Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration

Annual Performance Statistics Report

July 2018 to June 2019

Contents

About the Therapeutic Goods Administration

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

Products for which therapeutic claims are made are assessed by the TGA and entered on the Australian Register of Therapeutic Goods (ARTG). At 30 June 2019 there were 88,788 therapeutic goods on the ARTG, including 31,987 new products added during the reporting period. All therapeutic goods registered on the ARTG can be lawfully manufactured and supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices.

The TGA regulates the supply of:

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

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

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

Executive summary

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

The statistics contained within this report cover the period 1 July 2018 to 30 June 2019, and contribute to annual publications that track our progress against the priorities we have established for the financial year.

Performance highlights

Key observations for 2018-19 are summarised below, including trends and notable changes from previous reporting periods.

As part of our 2018-19 activity, we have continued to implement the Australian Government's Response to the Review of Medicines and Medical Devices Regulation (MMDR). Following the passage of amendments to the *Therapeutic Goods Regulations 1990* that follow on from commencement of the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* and Therapeutic Goods Amendment (2018 Measures No. 1) Bill 2018, this reporting period now includes new data sets in relation to:

- advertising compliance and enforcement
- medicine shortages/discontinuations reporting
- overseas regulator conformity assessment documents for medical devices
- patient information leaflet and patient implant card for permanently implantable devices
- work sharing with Comparable Overseas Regulators.

Also, new information about other reforms and programs implemented during this reporting period relate to:

- autologous human cells and tissues (HCT) therapies
- laboratory testing.

Reforms

Prescription medicines

- Consistent with the intent of the MMDR, we also initiated and publicly consulted on possible reforms to the registration process for generic medicines.

Over-the-counter medicines

- The total number of new medicine applications received was lower than in 2017-18. This was due to a significant decrease in the number of lower risk N1 applications received. There was an increase in the numbers of all other new medicines application categories (N2, N3, N4 and N5).
- The total number of applications received to vary existing medicines increased substantially, by approximately 25%. The number of negligible risk (CN and C1) applications increased slightly and there was a significant increase in the number of low risk variation (C2) applications. This increase in the number of C2 applications was largely due to receipt of applications for changes to labelling for compliance with the Labelling Order (Therapeutic Goods Order No. 92). The numbers of higher risk variation (C3 and C4) applications were consistent with previous years.
- Median approval times for the majority of new medicine application categories were longer than in 2017-18, but were consistent with previous years. Median approval times for higher risk variation (C2, C3, and C4) applications were longer than in 2017-18. This increase in median approval times can be attributed to the increase in numbers of N2, N3 and N4 applications and the large increase in the number of C2 applications received.
- For all application categories, the percentage of applications processed within target time was more than 80%, with many application categories at or close to 100%.

Listed medicines

- There was an increase in the number of new listed medicines that were entered into the ARTG this year (1,893) compared to last year (1,792).
- Permitted indications for complementary medicines were introduced in March 2018 following the MMDR review. There were no applications finalised in 2017-18.
- The new pathway for assessed listed medicines was introduced in March 2018 following recommendation from the MMDR review. There have been no applications received via this pathway as at 30 June 2019.
- The number of applications for variations under section 9D(1) of the Act has significantly increased this year (from 96 in 2017-18 to 144 in 2018-19). This is likely due to sponsors reviewing a large number of existing entries in anticipation of transitioning to permitted indications.

Work sharing with overseas regulators

- The Australia-Canada-Singapore-Switzerland (ACSS) Consortium's work sharing pilot on New Chemical Entities is a unique global collaboration between regulatory authorities and the pharmaceutical industry. The ACSS Consortium is a collaborative initiative of medium-sized regulatory authorities between the TGA, Health Canada, Singapore's Health Sciences Authority and the Swiss Agency for Therapeutic Products. Regulators undertake a single assessment for new products that will support regulatory decision-making within each jurisdiction.
- This partnership is benefiting the community by improving access to the most recent and innovative treatment options. In 2018-19, this initiative has resulted in three new medicines – apalutamide (Erlyand®), abemaciclib (Verzenio®) and niraparib (Zejula®) receiving market approval in Australia and Canada.
- The ACSS partnership maximises the use of up-to-date technical expertise and brings greater alignment of regulatory approaches, technical requirements, knowledge sharing and better use of resources. While also facilitating cooperation and collaboration, reductions in duplication, and increases each regulators capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products.

Biologicals

- Major reforms were introduced to increase the oversight of autologous human cell and tissue, such as stem cell clinics. The number of new and variation applications for biologicals has stabilised. The first Class 4 biological product (CAR-T cells) was approved.

Medicine and vaccine adverse event reports

- A new Adverse Event Management System was introduced in June 2018. Due to differences in the way adverse event report data is recorded in the new system, the data included in this report is not directly comparable to previous reports.
- During this period, we received a total of 24,016 medicine and vaccine adverse reaction reports (4,225 reports related to vaccines). The mean number of reports received by the TGA weekly was 462. Of the accepted cases, 62% (13,874) were submitted by pharmaceutical companies and 20% (4,415) were made by health professionals. The most prolific reporters among health professionals were pharmacists (including hospital pharmacists) with 1,918 reports submitted.

Medical device conformity assessment

- The target timeframes for the processing of conformity assessment applications were met, with continual focus on process improvement. The number of conformity assessment applications received decreased while the number of applications completed was comparable with the same reporting period in 2017-18.

Medical device incident reports

- The number of medical device adverse event reports increased by 10% in 2018-19 compared to the previous year (5,874 reports). This increase can be attributed to ongoing media and public attention about medical devices, continued education of health professionals on the value of reporting adverse events, and improved sponsor reporting compliance.
- Class I medical device reviews have increased since the introduction of fees to include these devices on the ARTG. A streamlined internal review process has resulted to ensure that the throughput is minimised.

Medicines and biologicals manufacturing

- There was a notable increase in the number of overseas inspections being undertaken within six months of manufacturers making application for initial inspections, from 68% in 2017-18 to 86% in 2018-19; and within six months of the due date for re-inspections, from 66% to 85%. This is due to manufacturers being ready for inspection and the prioritisation of these inspections within the target timeframe. The number of both local and overseas manufacturers with an unacceptable compliance rating has reduced. Notably, no inspections of overseas manufacturers completed in this period found manufacturers that had unacceptable compliance.
- Demand for Good Manufacturing Practice (GMP) clearances remained high with 6,628 applications received, however it is noted that a change in reporting method from 2017-18 now captures additional application types, such as extensions, which were not previously captured.

Recalls

- Overall, the total number of recall actions remained similar to that of the last financial year.
- There has been a significant increase (25%) for recall actions performed for in vitro diagnostic devices (IVDs).
- Medicine consumer level recall actions have increased, from 8 to 13.
- The new provision in the updated Uniform Recall Procedure for Therapeutic Goods (URPTG) pertaining to 'consumer recall notices' largely negates the previous mandatory requirement for costly print media advertising. This has also allowed for customisation in sponsors' communication to consumers regarding 'open seller products' via social media platforms and utilisation of their own websites, in addition to notices published by the TGA and in some cases the Australian Competition and Consumer Commission (ACCC).

Laboratory testing

- In 2019 the TGA started the periodic publication of more detailed reports related to specific testing projects. One such report related to a survey of microwaveable grain-filled heat packs to assess the safety and performance of products available on the Australian market. Another report related to testing of a range of human insulin products to compare the quality and content of products obtained directly from sponsors against those available in pharmacies. These reports provide consumers with additional context and detail.

Medicine shortages/discontinuations

- The Medicine Shortages Information Initiative was established to allow a more transparent and responsive approach to the management of medicine shortages and discontinuations.
- From 1 January 2019, it has been mandatory for sponsors to report shortages or discontinuations of all prescription medicines and some over the counter medicines to the TGA. This has resulted in a very significant increase in reports.
- All shortages deemed to be of critical patient impact are published, but sponsors are encouraged to publish information about all shortages on the TGA Medicine Shortages website.
- The compliance framework in relation to the reporting obligations under the reporting scheme came into effect on 1 July 2019.
- Where necessary, the TGA can work with sponsors to allow for the import and supply of overseas products to assist with a medicine shortage in Australia under Section 19A of the *Therapeutic Goods Act 1989*.

Processing and approval times

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

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

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

1. Prescription medicines

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

The framework for prescription medicines includes the following categories which are subject to legislated and/or target timeframes:

Application category	Description	Timeframe in working days
Category 1	An application to register a new prescription medicine (other than an additional trade name) or to make a variation to an existing medicine that involves the evaluation of clinical, pre-clinical or bio-equivalence data. For example, new chemical entities, extensions of indication and new routes of administration.	Legislated timeframe: 40 working days for notification of whether the application has passed preliminary assessment and 255 working days for the completion of the evaluation and notification of the decision. 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 *(from 1 January 2018)*	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
Category 3	An application to register or to vary the registration of a prescription medicine where the application does not require the support of clinical, pre-clinical or bio-equivalence data. For example, broader changes to the product specifications, manufacturing and labelling or a change in trade name.	Legislated timeframe: 45 working days to notify the applicant of the decision.

[a] Under COR-A, the TGA regulatory decision will be based on a critical review of the COR assessment reports and an evaluation of the Australian label, Product Information (PI) and where required, the Risk Management Plan (RMP). Under the COR-B approach, the TGA regulatory decision will still be mostly based on a critical review of the COR assessment reports. The amount and type of any additional data requiring evaluation, as well as the age of the assessment report, will determine whether the application is best processed under the COR-B approach or as a standard Category 1 application.

Application category	Description	Timeframe in working days
Correction to, or completion of, a Register entry	An application to vary the registration of a prescription medicine to correct or complete information that was inadvertently recorded incorrectly or omitted from the Register entry. For example, errors to product information, or quality-related documentation.	No legislated timeframe: TGA processes as soon as possible.
Safety-related request (SRR)	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 (SAR)	An application to register or to vary the registration of a prescription medicine where the application · does not require the support of clinical, pre-clinical or bio-equivalence data and · where no data are necessary or where the data can be self-assessed by the applicant. For example, certain changes to the pack size or approved product label.	Legislated timeframe: 45 working days for notification of acceptance or rejection of an application, completion of evaluation and notification of the decision.
Additional trade name	An application for an additional trade name for a registered prescription medicine.	Legislated timeframe: 45 working days.

1.1. Submission outcomes

Table 1 Number of completed prescription medicine submissions by type and outcome for July 2018 to June 2019

	Number			
Application Type	Approved	Withdrawn	Rejected	Total (% Approved)
Category 1				
A: New chemical entity/New biological entity/Biosimilar	34	3	0	37 (92%)
B: New fixed-dose combination	6	0	0	6 (100%)
C: Extension of indication	50	4	2	56 (89%)
D: New generic medicine	77	8	2	87 (89%)
F: Major variation	72	2	0	74 (97%)
G: Minor variation[a]	3	0	0	3 (100%)
H: Minor variation[b]	2	0	0	2 (100%)
J: Changes to Product Information	101	0	0	101 (100%)
Comparable Overseas Regulator (COR) – A				
C: Extension of indication	3	0	0	3 (100%)
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/Biosimilar	1	0	0	1 (100%)
B: New fixed-dose combination	1	0	0	1 (100%)
F: Major variation	1	0	0	1 (100%)
Minor Variations				
Category 3				
G: Minor variation[a]	131	3	0	134 (98%)
H: Minor variation[b]	1276	17	0	1293 (99%)
Additional trade name [ATN]	36	1	0	37 (97%)
Extension of Indications - Generic	7	0	0	7 (100%)
Safety-related request [SRR]	938	15	0	953 (98%)
Self-assessable request [SAR]	945	15	0	960 (98%)
Minor editorial change [MEC]	125	5	0	130 (96%)
Correction [9D(1)]	168	9	0	177 (95%)
Notification	1471	2	0	1473 (99.9%)
Total	5548	84	4	5536 (98%)

[a] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry.

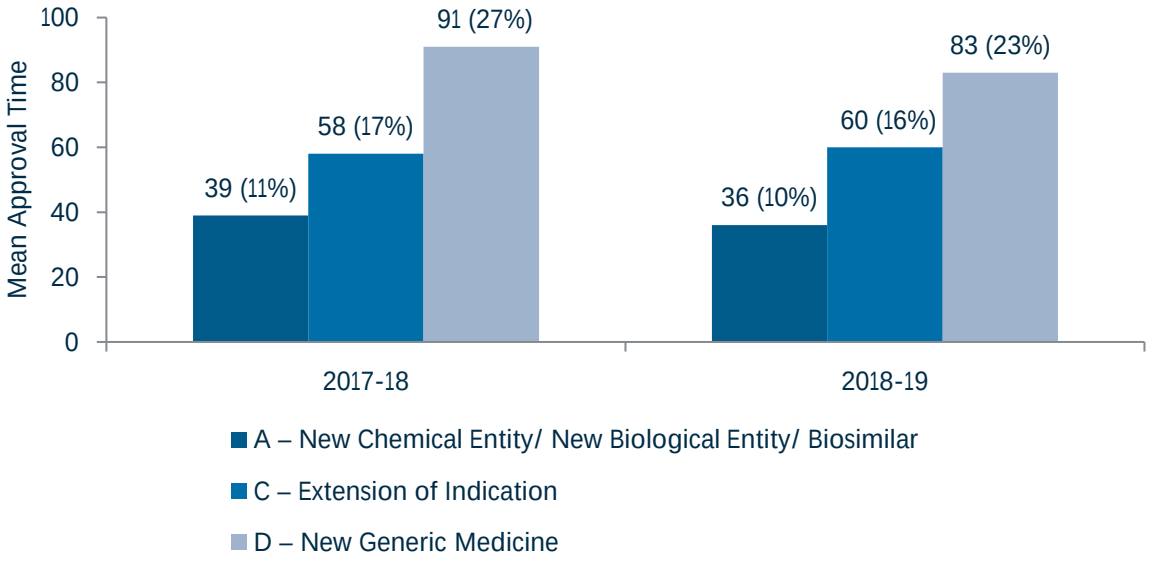
[b] The minor variations (type H) refer to applications to change the formulation, composition or design specification or the container for the goods or any other attribute that results in the goods being separate and distinct. These applications are typically 'Category 3' changes, unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

In accordance with the legislation, registered medicines must comply with numerous standards at the time they are registered and throughout their lifecycle. Following an appropriate application and review of the scientific data and safety considerations, approval may be sought to supply a product when it doesn't meet a particular standard.

Table 2 Number of other prescription medicine applications

	2017-18	2018-19
	July to June	
Exemptions to comply with a standard [S.14]	Number (% of Total)	
Approved	67 (100%)	62 (98%)
Rejected	0	1 (2%)
Total (excluding withdrawals)	67 (100%)	63 (100%)

Figure 1 Submissions received 2017-18 and 2018-19 – total amount and % of total[a]



[a] Total Category 1 and Comparable Overseas Regulator (COR) submissions received in each period.

1.2. Approval times

Table 3 Prescription medicine application approval time for July 2018 to June 2019

		Approval time (TGA working days)		
Application type	Legislated timeframe	Mean	Median	Range
Category 1				
A: New chemical entity/New biological entity/Biosimilar[a]	255	204	202	141 - 249
B: New fixed-dose combination	255	208	198	190 – 246
C: Extension of indication[b]	255	198	197	130 – 253
D: New generic medicine	255	181	170	96 – 254
F: Major variation	255	189	194	67 – 253
G: Minor variation	255	200	223	139 - 239
H: Minor variation	255	81	81	59 – 102
J: Changes to Product Information requiring the evaluation of data	255	134	141	4 - 249
Comparable Overseas Regulator (COR) – A				
C: Extension of indication	120	50	40	36 - 74
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/Biosimilar	175	172	172	172 - 172
B: New fixed-dose combination	175	161	161	161 – 161
F: Major variation	175	146	146	146 - 146

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

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

Table 4 Prescription medicine median approval time comparisons

		Median approval time (TGA working days)	
Application type	**Legislated timeframe**	**2017-18**	**2018-19 (% Change)**
Category 1			
A: New chemical entity/New biological entity/Biosimilar[a]	255	210	202 (▼4%)
B: New fixed-dose combination	255	192	198 (▲3%)
C: Extension of indication[b]	255	194	197 (▲2%)
D: New generic medicine	255	174	170 (▼2%)
F: Major variation	255	196	194 (▼1%)
G: Minor variation	255	250	223 (▼11%)
H: Minor variation	255	164	81 (▼51%)
J: Changes to Product Information requiring the evaluation of data	255	148	141 (▼5%)
Comparable Overseas Regulator (COR) – A			
C: Extension of indication	120	n/a	40
Comparable Overseas Regulator (COR) – B			
A: New chemical entity/New biological entity/Biosimilar	175	n/a	172
B: New fixed-dose combination	175	n/a	161
F: Major variation	175	n/a	146
Minor Variations			
Category 3			
G: Minor variation[c]	45	39	40 (▲3%)
H: Minor variation[d]	45	32	36 (▲13%)
Additional trade name [ATN]	45	27	41 (▲52%)
Safety-related request [SRR]	N/A	32	36 (▲9%)
Self-assessable request [SAR]	45	33	38 (▲15%)
Minor editorial change [MEC]	45	26	30 (▲15%)
Correction [9D(1)]	N/A	56	56

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

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

[c] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry.

[d] The minor variations (type H) refer to applications to change the formulation, composition or design specification or the container for the goods or any other attribute that results in the goods being separate and distinct. These applications are typically 'Category 3' changes, unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

Figure 2 Mean approval times for standard Category 1 submissions 2017-18 and 2018-19

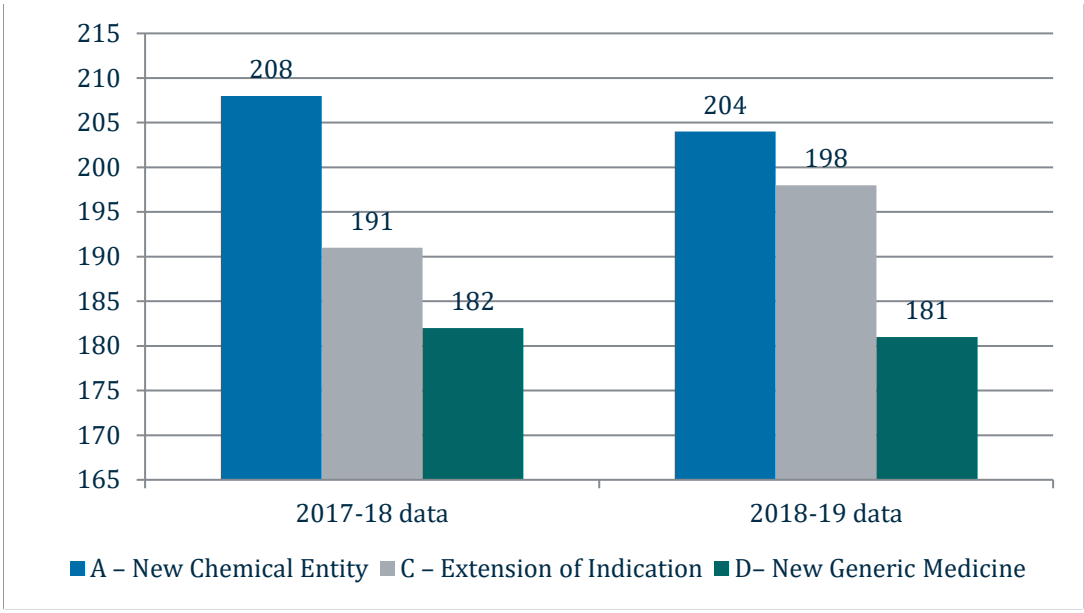
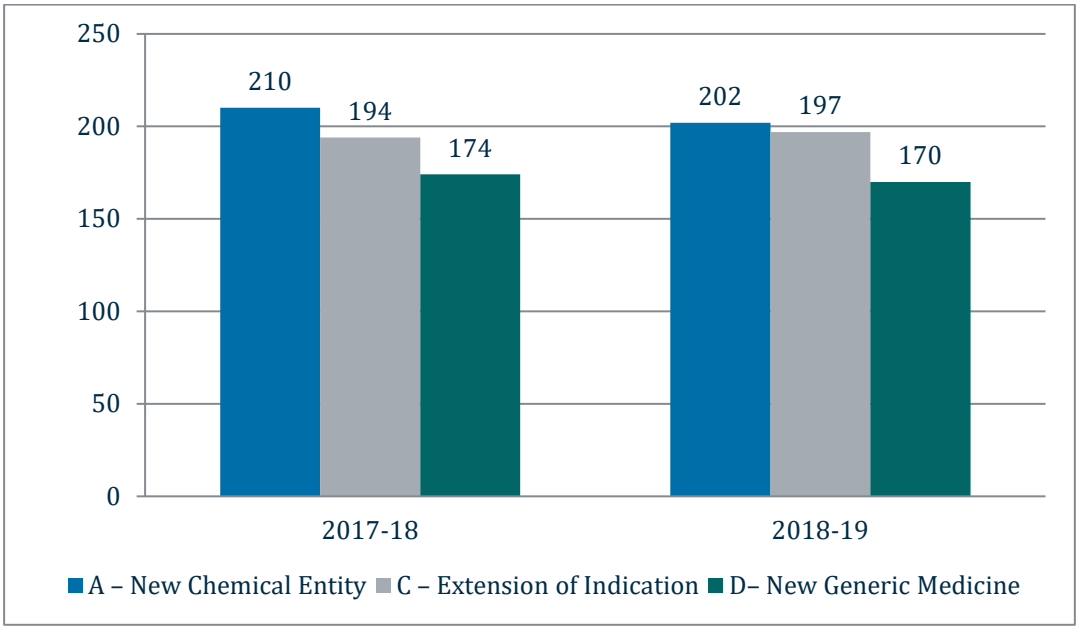


Figure 3 Median approval times for standard Category 1 submissions 2017-18 and 2018-19



1.3. Orphan drug destinations

The objective of the orphan drug program is to provide an incentive to sponsors to bring medicines for a small population to market and make medicines available to Australian patients who may not otherwise be able to access them. The program incentive is a 100% waiver of TGA fees for application and registration. Designation is a formal process that allows us to make a decision regarding whether a medicine is eligible for orphan drug designation. This precedes the registration application. The eligibility criteria aim is to focus the program on the greatest unmet need. A prescription medicine must have a valid orphan drug designation at the time of application to be eligible for a waiver of application and evaluation fees.

Table 5 Number of orphan drug designations

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	13 (81%)	16 (67%)
C: Extension of indications	2 (12%)	7 (29%)
F: Major variation	1 (6%)	1 (4%)
Total	16 (100%)	24 (100%)

Table 6 Number of orphan drug registrations

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

	2017-18[a]		2018-19	
	July to June			
Application Type	Number Approved (% of Total)	Median approval time (TGA working days)	Number Approved (% of Total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	9[b] (43%)	213	8[c] (36%)	163
C: Extension of indications	10 (48%)	198	7 (32%)	212
F: Major variation	2 (9%)	185	7 (32%)	194
Total	21[b] (100%)	197	22[c] (100%)	190

a Includes orphan drugs designated under the previous orphan drug program (where the designation application was lodged) and the current program.

b One new biological entity was registered under the new orphan drug program during 2017-18. This product also had a priority review determination.

c Two new biological entities were registered under the new orphan drug program and the priority review pathway, one new chemical entity was registered under the new orphan drug program and the COR-B review pathway.

1.4. Priority review pathway

The priority review pathway supports patient access to vital and lifesaving prescription medicines months earlier than through the standard pathway. Priority review involves the same amount and type of evidence as the standard review process. The same standards for quality, safety and efficacy apply as under the standard process. The flexible approach we take on priority applications is much more resource intensive than the standard pathway. The pathway is reserved only for medicines that represent a major therapeutic advance. The determination process is used to assess whether a medicine is eligible for the priority pathway but does not necessarily mean that the medicine will be approved after evaluation and registered on the ARTG.

Table 7 Number of priority review determinations granted

	2017-18	2018-19
	July-June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	4 (29%)	6 (67%)
C: Extension of indications	10 (71%)	3 (33%)
Total	14 (100%)	9 (100%)

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

	2017-18		2018-19	
	July to June			
Application Type	Number Approved (% of Total)	Median approval time (TGA working days)	Number Approved (% of Total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	1 (20%)	104	3 (27%)	129
C: Extension of indications	4 (80%)	97	8 (73%)	121
Total	5 (100%)	98	11 (100%)	122

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

1.5. Provisional approval pathway

The provisional approval pathway supports patient access to vital and lifesaving prescription medicines years earlier than through the standard pathway. Time limited approval through the provisional pathway is 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 are still required.

A prescription medicine must have a valid provisional determination before it can be evaluated for registration under the provisional approval pathway. The determination process is used to assess whether a medicine is eligible for the provisional pathway but does not necessarily mean that the medicine will be approved after evaluation and provisionally registered on the ARTG.

Table 9 Number of provisional determinations granted

	2017-18[a]	2018-19
	July-June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	1 (50%)	4 (44%)
C: Extension of indications	1 (50%)	5 (56%)
Total	2 (100%)	9 (100%)

[a] The 2017-18 data is provided for the period March to June 2018 only, since the provisional approval pathway was implemented in March 2018.

1.6. Pathway comparison

Table 10 Number of medicines[a] approved via each pathway

	2017-18	2018-19
	July-June	
	Number (% of Total)	
Pathway		
Priority Review	5 (4%)	11 (7%)
Comparable Overseas Regulator (COR) – A	0	3 (2%)
Comparable Overseas Regulator (COR) – B	0	3 (2%)
Standard	115 (96%)	135 (89%)
Total	120[bd] (100%)	152[cd] (100%)

[a] Medicine types that utilise these pathways (New chemical entity, New biological entity, Fixed dose combination, extension of indication, major variation).

[b] A new biological entity was processed as both an orphan drug and under the priority review pathway.

[c] Two new biological entities were processed as both an orphan drug and under the priority review pathway, one new chemical entity was processed as both an orphan drug and under the COR-B pathway.

[d] No new provisional medicines were approved in these periods.

2. Over-the-counter medicines

Over-the-counter (OTC) medicine applications are categorised as new medicine (N) or change (C) applications and are further categorised by risk (N1 and C1 are low risk, N5 and C4 are highest risk). The OTC application categorisation framework outlined on the following page defines the different OTC medicine application levels and the key application criteria.

Table 11 Categorisation of OTC medicine applications

Application category	Definition	Timeframe in days
N1	An application submitted as a 'clone'.	45 working days
N2	An application which complies with an OTC medicine monograph.	55 working days
N3	New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4.	150 working days
N4	An application for a 'generic' medicine where the medicine: · requires supporting safety and/or efficacy (clinical/toxicological) data or a justification for not providing such data; and/or · requires a higher level of assessment due to the umbrella branding segment of the product name; and/or · has not been previously registered as an OTC medicine following down-scheduling.	170 working days
N5	An application for a new product that is an extension to a 'generic category' product or an application for a product containing a new chemical entity as an active ingredient.	210 working days
CN	'Notification' changes, where their implementation would not impact the quality, safety or efficacy of a medicine. Includes quality and non-quality changes classified as 'negligible risk'. - Implemented 1 July 2017	N/A (Automated validation and approval)
C1	Quality and non-quality changes classified as 'negligible risk'.	20 working days
C2	Quality and non-quality changes classified as 'low risk' – no safety and/or efficacy data required; quality data may be required.	64 working days
C3	Quality and non-quality changes classified as 'low risk' – safety and/or efficacy data required unless justified; quality data may be required. Umbrella branding segment of new name requires a higher level of assessment.	120 working days
C4	Non-quality changes classified as 'moderate risk' – safety and/or efficacy data required unless justified.	170 working days
B1	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that does not contain clinical data.	20 working days
B3	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that contains clinical data or a justification as to why such data is not needed.	120 working days

Application category	Definition	Timeframe in days
Requests for consent under section 14/14A of the Act	Request for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard.	N/A

2.1. Approval times

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

Table 12 Median approval time for OTC medicine applications

	2017-18	2018-19
	July to June	
New medicine applications (days)		
N1	25	30
N2	35	48
N3	74	95
N4	55	97
N5	162	121
Change applications (days)		
C1	4	4.5
C2	31	36
C3	72	84
C4	95	109

Table 13 OTC medicine approval time against target time by application category for July 2018 to June 2019

Application type	Number completed (% of Total)	Range	Mean	Median	% within target
New medicines					
N1	129 (58%)	0-66	29	30	87
N2	18 (8%)	28-55	45	48	100
N3	52 (24%)	8-188	92	95	94
N4	13 (6%)	18-217	101	97	85
N5	9 (4%)	81-198	126	121	100
Total	221 (100%)				
Change applications					
C1	182 (25%)	0-88	7	4.5	96
C2	549 (74%)	0-121	37	36	89
C3	8 (1%)	33-214	87	84	88
C4	2 (0.2%)	82-136	109	109	100
Total	741 (100%)				

2.2. Applications

2.2.1 New OTC medicine applications

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

	2017-18	2018-19
	July to June	
	Number (% of Total)	
New medicine applications		
N1	169 (60%)	100 (40%)
N2	16 (6%)	18 (7%)
N3	64 (23%)	70 (28%)
N4	23 (8%)	39 (16%)
N5	8 (3%)	23 (9%)
Total	280 (100%)	250 (100%)
Change applications		
CN	171 (21%)	197 (18%)
C1	190 (24%)	197 (18%)
C2	438 (54%)	675 (62%)
C3	7 (0.8%)	7 (0.6%)
C4	3 (0.4%)	6 (0.6%)
Total	809 (100%)	1082 (100%)

2.2.2 Completed applications

Table 15 New OTC medicine applications completed and outcomes

	2017-18	2018-19
	July to June	
	Number (% of Total)	
N1		
Approved	144 (96%)	129 (98%)
Rejected	0	0
Withdrawn by sponsor	7 (4%)	3 (2%)
Returned/failed screening	0	0
Total	151 (100%)	132 (100%)
N2		
Approved	5 (45%)	18 (82%)
Rejected	0	0
Withdrawn by sponsor	6 (55%)	4 (18%)
Returned/failed screening	0	0
Total	11 (100%)	22 (100%)
N3		
Approved	37 (81%)	52 (81%)
Rejected	0	0
Withdrawn by sponsor	1 (2%)	0
Returned/failed screening	8 (17%)	12 (19%)
Total	46 (100%)	64 (100%)
N4		
Approved	19 (76%)	13 (65%)
Rejected	1 (4%)	0
Withdrawn by sponsor	3 (12%)	3 (15%)
Returned/failed screening	2 (8%)	4 (20%)
Total	25 (100%)	20 (100%)
N5		
Approved	8 (73%)	9 (90%)
Rejected	0	0
Withdrawn by sponsor	2 (18%)	0
Returned/failed screening	1 (9%)	1 (10%)
Total	11 (100%)	10 (100%)

Table 16 OTC change applications completed and outcomes

	2017-18	2018-19
	July to June	
	Number (% of Total)	
C1		
Approved	202 (99%)	182 (97%)
Rejected	0	0
Withdrawn by sponsor	2 (1%)	6 (3%)
Returned/failed screening	0	0
Total	204 (100%)	188 (100%)
C2		
Approved	386 (97%)	549 (99%)
Rejected	0	0
Withdrawn by sponsor	11 (3%)	7 (1%)
Returned/failed screening	2 (0.5%)	0
Total	399 (100%)	556 (100%)
C3		
Approved	5 (83%)	8 (80%)
Rejected	0	0
Withdrawn by sponsor	0	1 (10%)
Returned/failed screening	1 (17%)	1 (10%)
Total	6 (100%)	10 (100%)
C4		
Approved	4 (100%)	2 (100%)
Rejected	0	0
Withdrawn by sponsor	0	0
Returned/failed screening	0	0
Total	4 (100%)	2 (100%)

2.2.3 Other applications

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

Table 17 Number of other OTC medicine applications

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
B1	0	2 (100%)
B3	0	0
Total	0	2 (100%)
Requests for consent under section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard		
Approved	10 (100%)	21 (95%)
Rejected	0	1 (5%)
Total	10 100%)	22 (100%)

3. Registered complementary medicines

Registered complementary medicines are considered to be of relatively higher risk than listed medicines based on their ingredients or the indications for the medicine. These medicines are fully evaluated by us for safety, efficacy, performance and quality prior to being registered on the ARTG.

Table 18 Registered complementary medicine applications by outcome

	2017-18	2018-19
	July to June	
	Number (% of Total)	
New medicines		
Approved	5 (83%)	5 (71%)
Rejected	1 (17%)	0
Withdrawn	0	2 (29%)
Returned/failed screening	0	0
Total new applications completed	6 (100%)	7 (100%)
Variations		
Approved	19 (83%)	18 (100%)
Rejected	4 (17%)	0
Withdrawn	0	0
Returned/failed screening	0	0
Total variations completed	23 (100%)	18 (100%)
Application for consent to import, supply or export goods[a]		
Approved	12 (100%)	1 (100%)
Rejected	0	0
Withdrawn	N/A[b]	0
Total applications completed	12 (100%)	1 (100%)

[a] Applications can be made for consent to import, supply or export goods under section 14/14A of the *Therapeutic Goods Act 1989*.

[b] This figure has not been reported on previously.

4. Listed medicines

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

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

4.1. New ingredients permitted for use in listed medicines

Table 19 New listed medicine ingredient applications by outcome

	2017-18	2018-19
	July to June	
Application outcome		
Approved	24 (86%)	15 (88%)
Rejected	0	1 (6%)
Withdrawn	3 (11%)	1 (6%)
Returned/failed screening	1 (4%)	0
Total completed	28 (100%)	17 (100%)

4.2. Indications permitted for use in listed medicines

Table 20 Permitted indication applications by outcome

	2017-18	2018-19
	July to June	
Application outcome		
Approved	0[a]	2 (18%)
Rejected	0[a]	5 (46%)
Withdrawn	0[a]	4 (36%)
Total completed	0[a]	11 (100%)

[a] This data was not reported in 2017-18 as there were no completed applications.

4.3. Listed medicines

Table 21 New listed medicines

	2017-18	2018-19
	July to June	
New listed medicines	1792	1893

Table 22 Listed medicine variations under section 9D(1) of the Act

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

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Medicine variation		
Approved	91 (95%)	131 (78%)
Rejected	5 (5%)	13 (8%)
Withdrawn	N/A[a]	24 (14%)
Total	96 (100%)	168 (100%)

[a] This figure was not reported in 2017-18.

Table 23 Listed medicine applications under section 14/14A of the Therapeutic Goods Act 1989

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Application		
Exemption granted[a]	9[b] (100%)	11 (85%)
Rejected	0	0
Withdrawn	N/A[c]	2 (15%)
Total	9[b] (100%)	13 (100%)

[a] Sponsors can apply for certain exemptions under Section 14 of the *Therapeutic Goods Act 1989*. Applications seek consent to import, export or supply a listed medicine that does not comply with the applicable standards.

[b] The data for 2017-18 was incorrectly reported as 5 in the Annual Performance Statistics Report 2017-18.

[c] This figure was not reported in 2017-18.

4.3.1 Investigations

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

Table 24 Listed medicine investigations and actions undertaken

	2017-18	2018-19
	July to June	
	Number (% of total)	
Initiated investigations	56	81
Completed investigations[a]	55	36
Initiated compliance review(s)	22 (40%)	20 (55%)
Issued warning or educational letter	0 (0%)	1 (3%)
Advice provided to complainant	0 (0%)	0 (0%)
Referred to another TGA area or government organisation	4 (7%)	1 (3%)
No further action taken[b]	29 (53%)	14 (39%)
Total actions undertaken[c]	55 (100%)	36 (100%)

[a] Investigations with ensuing actions completed. The values for 2017-18 shown here differ from those provided in the Annual Performance Statistics Report 2017-18, which included 9 investigations completed with action still pending (prioritised for targeted review).

[b] The outcome 'no further action taken' includes examples where the investigation was resolved by other means such as the product has been or is currently under review; or the complaint was not justified and did not warrant further action. The values for 2017-18 shown here differ from those provided in the Annual Performance Statistics Report 2017-18 (10) because 19 investigations that had been prioritised for targeted review in 2017-18 were subsequently deemed to require no further action.

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

4.3.2 Compliance reviews

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

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

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

- no compliance breaches are identified against selected listing requirements, the review is concluded and the medicine remains on the ARTG
- compliance breaches are identified for the selected listing requirements
- the review is not completed as the sponsor has cancelled the medicine
- the review is closed due to the unavailability of information in determining its compliance status as the medicine is yet to be manufactured.

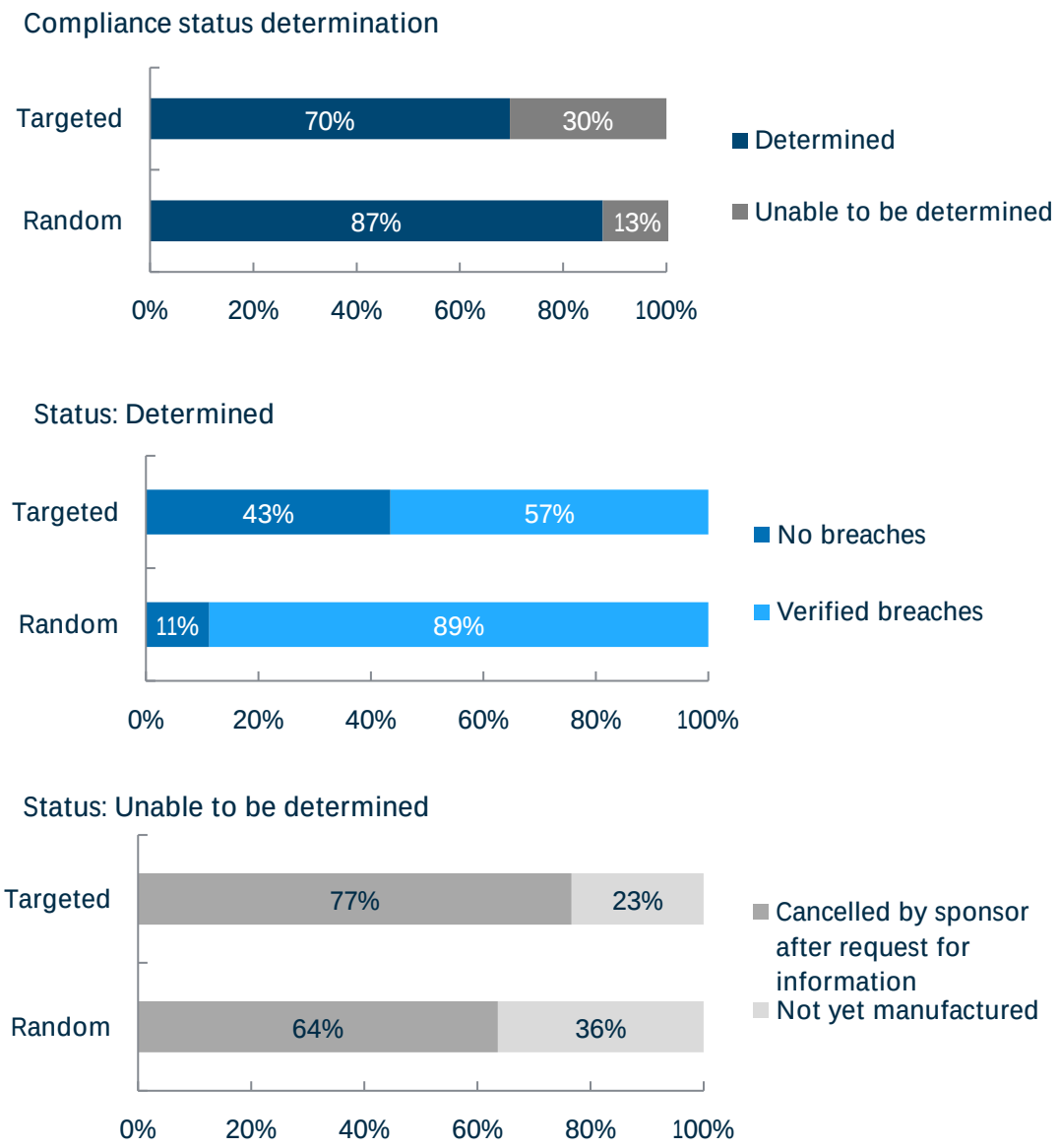
Table 25 Listed medicine reviews by type

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Initiated reviews		
Targeted reviews	82 (36%)	127 (91%)
Random reviews	143 (64%)	12 (9%)
Total	225 (100%)	139 (100%)
Reviews on hand	173	131
Completed reviews		
Targeted reviews	162 (67%)	99 (55%)
Random reviews	81 (33%)	82 (45%)
Total	243 (100%)	181 (100%)

Table 26 Completed listed medicine reviews by outcome

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Compliance status determined		
Medicines with no compliance breaches	42 (25%)	38 (27%)
Medicines with verified compliance breaches	129 (75%)	102 (73%)
Sub-total	171 (100%) **(70%)**	140 (100%) **(77%)**
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	51 (74%)	30 (73%)
Medicines not yet manufactured	13 (19%)	11 (27%)
Other	5 (7%)	0 (0%)
Sub-total	69 (100%) **(28%)**	41 (100%) **(23%)**
Product not a therapeutic good	3 **(1%)**	0 **(0%)**
Total completed	243 **(100%)**	181 **(100%)**

Figure 4 Outcomes of compliance reviews by reason for initiation[a]



[a] In this period, of the medicines for which we were able to determine a compliance status, 89% had verified compliance breaches when initiated by random selection, which is consistent with the non-compliance rate from the previous period (88%). For medicines that were targeted for review and the compliance status was determined, a markedly lower percentage (57%) were found to have compliance breaches; this was attributable to a significant number targeted of reviews to specifically check compliance with a requirement for label warning statements, for which many medicines were compliant.

Table 27 Types of listed medicine compliance issues identified

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

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Type of compliance issue		
Information provided in ARTG entry[a]	69 (21%)	30 (12%)
Manufacturing, quality and/or formulation	27 (8%)	15 (6%)
Labelling	58 (17%)	49 (20%)
Advertising	59 (18%)	40 (16%)
Unacceptable presentation[b]	63 (19%)	52 (21%)
Evidence[c]	50 (15%)	51 (21%)
Safety[d]	0	1 (0.4%)
Non-response to a request for information[e]	5 (2%)	2 (1%)
Other[f]	2 (1%)	4 (2%)
Total	333 (100%)	244 (100%)

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

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

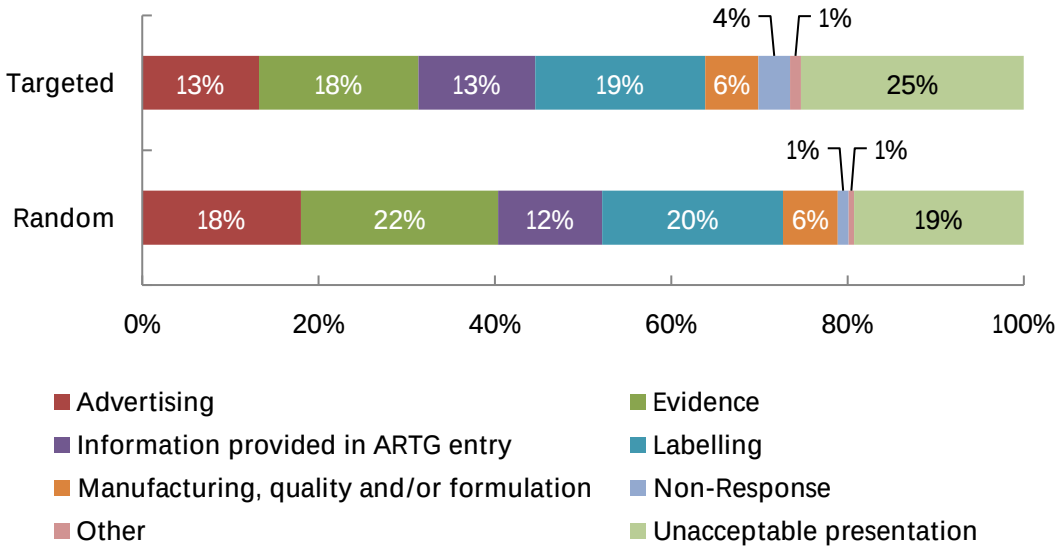
[c] 'Evidence' means the evidence held by the sponsor does not support the claims relating to the medicine.

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

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

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

Figure 5[a] Types of compliance issues identified by reason for initiation



[a] Reviews are either randomly selected or targeted for a particular issue. Multiple breaches may be identified for each medicine that is found to be non-compliant; for example, 44% of all randomly-selected non-compliant medicines were found to have insufficient evidence to support the medicine indication, yet this breach accounted for 22% of the total breaches identified across all randomly-selected non-compliant medicines. These figures are not corrected for the nature of information assessed during a review. For example, of those randomly-selected non-compliant medicines for which evidence was assessed, 92% were found to have an 'Evidence' breach.

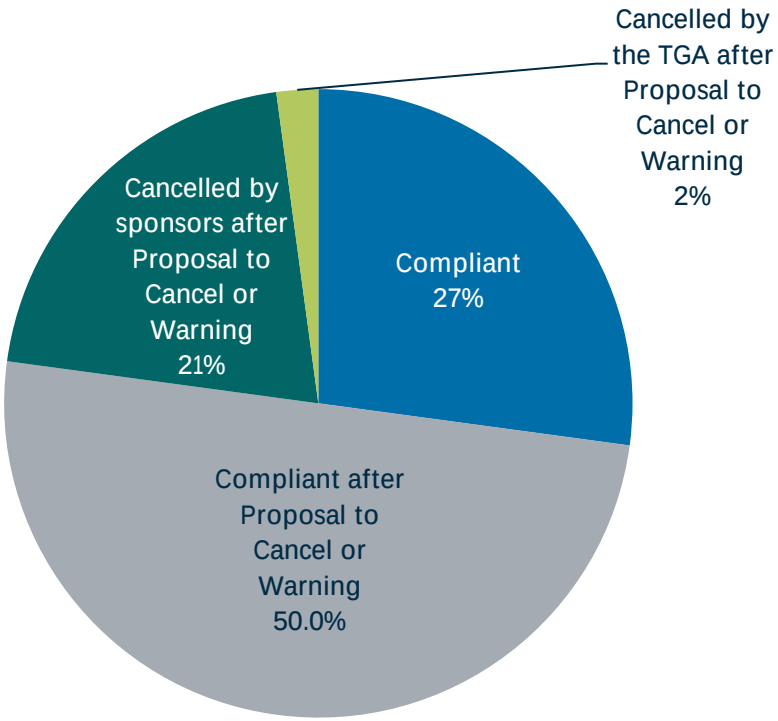
Table 28 Actions taken following listed medicine reviews

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Actions following a Request for Information		
Medicines found to be compliant and review concluded	42 (25%)	38 (27%)
Medicines cancelled by the TGA without a proposal to cancel notice	0	0
Proposal to cancel notice or warning[a] sent by the TGA	129 (75%)	102 (73%)
Total	**171 (100%)**	**140 (100%)**
Actions following Proposal to Cancel notice[b] by outcome		
Medicines no longer on the ARTG	55 (100%) **(43%)**	32 (100%) **(31%)**
Cancelled by the TGA	10 (18%)	3 (9%)
Cancelled by sponsors after being notified of compliance breaches	45 (82%)	29 (91%)
Medicines remaining on the ARTG	74 (100%) **(57%)**	70 (100%) **(69%)**
Reviews concluded after compliance breaches were addressed	74 (100%)	70 (100%)
Total	**129 (100%)**	**102 (100%)**

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

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

Figure 6[a] Outcomes of completed compliance reviews



[a] A significant proportion of listed medicine reviews are concluded after the sponsor has adequately addressed the compliance breaches identified by us. Under the *Therapeutic Goods Act 1989* sponsors are given an opportunity to respond to issues raised during a compliance review. There was a slight decrease in the number of listed medicines cancelled by the TGA following a Proposal to Cancel or warning letter (2%) compared with the previous period (5%).

5 Biologicals and blood components

5.1. Inclusion of biologicals

Table 29 Applications for biologicals[a] received and on hand

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Applications received		
Technical Master File (TMF)[b] new	0	0
TMF annual updates	3 (5%)	3 (4%)
TMF variations	14 (22%)	18 (23%)
TMF notifications	8 (12%)	12 (16%)
Plasma Master File[c] annual updates	10 (15%)	12 (16%)
Biological Class 2 – new applications	1 (1%)	1 (1%)
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	2 (3%)	1 (1%)
Biological Class 2 – variations	22 (34%)	23 (30%)
Biological Class 3 – variations	5 (8%)	3 (4%)
Biological Class 4 – variations	0	4 (6%)
Total received	65 (100%)	77 (100%)
Applications on hand		
TMF new	0	0
TMF annual updates	2 (10%)	1 (7%)
TMF variations	4 (19%)	5 (33%)
TMF notifications	0	0
Plasma Master File annual updates	7 (33%)	4 (27%)
Biological Class 2 – new applications	2 (10%)	1 (7%)
Biological Class 3 – new applications	1 (5%)	1 (7%)
Biological Class 4 – new applications	2 (10%)	1 (7%)
Biological Class 2 – variations	3 (14%)	2 (13%)
Biological Class 3 – variations	0	0
Biological Class 4 – variations	0	0
Total on hand	21 (100%)	15 (100%)

[a] The *Australian Regulatory Guidelines for Biologicals* (published on our website) define the different biological classes.

[b] Technical Master Files (TMF) contain information from manufacturers that demonstrate how product safety and quality standards have been met for Blood, Blood Components and Haematopoietic Progenitor Cells.

[c] Plasma Master Files contain control strategies that ensure the quality and safety of plasma, from collection through to plasma pooling prior to fractionation and including donor selection criteria and testing, which are part of medicinal products or medical devices.

Table 30 Completed applications for biologicals

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Biologicals applications		
Technical Master File (TMF) new	1 (2%)	0
TMF annual updates	2 (4%)	3 (4%)
TMF variations	8 (14%)	13 (19%)
TMF notifications	8 (14%)	12 (17%)
Plasma Master File annual updates	8 (14%)	9 (13%)
Biological Class 2 – new applications	3 (5%)	2 (3%)
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	0	1 (1%)
Biological Class 2 – variations	22 (39%)	23 (33%)
Biological Class 3 – variations	5 (9%)	3 (4%)
Biological Class 4 – variations	0	4 (6%)
Total completed	57 (100%)	70 (100%)

6 Medicine and vaccine adverse event reports

6.1 Adverse medicine and vaccine reaction notifications

Table 31 Source of notifications of medicine and vaccine adverse reactions[a]

	2017-18	2018-19
	July to June	
Accepted cases total	21096	22467
Reports by health professionals	4556	4415
Patients/consumers[b]	1190	704
Pharmaceutical companies	11912	13874
Other source	3438	3474
Rejected/withdrawn cases	2603	1550
Total received	23699	24017
Mean number of reports received weekly	456	462
Vaccine reports included in this table	4554	4225

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

[b] In 2018-19 the increased number of reports submitted by the pharmacists from the NPS MedicineWise phone service – a service for consumers to report adverse events and seek clinical advice from pharmacists - may explain the decreased number of reports submitted by consumers.

7 Medical devices

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

- **Conformity assessment:** This is the systematic examination by the manufacturer to determine that a medical device is safe and performs as intended and therefore, conforms to the Essential Principles. Certification of the manufacturer's conformity assessment procedure may (or for particular products, must) be undertaken by the TGA, or we may recognise conformity assessment certification from European notified bodies.
- **Inclusion on the ARTG:** Medical devices cannot be imported, supplied in, or exported from Australia unless they are included on the ARTG or a valid exemption applies, for example custom made medical devices, importation of samples, etc. A sponsor can apply to include a medical device on the ARTG if the device complies with the Essential Principles and appropriate conformity assessment procedures have been applied to the device.
- **Post-market monitoring:** Once a medical device has been included on the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.
- **Priority review of medical devices**: A new pathway has been developed to allow faster processing of applications for devices that meet certain criteria for novelty and health benefits.
- **Medical device manufacturing:** The TGA assesses the quality management systems of medical device manufacturers seeking TGA conformity assessment certification. This may be through onsite inspections or desktop assessment of third party inspection reports, or a combination of these methods. Surveillance inspections are also undertaken to assess continuing compliance. In addition, the TGA is a Regulatory Authority of the Medical Devices Single Audit Program (MDSAP) that assesses and recognises third party Auditing Organisations for the purposes of certifying medical device manufacturers.

7.1. Conformity assessment

7.1.1 Applications

Table 32 Number of conformity assessment applications (medical devices including IVDs)

	2017-18	2018-19
	July to June	
Conformity assessment applications		
Applications received	309	279
Applications on hand	251	252
Applications completed	273	273

7.1.2 Outcomes

Table 33[a] Outcomes of conformity assessment applications

	2017-18	2018-19
	July to June	
New		
Approved	58	63
Rejected	1	0
Withdrawn/ Lapsed	35	17
Variation (changes and re-certifications)		
Approved	166	169
Rejected	1	0
Withdrawn/ Lapsed	12	24

[a] The table has been broken down into 'New' and 'Variation' assessment application to provide additional transparency. In reviewing the changes in the reporting, the final total was increased by one.

7.1.3 Processing timeframes

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

Table 34 TGA processing times for new devices and variations

	2017-18	2018-19
	July to June	
New devices		
Mean TGA processing time (days)	131	160
Median TGA processing time (days)	189	196
Variations (changes and recertifications)		
Mean TGA processing time (days)	110	114
Median TGA processing time (days)	95	97

7.2. Inclusion of medical devices (including IVDs)

7.2.1 Applications

Table 35 Applications for inclusion – medical devices (including IVDs)

	2017-18	2018-19
	July to June	
Class I medical devices[a]		
Applications received	4805	1545
Applications completed	4804	1631
Class I measuring medical devices		
Applications received	62	46
Applications completed	64	46
Applications on hand[b]	5	0
Class I sterile medical devices		
Applications received	255	198
Applications completed	240	207
Applications on hand[b]	7	1
Class IIa medical devices		
Applications received	1219	1186
Applications completed	1191	1191
Applications on hand[b]	92	27
Class IIb medical devices		
Applications received	650	581
Applications completed	568	589
Applications on hand[b]	132	50
Class III medical devices		
Applications received	406	476
Applications completed	378	404
Applications on hand[b]	208	194
Class III Joint Reclassification medical devices		
Applications received	0	0
Applications completed	88	6
Applications on hand[b]	5	0

	2017-18	2018-19
	July to June	
Active Implantable Medical Devices (AIMD)		
Applications received	24	37
Applications completed	34	28
Applications on hand[b]	10	18
Class 1 IVDs[c]		
Applications received	74	72
Applications completed	76	72
Applications on hand[b]	2	1
Class 2 IVDs		
Applications received	81	67
Applications completed	80	71
Applications on hand[b]	13	7
Class 3 IVDs		
Applications received	58	53
Applications completed	60	43
Applications on hand[b]	14	20
Class 4 IVDs		
Applications received	27	30
Applications completed	27	30
Applications on hand[b]	1	0

[a] Class I medical devices are automatically included (i.e. these applications are completed within 24 hours). There are no applications for this classification of device 'on hand'. Differences in the number received and finalised relate to those applications received on the last day of the reporting period and/or data migration processes.

[b] Applications on hand – figures shown are correct as of the date when the data was extracted. There may also be delays between the date of the decision and the time when the system is updated due to administrative and/or data migration processes.

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

7.2.2 Outcomes

Class I automatically included medical devices are not counted in the outcomes for inclusion applications as these applications cannot be rejected.

Table 36 Outcomes of medical device applications by classification

	2017-18				2018-19			
	July to June							
	Number (% of Total)							
Device Classification	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Total of applications by classification	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Total of applications by classification
Class I	4,804 (65%)	0	0	4,804 (63%)	1691 (40%)	0	0	1691 (39%)
Class I Measurement	60 (1%)	0	4 (2%)	64 (1%)	45 (1%)	0	1 (0.6%)	46 (1%)
Class I Sterile	222 (3%)	0	18 (9%)	240 (3%)	193 (5%)	0	14 (9%)	207 (5%)
Class IIa	1,138 (16%)	7 (15%)	46 (24%)	1.191 (16%)	1148 (27%)	3 (17%)	42 (26%)	1191 (27%)
Class IIb	513 (7%)	9 (19%)	46 (24%)	568 (8%)	535 (13%)	3 (17%)	51 (31%)	589 (14%)
Class III	306 (4%)	17 (35%)	55 (28%)	378 (5%)	362 (9%)	6 (35%)	36 (22%)	404 (9%)
Class III Reclassification	59 (1%)	15 (31%)	14 (7%)	88 (1%)	5 (0.1%)	0	1 (0.6%)	6 (0.1%)
AIMD	33 (0.5%)	0	1 (0.5%)	34 (0.5%)	28 (1%)	0	0	28 (0.6%)
Class 1 IVD	73 (1%)	0	3 (2%)	76 (1%)	71 (2%)	1 (56%)	0	72 (2%)
Class 2 IVD	75 (1%)	0	5 (3%)	80 (1%)	60 (1%)	1 (6%)	10 (6%)	71 (2%)
Class 3 IVD	58 (0.7%)	0	2 (1%)	60 (1%)	32 (1%)	3 (18%)	8 (5%)	43 (1%)
Class 4 IVD	27 (0.3%)	0	0	27 (0.4%)	30 (1%)	0	0	30 (0.7%)
Total of all applications by status	7,368 (97%)	48 (0.6%)	194 (3%)	7,610 (100%)	4185 (96%)	17 (0.4%)	163 (4%)	4378 (100%)

7.2.3 Processing times

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

Table 37 Processing times for medical device application audits (including IVDs)

	2017-18			2018-19		
	Number of applications (% of Total)	Sponsor days	TGA days[a]	Number of applications (% of Total)	Sponsor days[b, d]	TGA days[a,d]
Mean Processing Time						
Medical devices						
Applications completed without audit	2,021 (79%)			1850 (76%)		
Non-compulsory audit[c]	197 (8%)	58	58	201 (8%)	44	99
Level 1 compulsory audit	27 (1%)	23	33	156 (6%)	37	24
Level 2 compulsory audit	318 (12%)	79	83	236 (10%)	63	99
Total	2,563 (100%)			2443 (100%)		
IVDs						
Applications completed without audit	115 (65%)			86 (59%)		
IVD non-compulsory audit	5 (3%)	34	57	8 (5%)	18	36
IVD compulsory audit	56 (32%)	29	81	53 (36%)	82	94
Total	176 (100%)			147 (100%)		
Median Processing Time						
Medical devices						
Applications completed without audit	2,021 (79%)			1850 (76%)		
Non-compulsory audit[c]	197 (8%)	33	24	201 (8%)	29	56
Level 1 compulsory audit	27 (1%)	22	23	156 (6%)	31	15
Level 2 compulsory audit	318 (12%)	54	47	236 (10%)	50	85
Total	2,563 (100%)			2443 (100%)		
IVDs						
Applications completed without audit	115 (65%)			86 (59%)		
IVD non-compulsory audit	5 (3%)	21	23	8 (5%)	19	25
IVD compulsory audit	56 (32%)	24	64	53 (36%)	66	84
Total	176 (100%)			147 (100%)		

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

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

[c] Non-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).

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

Table 38 Number of priority review determinations[a] granted

	2017-18	2018-19
	July-June	
Application type (proposed)		
A: Conformity Assessment (priority applicant) determinations	0	1
B: Medical Devices (priority applicant) determinations	0	0

[a] Priority designation is a formal decision by the TGA to assign priority to the assessment of an application to include a medical device in the ARTG. Granting of priority designation does not guarantee approval for the application itself. Designation decisions lapse after six (6) months, unless an application for either TGA conformity assessment or ARTG inclusion is received during this time.

7.3. Post-market monitoring

7.3.1 Compliance reviews

As Class I medical devices are automatically included on the ARTG, we undertake post-market compliance reviews for these devices. This includes restricted word reviews, where potentially inappropriate Class I device inclusions are identified by the use of specific words indicative of risk, or listing issues relating to the inclusion of the device.

We also conduct targeted compliance reviews that are initiated on a case by case basis. These may be conducted in relation to devices of any Class.

Table 39 Restricted word Class 1 medical device and targeted compliance reviews

	2017-18[b]	2018-19
	July to June	
Restricted word reviews		
Reviews completed	122	40
Reviews commenced	122	40
Reviews on hand	9	0
Targeted compliance reviews[a]		
Reviews completed	166	235
Reviews commenced	211	250
Reviews on hand	229	15

[a] The number of targeted reviews includes the number of compliance reviews undertaken in relation to all classes of medical devices.

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

7.3.2 Post-market reviews

Table 40 Medical device targeted reviews

	2017-18	2018-19
	July to June	
Post market reviews		
Reviews commenced – number of ARTG entries	620	545
Reviews completed – number of ARTG entries	568	285
Reviews on hand – number of ARTG entries	315	677

7.3.3 Medical device incident reports

A medical device incident is an event associated with the use or misuse of a medical device that resulted in, or could have resulted in (near-incident): serious injury, illness or death to patient, healthcare worker or other person. Australian sponsors of medical devices must actively monitor their devices' post market performance and report incidents to the TGA. Reporting of incidents, or near-incidents, by users is voluntary.

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

Table 41 Number of medical device incident reports and processing times

	2017-18	2018-19
	July to June	
Device incident reports		
Reports received	5348	5874
Reports completed	4653	5654
Reports still in progress	283	239
Processing time		
Mean TGA processing time (days)	1	14
Median TGA processing time (days)	6	9
Percentage processed within target timeframe	98%	94%

Table 42 Medical device incident report outcomes[a]

	2017-18	2018-19
	July to June	
Incident report outcome		
Reviewed and used for trend analysis purposes	4713	5129
Reviewed, no further action required	252	280
Product recall	27	55
Recall for product correction	57	72
Hazard alert	41	68
Product notification	0	0
Safety alert	2	22
Product enhancement/improvement notice	0	8
Instructions for use amended	6	8
Referral for post-market review	139	94
Refer to another TGA Branch [b]	51	24
Company warned	9	3
Product suspended from ARTG	0	4
Product cancelled from ARTG	2	16
Manufacturing process improvements	10	71
Quality system process improvements	2	3
Maintenance carried out by the hospital	0	1
Change to design	4	15
Not device related	3	2
Other	403	47

[a] Outcomes are not mutually exclusive.

[b] The Incident report (DIR) may be referred onto another section for their action. These areas include but are not limited to Recalls, Regulatory Compliance, Clinical Trials and Advertising. Generally these reports are closed off in the DVM database unless there is more than one issue noted within the report. It may also still be investigated by DVM depending on this issue.

7.3.4 Devices manufacturing

Table 43 Outcomes of Quality Management System (QMS) audits of Australian manufacturers

	2017-18	2018-19
	July to June	
QMS audits (Australia)		
Number of audits conducted	41	35
Satisfactory compliance (of completed audits)	92%	93%
Marginal compliance (of completed audits)	8%	7%
Unacceptable (of completed audits)	0%	0%
Close-out in Progress	37%	23%
Processing time		
Initial audits conducted within 3 months of application	83%	25%
Re-audits conducted within 6 months of due date	46%	57%

Table 44 Outcomes of QMS audits of overseas manufacturers

	2017-18	2018-19
	July to June	
QMS audits (overseas)		
Number of audits conducted	30	34
Satisfactory compliance (of completed audits)	100%	100%
Marginal compliance (of completed audits)	0%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in Progress	60%	38%
Processing time		
Initial certification audits conducted within 6 months of application	72%	48%
Certification re-audits conducted within 6 months of due date	42%	15%

Table 45 Outcomes of MDSAP

	2017-18	2018-19
	July to June	
MDSAP Assessments (overseas)		
Number of auditing organisation assessments	8	3
Number of witnessed manufacturing audits	5	5

8 Exports

8.1. Export only medicines

Export only medicines are listed under section 26 of the Act. The purpose of export only listings is to ensure that products exported from Australia comply with standards that are similar to the standards applied to products supplied in Australia.

In previous years the application number included all variations to existing export only listings as well as new listing applications. Starting from the 2018-19 financial year, new listing applications and variations to existing listings were separated to provide further data.

The target timeframe for processing export only listing applications is 30 working days.

Table 46 Approval times for export only medicines

	2017-18	2018-19
	July to June	
New applications		
Mean TGA processing time (days)	25	22
Percentage processed within target processing time	70%	87%
Variations		
Mean TGA processing time (days)	19	19
Percentage processed within target processing time	91%	85%

Table 47 Applications for new and variations to export only medicines

	2017-18	2018-19
	July to June	
Export only applications		
Applications received	254 (95%)	256
Applications approved	14 (5%)	210
Grouping and variation applications		
Applications received	Included with applications above	154
Applications approved		103

8.2. Export certifications for medicines

The TGA provides Certificates of Pharmaceutical Product (CPP) for medicines. The CPP is based on the World Health Organisation (WHO) scheme on the quality of pharmaceutical products moving in international commerce. This is an internationally harmonised template that provides assurance about the quality of pharmaceutical products moving in international commerce. The TGA also issues Certificates of Listed Product (CLP) and Certificates of Exempt Product (CEP) that are not formally issued under the WHO scheme.

The target processing time for applications for an export certificate for a medicine is 15 working days.

Table 48 Export certification applications and processing times

	2017-18	2018-19
	July to June	
Applications received	1799	1610
Export certificate issued	1849	1635
Processing times		
Mean TGA processing time (days)	14	12
Percentage processed within target time	69%	96%

8.3. Export certification assessment for medical devices

Certificates of free sale and export certificates are documents supplied by the TGA outlining that the relevant medical device(s) are included on the ARTG and are either able to be freely supplied and sold within Australia or are able to be exported from Australia.

In September 2018, the TGA updated the process for export certification for medical devices. This resulted in the removal of country specific certificates and the introduction of an electronic certificate for medical devices. There is now less requirement to submit multiple applications, decreasing the number of export certifications provided for medical devices.

The target processing time for applications for an export certificate for a medical device is 10 working days.

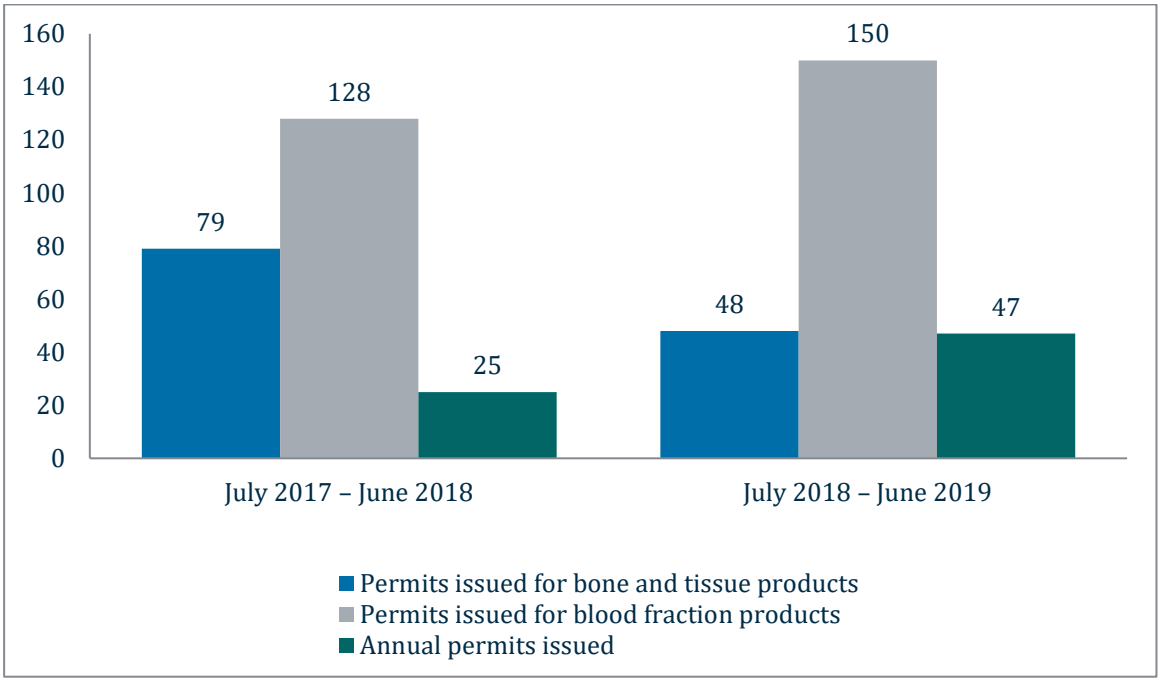
Table 49 Medical device applications and processing times for export certification assessments

	2017-18	2018-19
	July to June	
Applications received	625	401
Export certificates issued	617	410
Processing time		
Mean TGA processing time (days)	8	4
Percentage processed within target time	80%	96%

8.4. Permits for the export of human substances

The TGA issues permits for the export of human substances under regulation 8 of the *Customs (Prohibited Exports) Regulations 1958*. There are two types of permits issued, a single-use permit generally for an individual traveling overseas and an annual permit for organisations exporting multiple times throughout the year.

Figure 7 Permits for the export of human substances



9 Access to unapproved therapeutic goods

9.1. Special Access Scheme

The Special Access Scheme (SAS) refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. For this reporting period, three pathways existed under the scheme and they are categorised as follows:

- Category A is a **notification pathway** which can only be accessed by medical practitioners for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
- Category B is an **application pathway** which can be accessed by health practitioners for patients who do not fit the Category A definition. An approval letter from the TGA is required before the goods may be accessed.
- Category C is a **notification pathway** which allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval. The goods deemed to have an established history of use are specified in a list along with their indications and the type of health practitioner authorised to supply these products.

Any unapproved therapeutic good can potentially be supplied via the SAS except for drugs of abuse in Schedule 9 of the Poisons Standard (where the manufacture, possession, sale or use is prohibited by state or territory law) which cannot be accessed through the SAS Category A process.

Table 50 SAS medicine notifications and applications

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	36,881 **(58%)**	39,911[a] **(47%)**
Category B applications		
Approved	11641 (96%)	18388 (88%)
Cancelled	40 (0.3%)	168 (0.8%)
Withdrawn	N/A	802 (4%)
Rejected	28 (0.2%)	1 (0%)
Pending at end of reporting period[b]	370 (3%)	1464 (7%)
Total Category B applications	12079 (100%) **(19%)**	20823 (100%) **(24%)**
Category C notifications		
Total Category C notifications	14560 **(23%)**	24505[a] **(29%)**
Total SAS notifications/applications received (all categories)	63520 **(100%)**	85239[a] **(100%)**

[a] Due to system technical issues, the number of notifications received during some of this reporting period has been estimated.

[b] Pending applications are waiting on additional information to be supplied by the applicant.

Table 51 SAS device notifications and applications

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	4,511 (62%)	5117[a] (60%)
Category B applications		
Approved	2,466 (94%)	1,953 (90%)
Cancelled	15 (0.6%)	24 (1%)
Withdrawn	N/A	51 (2%)
Rejected	9 (0.3%)	13 (0.6%)
Pending at end of reporting period[b]	143 (5%)	142 (7%)
Total Category B applications	2,633 (100%) **(36%)**	2,183 (100%) **(25%)**
Category C notifications		
Total Category C notifications	177 **(2%)**	1394[a] **(16%)**
Total SAS notifications/applications received (all categories)	7,321 **(100%)**	8,694 **(100%)**

[a] Due to system technical issues, the number of notifications received during some of this reporting period has been estimated.

[b] Pending applications are waiting on additional information to be supplied by the applicant.

Table 52 SAS biological notifications and applications

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	110 **(7%)**	89[a] **(4%)**
Category B applications		
Approved	711 (98%)	1350 (92%)
Cancelled	8 (1%)	15 (1%)
Withdrawn	N/A	55 (4%)
Rejected	0	26 (2%)
Pending at end of reporting period[b]	9 (1%)	30 (2%)
Total Category B applications	728 (100%) **(44%)**	1476[a] (100%) **(66%)**
Category C notifications		
Total Category C notifications	802 **(49%)**	688[a] **(31%)**
Total SAS notifications/applications received (all categories)	1640 **(100%)**	2253 **(100%)**

[a] Due to system technical issues, the number of notifications received during some of this reporting period has been estimated.

[b] Pending applications are waiting on additional information to be supplied by the applicant.

9.2. Clinical trials

The Clinical Trial Notifications scheme provides an avenue through which unapproved therapeutic goods may be supplied for use solely for clinical trials. Unapproved therapeutic goods can include biologicals, devices or medicines or a combination of any of the three types of goods.

Table 53 Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	436 (45%)	466[b] (44%)
Device[a]	143 (16%)	173[b] (16%)
Biological	7 (1%)	13[b] (1%)
Medicine and device	325 (35%)	391[b] (37%)
Device and biological	1 (0.1%)	4[b] (0.4%)
Medicine and biological	5 (1%)	4[b] (0.4%)
Medicine, device and biological	3 (0.3%)	8[b] (0.8%)
Total	920 (100%)	1059[b] (100%)

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

[b] Due to system technical issues, the number of notifications received during some of this reporting period has been estimated.

Table 54 Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Clinical trial type		
Phase 1	262 (29%)	285 (27%)
Phase 2	209 (23%)	264 (25%)
Phase 3	246 (27%)	260 (25%)
Phase 4	65 (7%)	82 (8%)
Device	125 (14%)	147 (14%)
Bioavailability/equivalence	13 (1%)	21 (2%)
Total	920 (100%)	1059 (100%)

Table 55 Number of notifications for new clinical trials and variations to previously notified clinical trials, including non-fee attracting variations, involving unapproved therapeutic goods received by therapeutic good type

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	1154 (39%)	1201 (38%)
Device[a]	240 (8%)	287 (9%)
Biological	12 (0.4%)	19 (0.6%)
Medicine and device	1557 (52%)	1643 (52%)
Device and biological	5 (0.1%)	9 (0.3%)
Medicine and biological	11 (0.4%)	10 (0.3%)
Medicine, device and biological	4 (0.1%)	16 (0.5%)
Total	2983 (100%)	3185 (100%)

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

The online system captures the actual number of notifications received for new clinical trials and requests to change significant details to clinical trials already notified. A variation to a previously notified clinical trial may include an addition of a site(s), change to a therapeutic good, or change in principal investigator etc.

Table 56 Number of new clinical trials and variations[a] to previously notified clinical trials involving unapproved therapeutic goods received by phase

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Phases		
Phase 1	612 (20%)	687 (22%)
Phase 2	707 (24%)	921 (29%)
Phase 3	1280 (43%)	1196 (37%)
Phase 4	165 (5%)	123 (4%)
Device	195 (7%)	227 (7%)
Bioavailability/equivalence	24 (1%)	31 (1%)
Total	2983 (100%)	3185 (100%)

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

9.3. Authorised Prescribers

The Authorised Prescriber Scheme allows approved medical practitioners authority to prescribe a specified unapproved therapeutic good(s) to patients who are identified by their medical condition. If a medical practitioner becomes an Authorised Prescriber they may prescribe the product to patients in their immediate care, within the indication specified, without seeking further approval from the TGA.

Table 57 Authorised Prescriber approvals for medicines, medical devices and biologicals

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Approvals by therapeutic good type		
Number of approvals for medicines	605 (60%)	694 (57%)
Number of approvals for medical devices	407 (40%)	527 (43%)
Number of approvals for biologicals	0	1 (0.1%)
Total	1012 (100%)	1222 (100%)

10 Medicines and biologicals manufacturing

10.1. Manufacturing licences issued to Australian manufacturers

Table 58 Status of manufacturing licence applications

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Licence status (Australia)[a]		
New licences granted	23 (45%)	15 (47%)
Withdrawn application	5 (10%)	1 (3%)
Revoked licences – at request of licence holder	19 (37%)	13 (41%)
Revoked licences – TGA	2 (4%)	0
Suspended – at request of licence holder	2 (4%)	3 (9%)
Suspended – TGA	0	0
Total	51 (100%)	32 (100%)

[a] As at 30 June 2019, there were 254 Australian companies holding manufacturing licences covering 396 sites.

Table 59 Outcomes of inspections of Australian manufacturers

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Inspection status (Australia)		
Number of inspections conducted	229	195
Satisfactory compliance (of completed inspections)	179 (78%)	152 (78%)
Marginal compliance (of completed inspections)	21 (9%)	29 (15%)
Unacceptable (of completed inspections)	10 (5%)	8 (4%)
Close-out in progress	19 (8%)	6 (3%)
Processing time		
Initial inspections conducted within 3 months of application	22 (96%)	16 (94%)
Re-inspections conducted within 6 months of due date	111 (73%)	112 (75%)

10.2. Approval (certification) of overseas manufacturers

Table 60 Manufacturing certification application by status (overseas)

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Applications (overseas)[a]		
New applications received[b]	33 (38%)	36 (46%)
Re-inspection applications[b]	55 (62%)	42 (54%)
Total applications	88 (100%)	78 (100%)
Applications completed		
Certified	85 (63%)	83 (56%)
Rejected[c]	51 (37%)	66 (44%)
Total completed	136 (100%)	149 (100%)

[a] As at 30 June 2019, there were 141 overseas manufacturers covering 164 manufacturing sites that were subject to TGA inspection and approximately 2,600 overseas manufacturing sites that relied on evidence from recognised regulators.

[b] Refers to applications that generated an inspection, undertaken by the TGA. However, this does not correlate with completed applications, as the certification process may be continuing across financial years.

[c] Rejections include withdrawn applications.

Table 61 Outcomes of inspections of overseas manufacturers

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Inspection status (overseas)		
Number of inspections conducted	94	75
Satisfactory compliance (of completed inspections)	72 (77%)	64 (85%)
Marginal compliance (of completed inspections)	9 (10%)	11 (15%)
Unacceptable (of completed inspections)	3 (3%)	0 (0%)
Close-out in progress	10 (10%)	0 (0%)
Processing time		
Initial certification inspections conducted within 6 months of application	15 (68%)	21 (85%)
Certification re-inspections conducted within 6 months of due date	41 (66%)	44 (85%)

10.3. Good Manufacturing Practice (GMP) clearances

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

Table 62 GMP clearance application status

	2017-18	2018-19[a]
	July to June	
	Number (% of Total completed)	
Applications received	5327	6628
Applications completed		
Approved	5041 (94%)	6252 (88%)
Rejected	344 (6%)	854 (12%)
Total completed	5385 (100%)	7106 (100%)

[a] A change in the reporting method from 2017 now captures additional application types (e.g. extensions, variations etc.). It followed updates to the GMP Clearance application e-forms in September 2017 and has resulted in variations to some figures when comparing the two reporting periods.

Table 63 Number of GMP Clearance applications received and completed by type from 1 July 2018 to 30 June 2019

Application Category	Applications received	Applications completed
Cancel	2	8
Extend	1966	2087
New	2459	2768
Reactivate	0	1
Variation	2201	2242

Table 64 Number of GMP Clearance applications actioned by pathway from 1 July 2018 to 30 June 2019

Pathway	Applications received	Applications completed	Applications approved	Applications not approved
Compliance Verification	3110	3573	3018	555
Mutual Recognition Agreement	3518	3533	3234	299

11 Recalls

11.1. Medicine recalls

Table 65 Medicine recalls by reason for recall

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse reactions	1 (3%)	2 (5%)
Foreign matter	5 (14%)	5 (12%)
Illegal supply	2 (6%)	2 (5%)
Impurity and degradation	1 (3%)	4 (10%)
Labelling and packaging	8 (23%)	14 (34%)
Micro-organisms	1 (3%)	2 (5%)
pH	0	0
Potency	3 (8%)	1 (2%)
Sterility	1 (3%)	0
Other[a]	13 (37%)	11 (27%)
Total	35 (100%)	41 (100%)

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

11.2. Medical device recalls

Table 66 Medical device (including IVDs) recalls by reason for recall

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse incidents	3 (0.5%)	5 (0.8%)
Diagnostic inaccuracy	3 (0.5%)	66 (11%)
Electrical defect	41 (7%)	23 (4%)
Illegal supply	2 (0.4%)	1 (0.2%)
Labelling and packaging	14 (2%)	131 (22%)
Mechanical and physical defects	202 (37%)	203 (34%)
Software defects	97 (17%)	130 (22%)
Sterility	5 (1%)	3 (0.5%)
Other[a]	187 (34%)	34 (6%)
Total	554 (100%)	596 (100%)

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

11.3. Biological recalls

Table 67 Biological recalls

	2017-18	2018-19
	July to June	
Recalls to hospital level	25	29

12 Laboratory testing

The TGA conducts post-market monitoring and compliance testing, investigations and reviews, as well as market authorisation assessment of therapeutic goods.

We identify and prioritise therapeutic goods for testing to fulfil its regulatory compliance and monitoring requirements, and the transparency and accountability requirements of Government. The testing program also provides flexibility and capacity to provide testing for investigations into problem reports, complaints and urgent public health concerns.

A risk management approach is used, which is consistent with *ISO 31000: Risk Management principals and guidelines,* to identify products with a higher risk of not complying with the required quality standards. This risk based, targeted approach to testing is reflected in the failure rates reported in the table below.

Laboratory results are made available through the *Database of TGA Laboratory Testing Results*, Consumers and health professionals can identify which products have been tested by the TGA, whether they passed or failed, and for those that did fail, what regulatory action was taken. Providing this information has been an important enhancement to the transparency of the Government's regulatory processes and the vital role of the TGA in ensuring the safety, efficacy, performance and quality of medicines and medical devices for Australian consumers.

Table 68 Samples and products tested by type of therapeutic good and percentage which failed

		2017-18	2018-19
		July to June	
Therapeutic good type			
Prescription medicines	Total	1,106	1064
	% fail	0.5	0.1
OTC medicines	Total	59	20
	% fail	6.8	0.0
Complementary medicines[a]	Total	266	229
	% fail	10.2	16.6
Medical devices	Total	99	135
	% fail	41.4	25.2
External[a]	Total	70	29
	% fail	8.6	13.8
Pacific Medicines Testing Program	Total	21	57
	% fail	14.3	21.1
Unregistered[b]	Total	155	208
	% fail	56.1	68.8
Total samples (excluding AHQ samples)		1776	1742
Total samples[c]		2005	2071
Percentage fail		10%	13%
Total number of products tested[d]		836	857

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

[b] 'Unregistered' refers to products that meet the definition of therapeutic goods but are not included on the ARTG or otherwise specifically exempted from this requirement in the legislation. This often includes adulterated complementary medicines or counterfeit products.

[c] Includes accreditation, harmonisation and quality control (AHQ) samples.

[d] We may test a number of samples of each product per reporting period.

Table 69 Samples that failed laboratory testing by reason for July 2018 to June 2019

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Contamination	1	0	0	0	3	0	0	4 (0.2%)
Formulation	0	0	0	143	12	3	9	167 (10%)
Label and packaging deficiencies	21	0	0	0	21	0	0	42 (2%)
Performance	10	0	1	0	2	0	0	13 (0.7%)
Physical or mechanical properties	2	0	0	0	0	1	3	6 (0.3%)
Unregistered	0	0	0	0	0	0	0	0 (0.0%)
Total	34	0	1	143	38	4	12	232

Table 70 Batch release and export certification

	2017-18	2018-19
	July to June	
Batch releases and certifications		
Batch release[a]	432	385
Export certification[b]	34	33

[a] Evaluation of batch release documentation for vaccines, biotechnology and blood products.

[b] Certification of biological products being exported from Australian manufacturers to overseas markets.

The TGA provides the World Health Organisation-approved certificates for batches of biological products to be exported by Australian manufacturers to overseas markets. The number of certificates provided by us therefore depends on the number of requests received.

Table 71 Target timeframes in working days for laboratory testing by priority and testing type

Priority of testing	Biochemical/ chemical testing	Microbiological testing	Medical device testing
Urgent[a]	20 (95% of target times to be met)	40 (95% of target times to be met)	20 (95% of target times to be met)
Priority	40 (80% of target times to be met)	50 (80% of target times to be met)	40 (80% of target times to be met)
Routine	50	50	50

[a] Testing on products linked to potential public safety concerns are assigned to the 'Urgent' testing category. Urgent testing may impact on the timeframes for priority and routine testing. Priority is given to testing of products with the highest risk of a quality deficiency.

Table 72 Compliance with testing timeframes for July 2018 to June 2019

	Priority	Number (% of Total)
Therapeutic good type		
Medical devices	Routine	82 (23%)
	Priority	20 (20%)
	Urgent	0
OTC medicines	Routine	17 (88.2%)
	Priority	3 (100.0%)
	Urgent	0
Prescription medicines	Routine	215 (62%)
	Priority	14 (57%)
	Urgent	22 (36%)
Complementary medicines	Routine	206 (18%)
	Priority	23 (35%)
	Urgent	0
Unregistered products	Routine	2 (0.1%)
	Priority	195 (34%)
	Urgent	11 (91%)

13 Regulatory compliance

The TGA conducts compliance and enforcement activities against a risk based compliance framework. A range of tools are utilised to encourage compliance and address non-compliance including education and guidance, warnings, the issue of infringements, or product suspensions or cancellations. Investigations may also result in criminal or civil court proceedings. All compliance activities have the purpose of protecting public health.

Due to changes in the IT data capture process in December 2017 the categories against which data is presented has been altered. The tables below have been updated to reflect these changes.

Table 73 Number of compliance actions taken against completed investigations

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Completed investigations		
Criminal prosecution	2 (0.1%)	1 (0.1%)
Infringement notices	0 (0%)	9 (0.3%)
Warning letters issued[a]	2173 (73%)	2489 (72%)
Goods released under Personal Import Scheme	324 (11%)	534 (15%)
Referred to external agency	58 (2%)	86 (3%)
Referred to the Commonwealth Director of Public Prosecutions	3 (0.1%)	5 (0.1%)
Referred internally	28 (1%)	91 (3%)
No offence identified	397(13%)	248 (7%)
Total[c]	2985 (100%)	3463 (100%)
Units of goods referred to ABF for destruction[b]	850514	1069946

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

[b] Units refers to single dosage unit e.g. 1 tablet, 1 capsule, 1 tub of powder or a single device.

[c] There can be multiple actions per case resulting in a higher total figure than shown in finalised cases below.

Table 74 Regulatory compliance investigations by number

	2017-18	2018-19
	July to June	
Compliance cases[a]		
Cases received	3574	3658
Cases active	17	400
Cases finalised	3976	3271

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

Table 75 Number of different products investigated

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Therapeutic good type		
Prescription medicines (Schedule 4 and Schedule 8)	1319 (56%)	1650 (51%)
Schedule 9 medicines	8 (0.4%)	10 (0.3%)
Schedule 10 medicines	18 (0.8%)	20 (0.6%)
Medical devices	27 (1%)	40 (1%)
Complementary and homoeopathic medicines	400 (18%)	353 (11%)
OTC medicines	98 (4%)	75 (2%)
Biological and blood products	11 (0.5%)	14 (0.4%)
Other[a]	472 (21%)	1074 (33%)
Total[b]	2353 (100%)	3236 (100%)

[a] Due to system technical issues, some investigations were unable to be categorised by therapeutic good type.

[b] Multiple therapeutic goods types may appear in a single case.

Table 76 Regulatory compliance investigations by special interest categories

	2017-18	2018-19
	July to June	
	Number (% of Total)	
Compliance investigation category		
Unregistered	3851 (95%)	3544 (96%)
Registered	14 (0.3%)	11 (0.3%)
Counterfeit product	173 (4%)	121 (3%)
Other	25 (0.6%)	17 (0.5%)
Total[a]	4063 (100%)	3693 (100%)

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

Table 77 Number of offence types related to completed cases

	2017-18	2018-19
	July to June	
	Number (% of total)	
Offence type		
Import	5720[a] (90%)	4388 (87%)
Export	6 (0.1%)	5 (0.1%)
Manufacture	32 (0.5%)	63 (1%)
Supply	542 (9%)	605 (12%)
Total completed[b]	6300 (100%)	5061 (100%)

[a] There was a spike in cases in the second quarter of 2018 due to targeted action by Australian Border Force.

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

Table 78 Location of alleged offence by referral type for July 2018 to June 2019

Origin	ACT	NSW	NT	QLD	SA	VIC	WA	TAS	Total
Australian Border Force	31	423	173	521	288	1268	97	60	2861
External Agencies, Other Regulatory Body, State Health Department	0	3	1	1	0	4	38	0	47
General public	0	18	0	14	2	15	224	1	274
Sponsor/client, Patient/Practitioner	0	1	1	2	0	6	55	0	65
TGA internal[a]	0	23	0	13	3	8	70	1	118
Total	31	468	173	551	293	1301	484	62	3671

[a] Referred from within the TGA for investigation as a result of other work, e.g. Conformity assessments, advertising complaints.

14 Pharmacovigilance Inspection Program

Table 79 Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified

	2017-18[a]	2018-19
	July to June	
Compliance investigation category		
Total inspections completed	5	10
Total with completed findings	5	7
Critical deficiencies[b]	0	1
Major deficiencies[c]	25	34
Minor deficiencies[d]	12	24
Average deficiencies per inspection	0 critical 5 major 2 minor	0 critical 5 major 3 minor

[a] Inspections commenced in January 2018, so the 2017-18 figure represents a half-year of data.

[b] 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.

[c] 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.

[d] 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.

15 Reporting of medicine shortages

Table 80 Number of medicine shortage reports[a] by shortage reason

	2017-18	2018-19
	July-June	
	Number (% of Total)	
Shortages reported		
New – Commercial changes	9 (3%)	237 (16%)
New - Discontinuation	24 (9%)	63 (4%)
New – Manufacturing related	141 (52%)	676 (47%)
New – Other	66 (24%)	237 (16%)
New – Product recall	0 (0%)	18 (1%)
New – Unexpected increase in demand	34 (12%)	224 (15%)
Total	274 (100%)	1455 (100%)

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

Table 81 Number of medicine shortage notifications processed

	2017-18	2018-19
	July-June	
Notifications processed		
New	274	1455
Update[b]	799	2605
Total	1073	4060

[b] Updates of previously reported shortages, including updates to 'Resolved' status. All reports submitted voluntarily, with mandatory reporting of all shortages of prescription medicines and select over-the-counter medicines commencing 1 January 2019.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Reporting and Collaboration Services	21 October 2019

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