Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration

Half Yearly Performance Snapshot

1 July to 31 December 2019

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.

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 1 July to 31 December 2019 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 2019-20 financial year, to be published on the TGA website in the second half of 2020.

As part of our annual Business Plan we continue to implement the Australian Government response to the Review of Medicines and Medical Devices Regulation (MMDR) involving a significant program of work. Throughout 2019-20 we will continue to roll out reforms in a staged approach with the majority of activities set to conclude by the end of the financial year.

Performance highlights

The TGA has maintained a high level of activity while also implementing regulatory reforms over the period from 1 July to 31 December 2019. Highlights are as follows:

Medicines

International collaboration

- TGA collaborated with the US Food and Drug Administration's (FDA) Project Orbis which facilitates earlier patient access to new oncology products and haematological malignancy products. Three medicines were collaboratively reviewed in two applications in 2019:
  - Lenvima® (lenvatinib) in combination with Keytruda® (pembrolizumab) for the treatment of patients with advanced endometrial carcinoma; and
  - Calquence® (acalabrutanib) for the treatment of chronic lymphocytic leukaemia (CLL) / small lymphocytic leukaemia (SLL).
- Significant activity has continued within the Australia-Canada-Singapore-Switzerland (ACSS) Consortium's New Chemical Entities Work Sharing Pilot. Together with those already approved, four additional submissions have been received and are currently under evaluation.

Generic medicine market authorisation process

- In December 2019, we implemented changes to the registration process for prescription generic medicines that reduce regulatory barriers for applicants, and support international work sharing initiatives. Australian-specific requirements for use of overseas reference products in bioequivalence studies have been reduced, and templates aligned with international requirements for summarising bioequivalence and biowaiver study data are now available to assist applicants. These changes better align Australian regulatory requirements and documentation with approaches used by other regulatory agencies.

Provisional approval

- Early access to life-saving medicines likely to provide a major therapeutic advance was supported through the first provisional registrations for prescription medicines, on the basis of promising clinical data. Six provisional registrations were approved in this period.

Increased transparency

- Consumers have told us of their frustration in not being able to easily access information about medicine formulations through existing mechanisms. We held a public consultation on a proposal to publish the names of excipient ingredients used in therapeutic goods the Australian Register for Therapeutic Goods (ARTG). Feedback confirmed that this would assist Australian patients and consumers to make more informed choices about their medicines. It may also assist in identification and avoidance of substances that cause idiosyncratic reactions in some people. The proposal has now been agreed by the Australian Government and changes to the TGA website will be implemented in early 2020. Comprehensive communications to assist consumers' understanding of how to access and interpret this information will accompany the launch.

Prescription medicines

- A second round of enhancements to the electronic processing of applications to vary existing medicines was implemented.
- We implemented new processes that support timely approval and early access to new prescription medicines, or new uses for existing medicines. During this reporting period, we approved:
  - fifteen orphan drug designations, four priority review approvals for registration, with a median approval time of 125 working days
  - three provisional determinations and six provisional approvals for registration, with a median approval time of 71 working days
  - five approvals for registration after undergoing Comparable Overseas Regulator (COR)-B review with a median approval time of 148 working days, and
  - three medicines reviewed collaboratively through Project Orbis.
- Over the reporting period, 185 Category 1 and COR (including 22 New Chemical Entities [NCE] and 36 new generic medicines), and 743 Category 3 applications were approved. This is consistent with the equivalent period in 2018 (183 Category 1 and 697 Category 3 applications). Mean and median approval times were well below the statutory timeframes, as detailed in chapter 1.
- Rapid access to regulatory information was improved through a more efficient AusPAR format, and an overhaul of the regulatory guidelines (ARGPM) with an improved structure and search capability. We also introduced Australian Prescription Medicine Decision Summaries to provide a short overview of the TGA's evaluation process leading to the registration of a new prescription medicine on the ARTG.

Over-the-counter medicines

- We approved 78 new over-the-counter medicine applications (N1 to N5) during this period, which was similar to the previous six months (82).
- The number of approved applications to change existing medicines (C2 to C4; 380) increased in comparison to the previous six months (340).
- For all application types, more than 80% were completed within target times.

Listed medicines

- The number of new listed medicine applications increased by 21% in July to December 2019 (1,141) compared with the same period in 2018 (943), and is likely as a result of sponsors transitioning to permitted indications.
- We approved a higher number of Registered Complementary Medicine variation applications during this period. The majority of applications were for label variations to comply with the Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.
- The number of compliance reviews that were completed in this period (105) was higher than for the same period last year (57). This increase is mainly due to targeting of medicines with potential high-risk compliance issues identified through our internal data analytics. This is reflected by the higher proportion of targeted reviews completed in this period compared with the same period last year (82% compared with 21%).

Exports

- The TGA is in the process of updating information on the website for the export of therapeutic goods from Australia, with a new webpage to be published in early 2020. The updated webpage will provide clear and concise information regarding the export of therapeutic goods from Australia, and will be user-focused to ensure that finding required information is easy and streamlined.

Access to unapproved therapeutic goods

- We approved 1,236 Authorised Prescriber applications, including 446 applications for medicines, 119 for unapproved medicinal cannabis products, and 253 applications for medical devices.
- We processed a total of 65,872 applications and notifications through the Special Access Scheme (SAS). We processed 60,227 SAS applications and notifications for medicines, including 18,870 for unapproved medicinal cannabis products, 4,850 for medical devices, and 795 for biologicals.
- We processed large increases in SAS Category B applications for medicines, up 277% compared with the same period in 2018 (27,714 in July to December of 2019, compared with 7,336 during the same period in 2018). This is attributable to significant increases in applications for unapproved medicinal cannabis products.
- We also processed a 25% increase in SAS Category A notifications for medicines, when compared with the same period in 2018 (23,859 in July to December of 2019, compared to 19,178 during the same period in 2018), though this is not attributable to medicinal cannabis increases.

Clinical trials

- During this period, there were 499 notifications for new clinical trials through the CTN scheme, which is comparable to the same reporting period in 2018 of 494.

Licensing and manufacturing

- Initial inspections are performed when a manufacturer has applied for a Good Manufacturing Practice (GMP) licensed site in Australia, or when sponsors have requested a GMP clearance for a new overseas manufacturing site and TGA have performed a GMP certification inspection for this to occur. Initial inspections continue to be performed within the target dates for Australian manufacturers (85% within three months of the application) which is similar to the last reporting period. There was a decrease in the number of initial inspections for overseas manufacturers performed within the target dates (57% within six months of the application in 2019, compared to 78% for the equivalent period in 2018). This is as a result of the TGA working with a manufacturing facility to ensure they are ready for inspections before they are conducted, as applications are often submitted before manufacturing systems and processes are finalised.
- Re-inspections are undertaken to confirm Australian licensed manufacturer compliance and also overseas manufacturers compliance, using a risk-based approach to determine how frequently these inspections need to occur. There was a decrease (from 78% in 2018 to 67% for the equivalent period in 2019) of inspections performed for Australian manufacturers within the six-month timeframe.
- The overall compliance of Australian and overseas manufacturers was similar compared to the same period in 2018. 6% of the inspections completed in this period had unacceptable compliance.

Medicine and vaccine adverse event reports

- The TGA received 12,295 cases between July and December 2019. The number of reports received was similar to the same period in 2018. Nearly two-thirds (64%) of reports were received from sponsors. Health professionals reported 2,321 (20%) of accepted cases, with pharmacists the most common health professional reporter type (48%).

Regulatory compliance

- During this period the TGA continued its focus on areas of alleged non-compliance relating to products used in cosmetic procedures and the import, manufacture, supply and advertising of peptides and Selective Androgen Receptor Modulators (SARMs). We continued to broaden our compliance and enforcement approaches to ensure a proportionate and appropriate response, including ongoing focus and investment in education. Two referrals were made to the Commonwealth Department of Public Prosecutions, with 184 alleged offences representing the largest case referred by the TGA. A civil court proceeding was also concluded. There was a significant increase in the use of infringement notices as an alternative to court action.

Advertising complaints

- In its second financial year as the sole body for handling complaints about the advertising of therapeutic goods to the Australian public, the TGA is on track to receive a greater number of complaints than it did in its first year. We completed 1,493 advertising cases between June to December 2019, compared to 746 during the same period in 2018.
- Throughout the second half of 2019 we have continued to strengthen our capabilities to support the effective use of advertising sanctions and penalties with an increase in the number of advertising directions and infringement notices issued in the reporting period.
- We have continued to focus on stakeholder engagement and expand our educational offerings. This includes the Therapeutic goods advertising compliance: 2018-19 annual report[1].

Recalls

- The total recalls activity across three of the four product categories has shown a significant increase (23%) from the previous six-monthly reporting period (426 in July to December 2019 compared to 347 in the same period in 2018). Whilst showing an overall increase in volume, proportionally, each product category has remained relatively consistent with the previous period.

Laboratory testing

- The six months between July and December 2019 saw a large increase in the number of unregistered products tested by the Laboratories Branch (236 samples tested in July to December 2019, compared to 67 samples in the same period in 2018). This was the result of the seizure of large numbers of samples. Testing of the suspect samples informed regulatory actions to ensure the continued safety of the Australian public.
- A significant rise in the failure rates of tested Prescription and Over-the-Counter products was observed during the reporting period. This was predominantly due to the testing of large numbers of Ranitidine samples to determine the extent of nitrosamine contamination in these commonly used products.

[1] www.tga.gov.au/publication/therapeutic-goods-advertising-compliance-2018-19-annual-report

Pharmacovigilance Inspection Program

- During this period, we inspected five medicine sponsors. Inspections were scheduled using a risk-based approach and included an internal assessment of the sponsor's pharmacovigilance system, product portfolio, and regulatory compliance history. Deficiencies were identified in each inspection with 21 major deficiencies and 17 minor deficiencies total. No critical deficiencies were identified during this period.

Reporting of medicine shortages

- The number of medicine shortages reported to the TGA greatly increased as a result of the implementation of mandatory reporting (765 reported during July to December 2019 compared to 403 for the same period in 2018). Since 1 January 2019, sponsors of prescription medicines and some over-the-counter medicines have been required to report all shortages or discontinuations of their products to the TGA.

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 Act, 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:

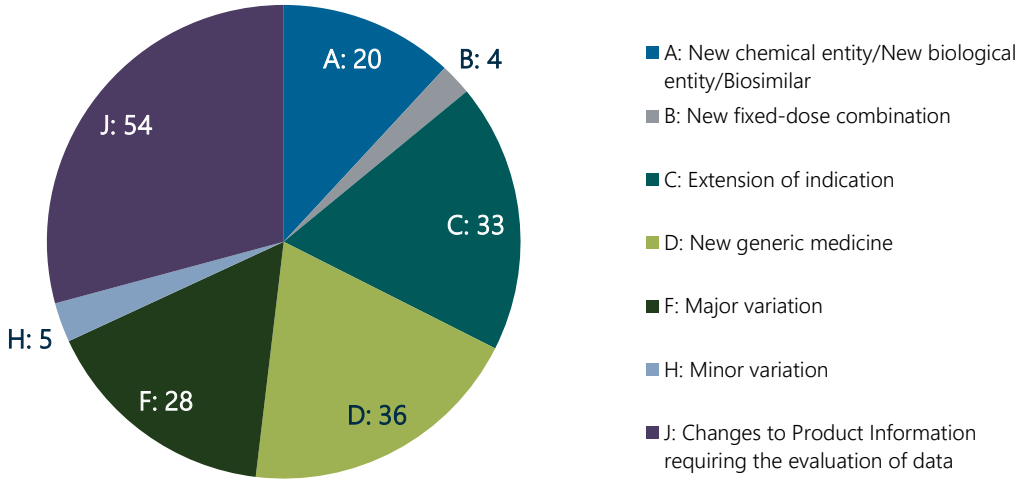
Application category	Description	Timeframe in working days
Category 1	An application to register a new prescription medicine (other than an additional trade name) or to make a variation to an existing medicine that involves the evaluation of clinical, pre-clinical or bio-equivalence data. For example, 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 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

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.

Figure 1 Number of approved Category 1 and COR submissions by type for July to December 2019

Prescription medicine submissions may include a number of applications submitted at the one time. The data below relates to the number of submissions.



A: Includes three submissions processed via the priority review.

C: Includes one submission processed via the priority review.

1.1. Submission outcomes

Table 1 Number of completed prescription medicines submissions by type and outcome for July to December 2019

	Number			
Submission Type	Approved	Withdrawn	Rejected	Total (% approved)
Category 1				
A: New chemical entity/New biological entity/ Biosimilar[a]	20	1	0	21 (95%)
B: New fixed-dose combination	4	0	0	4 (100%)
C: Extension of indication	33	1	2	36 (92%)
D: New generic medicine	36	2	0	38 (95%)
F: Major variation	28	1	1	30 (93%)
G: Minor variation[b]	0	0	0	0
H: Minor variation[c]	5	0	0	5 (100%)
J: Changes to Product Information	54	2	0	56 (96%)
Comparable Overseas Regulator (COR) – B[d]				
A: New chemical entity/New biological entity/ Biosimilar	2	0	0	2 (100%)
C: Extension of indication	1	0	0	1 (100%)
F: Major variation	2	0	0	2 (100%)
Minor Variations				
Category 3				
G: Minor variation[b]	53	3	0	56 (95%)
H: Minor variation[c]	690	13	0	703 (98%)
Additional Trade Name [ATN]	15	0	0	15 (100%)
Safety-related request [SRR]	568	10	0	578 (98%)
Self-assessable request [SAR]	623	9	0	632 (99%)
Minor editorial change [MEC]	123	3	0	126 (98%)
Correction [9D(1)]	79	10	0	89 (89%)
Notification	776	1	0	777 (99.9%)
Total	3112	56	3	3171 (98%)

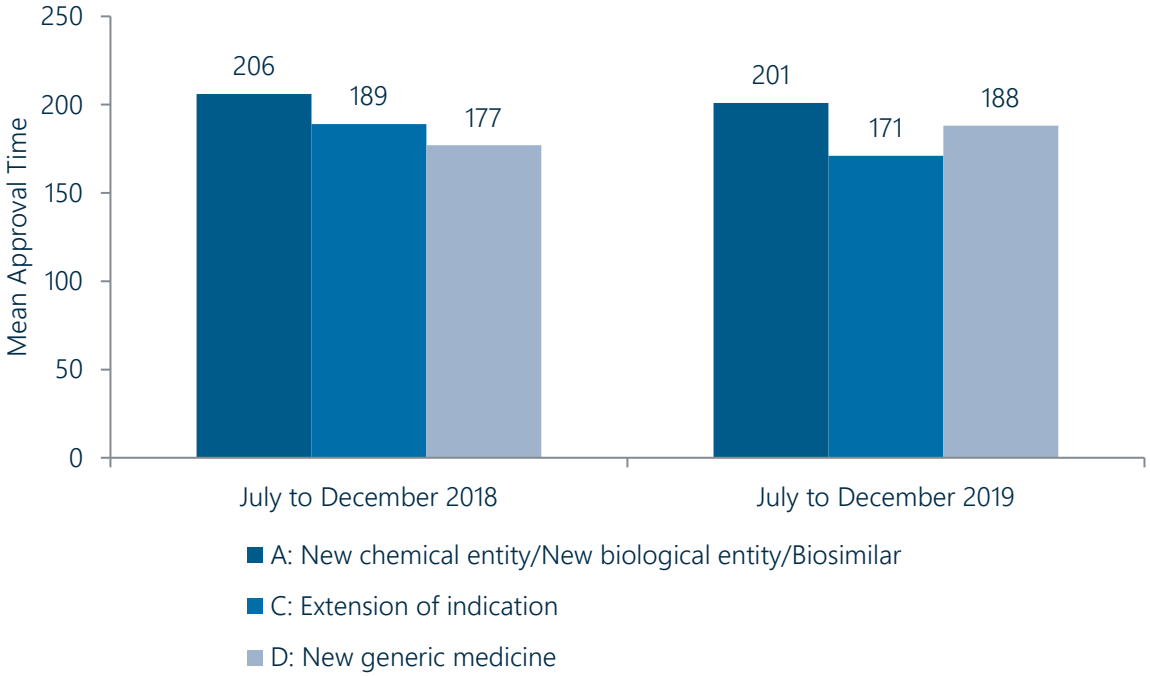
a Includes submissions processed via the priority review.

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.

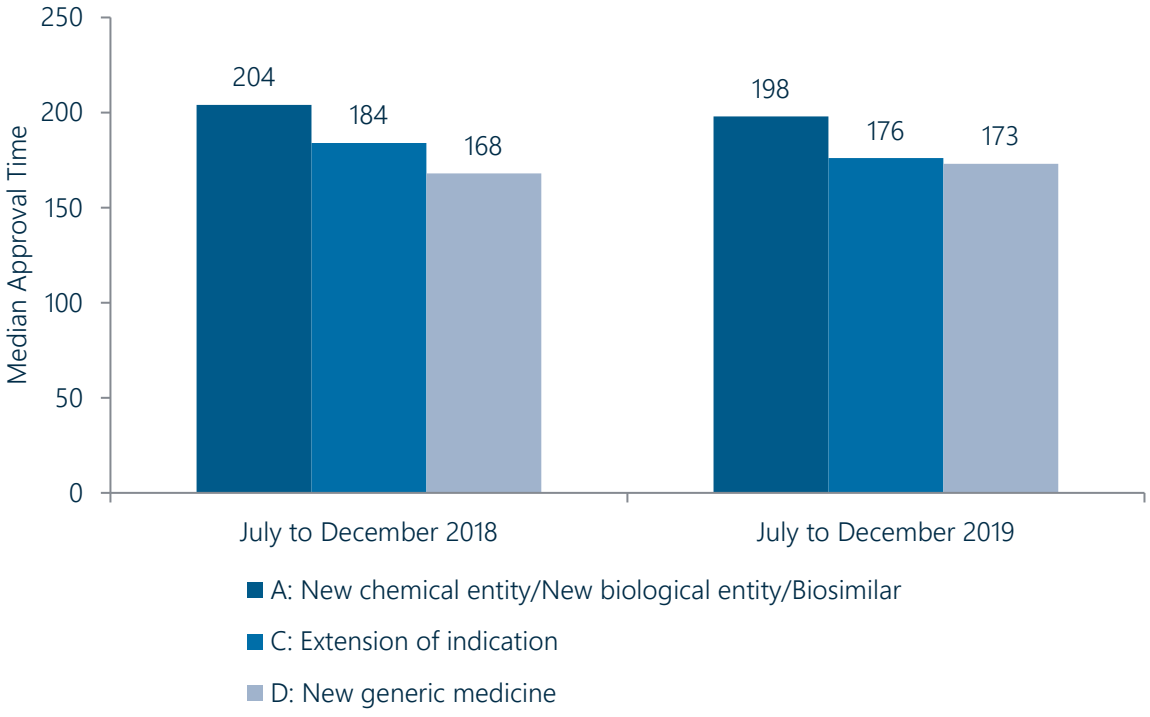
d No COR-A submissions were completed during this period.

Figure 2 Prescription medicine standard registration[a] mean approval times



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

Figure 3 Prescription medicine standard registration[a] median approval times



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

1.2. Approval times

Table 2 Prescription medicine standard registration application approval time for July to December 2019

Application type	Submissions Approved	Legislated timeframe	Approval time (working days) July to December		
			Mean	Median	Range
Category 1					
A: New chemical entity/New biological entity/Biosimilar[a]	17	255	201	198	153-247
B: New fixed-dose combination	4	255	195	192	168-228
C: Extension of indication[b]	32	255	171	176	54-248
D: New generic medicine	36	255	188	173	96-254
F: Major variation	28	255	184	190	124-252
G: Minor variation	0	255	n/a	n/a	n/a
H: Minor variation	5	255	126	126	89-169
J: Changes to Product Information requiring the evaluation of data	54	255	135	125	17-220
Comparable Overseas Regulator (COR-B)[c]					
A: New chemical entity/New biological entity/Biosimilar	2	175	112	112	73-168
C: Extension of indication	1	175	158	158	158-158
F: Major variation	2	175	148	148	143-152

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

b Application type C figures do not include one submission processed via the priority review pathway.

c No COR-A submissions were completed during this period.

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 Number of other prescription medicine submissions for July to December

	2018	2019
	July to December	
Exemptions to comply with a standard (S.14)	Number (% of total)	
Approved	28 (97%)	50 (86%)
Rejected	1 (3%)	8 (14%)
Total	29 (100%)	58 (100%)

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

Application type	Legislated timeframe	Median approval time (TGA working days) July to December	
		2018	2019 (% Change)
Category 1			
A: New chemical entity/New biological entity/Biosimilar[a]	255	204	198 (▼3%)
B: New fixed-dose combination	255	216	192 (▼11%)
C: Extension of indication[a]	255	184	176 (▼5%)
D: New generic medicine	255	168	173 (▲3%)
F: Major variation	255	193	190 (▼2%)
G: Minor variation[b]	255	189	n/a
H: Minor variation[c]	255	81	126 (▲56%)
J: Changes to Product Information requiring the evaluation of data	255	146	125 (▼14%)
Comparable Overseas Regulator (COR-B)[d]			
A: New chemical entity/New biological entity/Biosimilar	175	n/a	112
C: Extension of indication	175	n/a	158
F: Major variation	175	n/a	148
Additional trade name (ATN)			
E: Additional trade name	45	41	43 (▲5%)
Minor Variations			
Category 3			
G: Minor variation[b]	45	42	40 (▼5%)
H: Minor variation[c]	45	38	36 (▼5%)
Safety-related request [SRR]	n/a	35	35
Self-assessable request [SAR]	45	40	41 (▲2%)
Minor editorial change [MEC]	45	32	27 (▼16%)
Correction [9D(1)]	n/a	54	33 (▼39%)

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.

d No COR-A submissions were completed during this period.

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 July to December

	2018	2019
	July - December	
Application type (proposed)	Number (% of total)	
A: New chemical entity/New biological entity/Fixed dose combination	4 (44%)	13 (87%)
C: Extension of Indications	5 (56%)	2 (13%)
Total	9 (100%)	15 (100%)

Table 6 Orphan drug registrations for July to December

	2018		2019	
	July- 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	4 (33%)	150	5 (56%)	198
C: Extension of Indications	4 (33%)	176	4 (44%)	196
F: Major Variation	4 (34%)	191	0 (0%)	N/A
Total	12 (100%)	176	9 (100%)	198

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 July to December

	2018	2019
	July – December Number (% of total)	
Application Type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	2 (50%)	4 (100%)
C: Extension of Indications	2 (50%)	0 (0%)
Total	4 (100%)	4 (100%)

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

	2018		2019	
	July - 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	2 (71%)	105	3 (75%)	130
C: Extension of Indications	5 (29%)	122	1 (25%)	105
Total	7 (100%)	122	4 (100%)	125

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. Knowledge of the risks and benefits of these medicines is less certain than for other approved prescription medicines. Provisional approval is granted for promising new medicines where we assess that the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data 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 is used to assess whether a medicine is eligible for the provisional pathway, but does not necessarily mean that the medicine will be approved after evaluation and provisionally registered on the ARTG.

Table 9 Provisional determinations granted for July to December

	2018	2019
	July – December Number (% of total)	
Application type (proposed)	Granted	
A: New chemical entity/New biological entity/Fixed dose combination	2 (50%)	2 (67%)
C: Extension of Indications	2 (50%)	1 (33%)
Total	4 (100%)	3 (100%)

Table 10 Provisional approval registrations[a] for July to December

	2019	
	July - December	
Application type	Number Approved (% of total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	2 (33%)	135
C: Extension of Indications	4 (67%)	62
Total	6 (100%)	71

a There is no 2018 comparison data as the first provisional approval registration was completed in 2019.

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 July to December 2019

Application type	Number completed (% of total)	Target Approval time (days)	Range	Mean	Median	% within target
New medicine applications						
N1 Lower risk	32 (41%)	45	4-59	21	16.5	97
N2	1 (1%)	55	46	46	46	100
N3	25 (32%)	150	31-269	115	90	84
N4	13 (17%)	170	93-241	152	159	93
N5 Higher risk	7 (9%)	210	113-207	140	113	100
Total	78 (100%)					
Change Applications						
C1 Lower risk	139 (27%)	20	0-36	8	6	94
C2	379 (73%)	64	0-116	28	23	95
C3	0	120	N/A	N/A	N/A	N/A
C4 Higher risk	1 (>0.1%)	170	75	75	75	100
Total	519 (100%)					

Table 12 Other OTC medicine applications processed for July to 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. 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.

	2018	2019
	July – December Number (% of total)	
Notification changes, where their implementation would not impact the quality, safety or efficacy of a medicine		
CN	101	78
Request for advice for the purpose of listing a medicine as a pharmaceutical benefit		
B1	2 (100%)	0
B3	0	0
Total	2 (100%)	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	5 (100%)	4 (100%)
Rejected	0	0
Total	5 (100%)	4 (100%)

3. Complementary medicines

3.1. Registered complementary medicines

Table 13 Number of approved registered complementary medicine applications for July to December

	2018	2019
	July to December	
New registered medicines	2	2
Variation to registered medicines	12	27

3.2. Listed complementary medicines

Table 14 Number of new ingredients permitted for use in listed medicines for July to December

	2018	2019
	July to December	
New permitted ingredients	5	4

Table 15 Number of new listed medicines for July to December

	2018	2019
	July to December	
New listed medicines	943	1141

Table 16 Number of listed medicine reviews by type for July to December

	2018	2019
	July to December Number (% of total)	
Reviews initiated		
Random reviews	6 (86%)	5 (4%)
Targeted reviews	1 (14%)	136 (96%)
Total	7 (100%)	141 (100%)
Reviews completed		
Random reviews	45 (79%	19 (18%)
Targeted reviews	12 (21%)	86 (82%)
Total	57 (100%)	105 (100%)

Table 17 Number of completed listed medicine reviews by outcome for July to December

	2018	2019
	July to December Number (% of total)	
Compliance status determined		
Medicines with no compliance breaches	5 (10%)	29 (32%)
Medicines with verified compliance breaches	45 (90%)	63 (68%)
Sub-total	50 (100%)	92 (100%)
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	7 (100%)	9 (69%)
Medicines not yet manufactured or information unavailable	0	4 (31%)
Sub-total	7 (100%)	13 (100%)
Total completed	**57 (100%)**	**105 (100%)**

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 18 Number of completed biological applications for July to December

	2018	2019
	July to December Number (% of total)	
Applications received		
New Technical Master File (TMF)	0	0
TMF annual updates	2 (6%)	1 (3%)
TMF variations	7 (23%)	5 (13%)
TMF notifications	3 (10%)	3 (8%)
Plasma Master File annual updates	6 (19%)	7 (18%)
Biological Class 2 – new applications	1 (3%)	0
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	2 (6%)	0
Biological Class 2 – variations	8 (26%)	15 (38%)
Biological Class 3 – variations	2 (6%)	4 (10%)
Biological Class 4 - variations	0	4 (10%)
Total completed	31 (100%)	39 (100%)

5. Medical devices

The regulatory framework for medical devices spans the life cycle of these products. Conformity assessment is the processes used to demonstrate that a device and manufacturing process meet specified requirements. In Australia this means that the manufacturer must be able to demonstrate that both the medical device and the manufacturing processes used to make the device conform to the requirements of the therapeutic goods legislation. Once assessed, items are included on the ARTG and can be lawfully supplied in Australia. Post-market monitoring is also conducted to evaluate the ongoing safety and efficacy of a device.

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 lodgement of the conformity assessment or ARTG inclusion application, and the granting of priority designation does not guarantee approval of the application itself.

Table 19 Priority review determinations for medical devices granted for July to December

Application type	Granted
ARTG inclusion	0
Conformity assessment	3
Total	3

Table 20 Number of completed applications and processing time for conformity assessments of medical devices (including IVDs) for July to December

	2018	2019
	July to December Number (% of total)	
New devices		
Total completed	48	40
Percentage processed within target processing timeframes	100%	100%
Mean TGA processing time (working days)	177	143
Median TGA processing time (working days)	197	197
Changes to recertification		
Total completed	96	119
Percentage processed within target processing timeframes	100%	100%
Mean TGA processing time (working days)	115	153
Median TGA processing time (working days)	98	181

Note: The TGA is required to complete conformity assessment applications within 255 working days.

Table 21 Number of completed applications for inclusion of medical devices and IVDs on the ARTG for July to December

	2018	2019
	July to December Number (% of total)	
Class I medical devices	1013 (42%)	994 (37%)
Class I measuring medical devices	12 (0.4%)	36 (1%)
Class I sterile medical devices	109 (5%)	160 (6%)
Class IIa medical devices	634 (26%)	794 (30%)
Class IIb medical devices	304 (13%)	361 (14%)
Class III medical devices	204 (9%)	210 (8%)
Class III Joint Reclassification medical devices	5 (0.2%)	0
Active Implantable Medical Devices (AIMD)	10 (0.4%)	19 (0.7%)
Class 1 IVDs	27 (1%)	29 (1%)
Class 2 IVDs	33 (1%)	39 (1.4%)
Class 3 IVDs	24 (1%)	22 (0.8%)
Class 4 IVDs	26 (1%)	4 (0.1%)
Total	2401 (100%)	2651 (100%)

Table 22 Number of application audits completed and processing time for medical devices and IVDs July to December 2019

	Total completed	Processing times	
		Mean	Median
Medical devices			
Auto-included applications[a]	994		
Applications completed without audit[b]	1278	10	9
Non-compulsory audits[c]	53	126	97
Level 1 compulsory audits	6	77	46
Level 2 compulsory audits	155	139	114
IVDs			
Auto-included applications [a]	30		
Applications completed without audit [b]	39	5	39
IVD non-compulsory audit	3	136	3
IVD compulsory audit	28	111	28

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. Exports

Table 23 Number of approved applications for export-only medicines and export certifications and relevant processing time for July to December 2019

	Total approved	Target processing time (days)	2018	2019
			Average processing time (days)	
Export-only medicines				
New applications	70	30	20	18
Variation and grouping applications	44	30	18	14
Export certification				
Medicines	736	15	10	12
Medical devices	225	10	5	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 which are human body fluids, organs and other tissues or substances derived from human blood.

In August of 2019, the TGA updated the guidance for the export of human substances. This update included a new online application form. The introduction of the online application form has been very successful and has allowed Australians who require a permit for human substances to interact with the TGA directly.

Table 24 Number of issued permits for the export of human substances for July to December 2019

	2018	2019
	Total issued	
Permit type		
Annual permit	23	29
Bone and tissue permit	25	23
Blood fraction permits	86	100

7. Access to unapproved therapeutic goods

7.1. Special Access Scheme

Table 25 Number of completed applications and notifications for the Special Access Scheme for July to December

	2018	2019
	July to December Number (% of total)	
Medicines		
Category A	19178 (54%)	23859 (40%)
Category B[a]	7336 (20%)	27714 (46%)
Category C	9315 (26%)	8654 (14%)
Total	35829 (100%)	60227 (100%)
Medical devices		
Category A	2343 (60%)	2763 (57%)
Category B	1075 (28%)	1593 (33%)
Category C	452 (12%)	494 (10%)
Total	3870 (100%)	4850 (100%)
Biologicals		
Category A	60 (6%)	40 (5%)
Category B	780 (71%)	613 (77%)
Category C	249 (23%)	142 (18%)
Total	1089 (100%)	795 (100%)

a The significant increase in SAS Category B applications for medicines in 2019, when compared with the same period of 2018, is attributable to large increases in applications for unapproved medicinal cannabis products.

7.2. Authorised prescribers

Table 26 Number of authorised prescriber approvals for medicines and medical devices for July to December

	2018	2019
	July to December Number (% of total)	
Medicines	418 (61%)	446 (64%)
Medical devices	268 (39%)	253 (36%)
Total	686 (100%)	699 (100%)

7.3. Clinical trials

Table 27 Number of notifications for new clinical trials received by therapeutic good type for July to December

	2018	2019
	July to December Number (% of total)	
Medicine only	220 (45%)	205 (41%)
Medical device only	71 (14%)	91 (18%)
Biological only	10 (2%)	6 (1%)
Medicine and medical device	193 (39%)	197 (40%)
Medical device and biological	0	0
Medicine and biological	0	0
Medicine, medical device and biological	0	0
Total	494 (100%)	499 (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 28 Number of notifications for new clinical trials received by phases for July to December[a]

	2018	2019
	July to December	
Phase 1	118	110
Phase 1 and 2 in combination	24	24
Phase 2	102	104
Phase 2 and 3 in combination	2	3
Phase 3	131	116
Phase 4	36	32
Bioavailability / equivalence	9	6
Other phases in combination	1	9
Device only	71	95

a No clinical trials applications (CTX) were approved during this period.

8. Licensing and manufacturing

Number of manufacturing inspections by outcome

Table 29A Medicines and blood, tissue and cellular therapies for July to December

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.

	2018	2019
	July to December	
Outcomes of inspections of Australian manufacturers		
Number of inspections conducted	104	80
Satisfactory compliance (of completed inspections) [a]	81%	47 (59%)
Marginal compliance (of completed inspections) [a]	19%	14 (18%)
Unacceptable (of completed inspections) [a]	0%	5 (6%)
Close-out in progress	18%	14 (18%)
Processing time		
Initial inspections conducted within 3 months of application	88%	11 of 13 (85%)
Re-inspections conducted within 6 months of due date	78%	31 of 46 (67%)
Outcomes of inspections of overseas manufacturers		
Number of inspections conducted	39	41 (100%)
Satisfactory compliance (of completed inspections) [a]	85%	26 (63%)
Marginal compliance (of completed inspections) [a]	15%	11 (27%)
Unacceptable (of completed inspections) [a]	0%	0 (0%)
Close-out in progress	13%	4 (10%)
Processing time		
Initial certification inspections conducted within 6 months of application	78%	8 of 14 (57%)
Certification re-inspections conducted within 6 months of due date	52%	17 of 22 (77%)

a Compliance data for this period excludes 'Close-out in progress' in the calculation of percentages (i.e. the percentages reported are limited to those inspections that were completed).

Table 29B Medical Devices Audits for July to 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.

	2018	2019
	July to December	
Quality Management System (QMS) Audits (domestic manufacturers)		
Number of audits conducted	15	14
Satisfactory compliance (of completed audits)	60%	28%
Marginal compliance (of completed audits)	13%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in progress	27%	50%
Processing time		
Initial audits conducted within 3 months of application	0%	33%[a]
Re-audits conducted within 6 months of due date	35%	27%
QMS Audits (overseas manufacturers)		
Number of audits conducted	18	9
Satisfactory compliance (of completed audits)	67%	11%
Marginal compliance (of completed audits)	0%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in progress	33%	11%
Processing time		
Initial certification audits conducted within 6 months of application	55%	50%[b]
Certification re-audits conducted within 6 months of due date	0%[b]	50%

a During the Jul-Dec 2019 reporting period, only one domestic initial audit was conducted. The remaining 13 audits were re-audits and surveillance audits.

b Due to the increased demand for overseas audits and assessments of MDSAP Auditing Organisations, and a temporary reduction in the number of TGA auditors, only 50% of overseas certification initial and re-audits were completed within the July - Dec 2019 reporting period. These manufacturers are typically subject to regular surveillance through MDSAP or Notified Body audits. TGA receives applications for Conformity Assessment Certification and conducts assessment of these applications. It may be determined that an audit of one or more manufacturer included in the Conformity Assessment Application is required. The timeframes used for calculation of conducted audits are from the date of notification of this requirement.

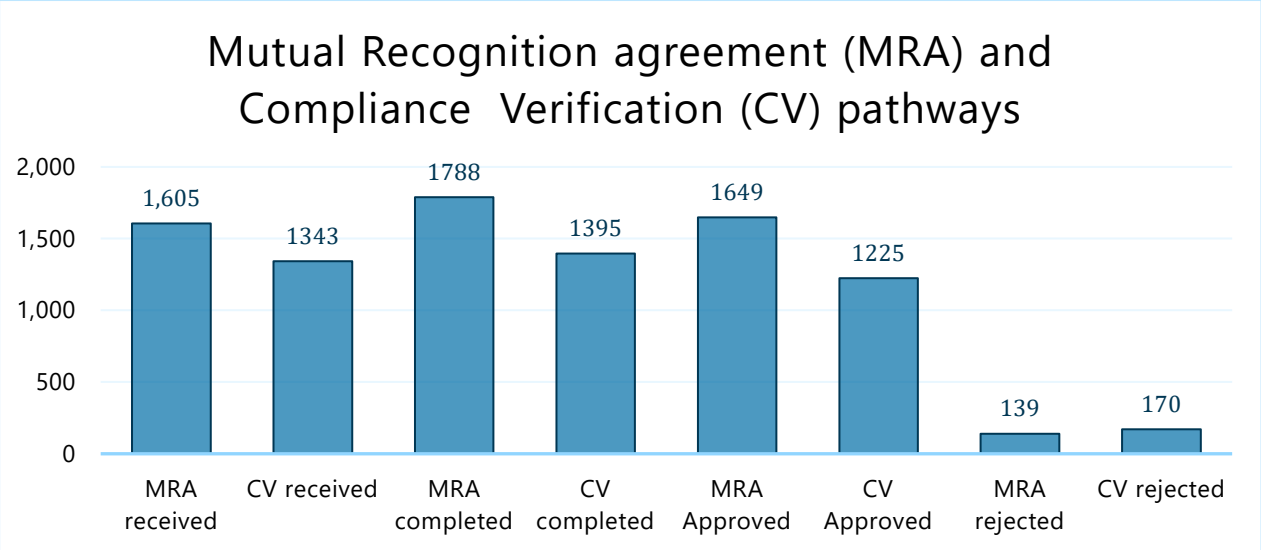
The implementation of the MDSAP has enabled a reduction in the overall number of on-site audits required, substituted by a desktop assessment on the MDSAP audit report.

Table 30 Number of GMP clearance applications for July to December

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

	2018 [a]	2019
	July to December Numbers (% of total)	
Applications received	2895	2948
Approved	2861 (87%)	2874 (90%)
Rejected	427 (13%)	309 (10%)
Total completed	3288 (100%)	3183 (100%)

Figure 4 Number of GMP clearance applications actioned by pathway from July to December 2019[a]



a The data is representative of all GMP Clearance application types.

9. Laboratory testing

Table 31 Number of samples tested by type of therapeutic good and percentage which failed for July to December

	2018		2019	
	July - December			
Product type	**Total**	**% fail**	**Total**	**% fail**
Prescription medicines	496	0.2%	665	15.6%
OTC medicines	17	0.0%	14	57.1%
Complementary medicines	149	21%	121	4.1%
Medical devices	81	41%	119	49.6%
External/contract[a]	28	14%	8	12.5%
Pacific Medicines Testing Program[b]	9	0%	27	0%
Unregistered[c]	67	57%	236	15.7%
Total samples (excluding AHQ samples)[c]	838	13%	1190	18%
Total samples (including AHQ samples)[d]	991	11%	1435	14.9%
Total number of products tested[e]	415	N/A	622	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.

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.

10. Medicine and vaccine adverse event reporting

Table 32 Source of notifications of medicine and vaccine adverse reaction for July to December

	2018	2019
	July to December	
Accepted cases total	**11660 (93%)[a]**	**11662 (95%)**
Reports by health professionals (total)	1928	2327
Medical practitioners	483	537
Pharmacists	900	1123
Nurses	220	221
Others[a]	201	249
Unknown[a]	178	197
Patients/consumers[a]	345	395
Pharmaceutical companies	7803	7484
Other source	1584	1456
Rejected/withdrawn cases	**867 (7%)**	**633 (5%)**
Total received	**12527**	12295
Average number of reports received weekly	482	473
Vaccine reports included in this table	1853	1706

A The data for July – December 2018 has been updated from the previous Half Yearly Performance Snapshot to include reports that were received by the TGA during this time period but not entered into the Adverse Event Management System at the time of the previous report's drafting.11. Medical device incident reports

11. Medical device incident reports

Table 33 Number of completed medical device incident reports and processing time for July to December

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.

	2018	2019
	July - December	
Reports completed	2661	3042
Mean TGA processing time	33	47
Percentage processed within target timeframe	91%	93%

12. Regulatory compliance

Data in relation to investigations may appear in multiple tables as compliance matters may be captured under several categories. Tables 31, 32 and 33 exclude advertising offences.

Table 34 Number of products investigated by product type for July to December

	2018	2019
	July to December Number (% of total)	
Complementary and homeopathic medicines	2308 (78%)	217 (14%)
Prescription medicines	60 (2%)	1118 (71%)
Medical devices	16 (1%)	12 (1%)
OTC medicines	229 (8%)	65 (3%)
Biological products	61 (2%)	5 (1%)
Other	262 (9%)	147 (9%)
Total[a]	2936 (100%)	1564 (100%)

a Each product type is counted once in this table but may have multiple associated cases.

Table 35 Number of offence outcomes for July to December

	2018	2019
	July- December Number (% of total)	
Criminal prosecution	2 (0.1%)	0
Referrals to Commonwealth Department of Public Prosecutions	0	2 (0.1%)
Infringement notices	5 (0.1%)	24 (1%)
Warning letters issued[a]	2613 (77%)	1402 (78%)
Advertisements removed from online trading platforms[b]	47 (1%)	23 (1%)
Goods released under the Personal Importation Scheme	445 (13%)	205 (11%)
Referred to external entity	81 (2%)	52 (3%)
No offence identified	193 (6%)	85 (5%)
Total completed	3386 (100%)	1793 (100%)

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

b This figure does not include those offences reviewed by the Advertising Compliance Section.

During the reporting period, there was a reduction in the number of referrals from the Australian Border Force when compared with the 2018 reporting period.

There has been an increase in the number of compliance matters that have resulted in the issue of infringement notices. The combined number of infringements issued from regulatory compliance and advertising compliance in the six month reporting period increased to 84 in July to December 2019, compared to 5 in the same period in 2018 (see section 13).

Table 36 Number of offence types completed for July to December

	2018	2019
	July – December Number (% of total)	
Import	3187 (92%)	1443 (84%)
Supply	272 (8%)	229 (13%)
Manufacture	16 (0.5%)	38 (2%)
Export	4(0.1%)	6 (1%)
Total completed	3479 (100%)	1716 (100%)

13. Advertising complaints

Minor amendments to the *Therapeutic Goods Advertising Code (No 2) 2018* came into effect on 30 July 2019.

We received a large number of complaints about non-compliant advertising of therapeutic goods, which generated 1,280 cases. The following data reflects the time to action and time to close for cases that were finalised within the reporting period.

The target period of time to action or close a complaint will depend on the categorisation of the complaint. These KPIs were established prior to the commencement of the reforms to advertising complaints handling. Further information about the categorisation of advertising complaints is available on the TGA website[2].

Table 37 Number of advertising cases meeting time to action and time to close KPIs

	2018	2019
	July - December	
Low		
Total completed cases	693	1051
Time to Action (target 95% in 14 days)	623 (90%)	580 (60%)
Time to Close (target 90% in 20 Days)	667 (96%)	729 (76%)
Medium		
Total completed cases	47	44
Time to Action (target 95% in 40 days)	35 (74%)	22 (50%)
Time to Close (target 90% in 90 Days)	47 (100%)	13 (30%)
High		
Total completed cases	1	1
Time to Action (target 95% in 20 days)	1 (100%)	0 (0 %)
Time to Close (target 90% in 90 Days)	1 (100%)	0 (0 %)
Critical		
Total completed cases	5	1
Time to Action (target 100% in 10 days)	4 (80%)	0 (0 %)
Time to Close (target 90% in 60 Days)	5 (100%)	1 (100 %)

The single matter categorised as high in 2019 proceeded to civil court proceedings, and hence the target timeframe was not met.

The continuing high volume of complaints is reflected in the KPI data. Although the single critical case closed in the period did not meet the target time to action, this was due to a decision to the change the case from medium to critical resulting in missing the target timeframe for a critical case. However, the original target time to close KPI for this case was met, resulting in the timely removal of the advertising concerned.

In this period, two advertisers were directed to cease the advertising of illegal therapeutic goods, including prescription medicines (Auzsupps Pty Ltd, ESR You Pty Ltd[3]). One further advertiser (Cat Media Pty Ltd[4]) was directed to cease using specific claims and representations.

We also issued 60 infringement notices. Once infringement notices are paid, details are published in the TGA's compliance and enforcement hub[5].

[2] www.tga.gov.au/publication/complaints-handling-advertising-therapeutic-goods-australian-public
[3] www.tga.gov.au/direction-about-advertisements-esr-you-pty-ltd
[4] www.tga.gov.au/direction-about-advertisements-cat-media-pty-ltd
[5] www.tga.gov.au/hubs/compliance-and-enforcement

14. Recalls

Table 38 Number of therapeutic goods recalls for July to December

	2018	2019
	July - December	
Medicines	19 (6%)	32 (8%)
Medical devices (including IVDs)	268 (77%)	326 (76%)
Biologicals	17 (5%)	8 (2%)
Bloods	43 (12%)	60 (14%)
Total recalls	347 (100%)	426 (100%)

The total recalls activity across three of the four product categories has shown a significant increase (23%) from the previous six-monthly reporting period – 347 in 2018 compared with 426 in 2019. Whilst showing an overall increase in volume, proportionally, each product category has remained relatively consistent with the previous period.

15. Pharmacovigilance Inspection Program (PVIP)

Table 39 PVIP inspections undertaken and deficiencies identified from July to December

	2018	2019
	July- December	
Total completed	5	5
Total with completed findings	5	5
Critical deficiencies[a]	0	0
Major deficiencies[b]	25	21
Minor deficiencies[c]	17	17
Average deficiencies per inspection	5 major 3.4 minor	4.2 major 3.4 minor

a A deficiency 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 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.

c A deficiency that would not be expected to adversely affect the rights, safety, or well-being of patients.

16. Reporting of medicine shortages

Table 40 New medicine shortage reports by month for July to December [a]

	2018	2019
	July- December	
July	28	131
August	25	89
September	47	129
October	58	149
November	71	117
December	174	150

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

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Reporting and Collaboration Services	09/04/2020

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https://www.tga.gov.au

Reference/Publication D20-501895