	74%

13. Regulatory compliance

In October 2020, a new case management system for non-advertising related compliance matters was implemented providing enhanced access to case data. 2019 comparative data has been restated where appropriate for adjustments to the table format, utilising the new IT solution.

Table 41 Different Products investigated 1 July to 31 December

	2019	2020[a]
	1 July to 31 December Number (% of total)	
Prescription medicines	2,071 (83%)	2,388 (90%)
Schedule 9 medicines	34 (1%)	5 (1%)
Schedule 10 medicines	27 (1%)	19 (1%)
Medical devices	22 (1%)	66 (2%)
Complementary and homeopathic medicines	311 (12%)	156 (6%)
OTC medicines	25 (1%)	22 (1%)
Biological products	4 (1%)	2 (1%)
Total[a]	2,494 (100%)	2,658 (100%)

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

Table 42 Number of compliance actions taken for completed investigations 1 July to 31 December

	2019	2020[a]
	1 July to 31 December Number (% of total)	
Criminal prosecution	0	2 (1%)
Infringement notices issued	24 (1%)	100 (2%)
Warning letters issued[a]	1,402 (48%)	1,780 (42%)
Destruction certificates issued	1,126 (39%)	1,549 (37%)
Goods released under the Personal Importation Scheme	205 (7%)	687 (16%)
Referred to external entity	52 (2%)	27 (1%)
Referrals to Commonwealth Department of Public Prosecutions	2 (1%)	2 (1%)
No offence identified[b]	85 (3%)	80 (2%)
Total completed[c]	2,896 (100%)	4,227 (100%)

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

[b] 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.

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

COVID-19 related therapeutic goods contributed to an increase in the number of referrals from Australian Border Force from 1 July to 31 December 2020.

Table 43 Offence types related to completed cases for 1 July to 31 December

	2019	2020[a]
	1 July to 31 December Number (% of total)	
Import	1,553 (86%)	2,493 (99%)
Supply	216 (12%)	19 (1%)
Manufacture	35 (2%)	2 (1%)
Export	6 (1%)	7 (1%)
Total completed[a]	1,810 (100%)	2,521 (100%)

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

14. Recalls

Table 44 Therapeutic goods recalls for 1 July to 31 December

	2019	2020[a]
	1 July to 31 December	
Medicines	32 (8%)	47 (12%)
Medical devices (including IVDs)	326 (76%)	286 (73%)
Biologicals	8 (2%)	11 (3%)
Bloods	60 (14%)	50 (13%)
Total recalls	426 (100%)	394 (100%)

The total recalls activity dropped by about 8% between 1 July to 31 December 2019 and 1 July to 31 December 2020 . However, medicine recall actions which increased from 32 to 47 overall. This was in part due to 'class wide' recall actions for products containing the herbal ingredient, *Fallopia multiflora* and non-prescription medicine, *bufexamac*.

15. Pharmacovigilance Inspection Program

Table 45 Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified from 1 July to 31 December

	2019	2020[a]
	1 July to 31 December	
Total completed	**5**	**3**
Total with completed findings	5	3
Critical deficiencies[a]	0	1
Major deficiencies[b]	21	13
Minor deficiencies[c]	17	10
Average deficiencies per inspection	0.0 critical 4.2 major 3.4 minor	0.3 critical 4.3 major 3.3 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.

16. Reporting of medicine shortages

Table 46 New medicine shortage reports by month for July to December[a]

	2019	2020[a]
	1 July to 31 December	
July	131	112
August	89	120
September	129	111
October	149	82
November	117	123
December	150	110
Total reports	**765**	**658**

[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 47 Number of medicine shortage reports a by shortage reason 1 July to 31 December

	2019	2020[a]
	1 July to 31 December Number (% of total)	
Shortages Reported		
New - Commercial changes	N/A	50
New - Manufacturer related	N/A	249
New - other	N/A	237
New - Product Recall	N/A	1
New - Unexpected increase in demand	N/A	121
Total	765[b]	658

[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.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Reporting and Collaboration Services	31/03/2021

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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